

**Treatment Outcome of Tuberculosis and Associated Factors at  
Jimma University Specialized Hospital and Ommo-Nada Training  
Health Center, South West Ethiopia**



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**A Thesis submitted to the Department of Pharmacy, College of Public Health  
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## **Abstract**

**Background:** Tuberculosis (TB) is the leading cause of death from a curable infectious disease. Several risk factors for poor tuberculosis treatment outcomes have been reported. Monitoring the treatment outcome of TB is essential in order to evaluate the effectiveness and efficiency of TB intervention programs.

**Objective:** The main objective of this study was to assess treatment outcome of tuberculosis and associated factors for treatment outcomes at Jimma University Specialized Hospital and Ommo-Nada Training Health Center.

**Patients and Methods:** A general retrospective cohort study was employed and data were collected through medical record review of tuberculosis patients. Data were analyzed using Statistical Package for Social Sciences of windows version 16. Binary logistic regression analysis was conducted to determine factors that were associated with treatment outcomes of tuberculosis and its independent predictors. P-value 0.05 was considered statistically significant. Privacy and confidentiality was secured during the data collection.

**Results:** Out of the total 2107 TB patients, 59.2% were male with a mean age of 29.5  $\pm$ 1.31 years and of those patients, successfully treated were 1504 (85.9%). In the multivariate logistic regression model, age range of (35-44.9 years(AOR=6.5, 95% CI: 3.2-13.4),45-54.9years(AOR=12.4, 95% CI: 5.9-26.2),55-64.9 years(AOR=26.9, 95% CI:11.3-64.2) and greater than or equal to 65years(AOR=25.93, 95% CI: 6.9-98.3);male patients (AOR=2.9, 95% CI: 1.9-4.5);rural residence(AOR=3.07, 95% CI: 2.08-4.53);being at prison (AOR=2.67, 95% CI: 1.11-6.37);retreatment with anti-tuberculosis medications (AOR=1.9, 95% CI: 1.25-2.89);smear negative tuberculosis (AOR=6.7,95% CI: 4.2-10.7); extra-pulmonary tuberculosis (AOR=5.2, 95% CI: 3.1- 8.7); tuberculosis patient with HIV who didn't start co-trimoxazole preventive therapy (AOR=58.6, 95% CI: 6.7-507.8); tuberculosis patient with HIV who didn't start antiretroviral treatment(AOR=10.5, 95% CI: 1.4-77.5);were identified as independent risk factors for poor treatment outcome.

**Conclusions:** Treatment outcome among tuberculosis patients was satisfactory in the study area. Male gender, age greater than 35 years, smear negative and extra-pulmonary tuberculosis, retreatment with anti-tuberculosis medications, rural residence, being at prison, TB-HIV co-infection without co-trimoxazole preventive therapy and antiretroviral therapy, and treatment years of 2001 and 2002 were known to be independent predictors of poor treatment outcome among tuberculosis patients in the study area.

**Keywords:** Tuberculosis; Treatment outcome; Risk factors; Southwest Ethiopia

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## **List of Acronyms and Abbreviation**

- AFB: Acid-fast bacilli
- ART: Antiretroviral therapy
- CPT: co-trimoxazole preventive therapy
- DOT: Directly observed treatment
- DST: Drug Sensitivity Test
- DM: Diabetes Mellitus
- EPTB: Extra-pulmonary Tuberculosis
- FMOH: Federal Ministry of Health
- HIV: Human Immunodeficiency Virus
- JUSH: Jimma University Specialized Hospital
- NTP: National tuberculosis control programme
- ONTHC: Ommo-Nada Training Health Center
- PTB: Pulmonary Tuberculosis
- TB: Tuberculosis
- WHO: World Health Organization

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# 1. INTRODUCTION

## 1.1. Background

Tuberculosis, which is one of the oldest diseases known to affect humans and a major cause of illness and death worldwide, especially in Asia and Africa (1). World Health Organization (WHO) declared TB as a global public health emergency in 1993. Starting in the mid-1990s, efforts to improve TB care and control intensified at national and international levels. Geographically, the burden of TB is highest in Asia and Africa. India and China together account for almost 40% of the world's TB cases. The African region has 24% of the world's cases and the highest rates of cases and deaths (2). Tuberculosis typically affects the lungs (pulmonary TB) but can also affect other sites as well (extra pulmonary TB) (3). In Sub Saharan Africa, it was estimated that a single TB patient with active disease if not treated can infect on average 10-15 people every year (4).

The severity of the illness depends on the bacillary load, the extent and the anatomical site of the disease and the background condition of the patient. The involvement of an anatomical site helps in classifying if the disease is severe. Extrapulmonary TB and smear negative pulmonary TB are classified as "seriously ill" (5). Important challenges for TB control are human immunodeficiency virus (HIV) co-infection and drug resistance. HIV co-infection is the strongest known risk factor for progression of latent TB infection to TB disease. Although HIV co-infection has been shown not to affect the failure rate of TB treatment, high mortality has been reported among HIV-infected TB patients in sub-Saharan Africa (4).

In Ethiopia a standardized TB prevention and control programme, incorporating directly observed treatment, short course was started in 1992. The drugs used for TB treatment are safe and effective if properly used. All the drugs should be taken together as a single, daily dose, preferably on an empty stomach. The treatment of TB has two phases Intensive (initial) phase and Continuation phase. Intensive phase consists of three or more drugs for the first 8 weeks for new cases, and 12 weeks for re-treatment cases. It renders the patient non-infectious by rapidly reducing the load

of bacilli in the sputum, usually within 2-3 weeks (except in case of drug resistance). During the intensive phase, the drugs must be collected daily by the patient and must be swallowed under the direct observation of a health worker. Continuation phase immediately follows the intensive phase and is important to ensure cure or completion of treatment. It is necessary in order to avoid relapse after completion of treatment. This phase requires at least two drugs, to be taken for 4 – 6 months. During the continuation phase, the drugs must be collected every month and self-administered by the patient, except for retreatment cases and for regimens containing Rifampicin (5).

Drugs used as a first line treatment of TB in Ethiopia are Rifampicin, Ethambutol, Isoniazid and Pyrazinamide. The drugs available in fixed dose combination are:

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

The drugs available as single drugs are:

- ❖ Ethambutol 400 mg.
- ❖ Isoniazid 150 mg and 300 mg.
- ❖ Streptomycin sulphate vials, 1 g; where Streptomycin is administered by injection while the other drugs are to be taken orally (5).

Correct treatment of tuberculosis aims at curing the patient, interrupting transmission of tuberculosis to other persons and preventing bacilli from becoming drug resistant. These aims are not achieved in many regions of the Ethiopia even when anti tuberculosis drugs are available (6). Patient education by TB clinic should be enhanced to improve the patients understanding of their disease and its treatment and to improve compliance with treatment and follow up (7). Well-organized TB control services are necessary to ensure that TB patients have the best chance of successful disease detection and treatment outcome (8).

## 1.2. **Statement of the Problem**

TB is estimated to cause at least three million deaths per year worldwide (1). WHO has published a global report on TB every year since 1997 and the main aim of the report is to provide a comprehensive and up-to-date assessment of the TB epidemic and progress made in prevention, care and control of the disease at global, regional and country level (2).

The 2012 global tuberculosis report indicated that tuberculosis remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, in particular after the human immunodeficiency virus (HIV). The latest estimates included in this report are that there were almost 9 million new cases in 2011 and 1.4 million TB deaths (990 000 among HIV negative people and 430 000 HIV-co-infected patients). This is despite the availability of treatment that will cure most cases of TB. Short-course regimens of first-line drugs that can cure around 90% of cases have been available since the 1980s (2).

TB burden in Africa showed that 12 out of the 15 countries with the highest estimated TB incidence rates per capital are in Africa. In 2007, TB notifications from the African region accounted for 30% of all notified cases in the world (9). In the same year, 9 million new cases of TB were diagnosed worldwide, and 1.8 million people died due to TB (4).

Many factors have been linked to anti-tuberculosis treatment discontinuation in sub-Saharan Africa, including infrequent bacilloscopic monitoring, transfer of patients across health service units, lack of family support, side effects of medications, patient misinformation and healthcare system factors such as distant place, inadequate laboratory equipment and reagents, and insufficient health education programs (10). Demographic factors, social factors, lifestyle factors, and clinical factors were reported to be the predictors of death due to TB among people co-infected with HIV and those infected with TB only. Depletion of CD4+ cells in HIV-infected persons increases the risk of both primary and reactivation tuberculosis. HIV-positive people infected with TB are fifty times more likely to develop active TB in their lifetime than people who are HIV-negative (11).

Despite the recent progress of global efforts, tuberculosis is still one of the leading causes of morbidity and mortality world-wide, and remains as a major public health burden in many developing countries (12).

Patient default from treatment is one of the most important problems in TB control, tuberculosis treatment defaulters, especially those who are smear positive, propagate ongoing community transmission and promote the development and acquisition of drug-resistant TB strains resulting in a higher number of TB cases (13).

In many industrialized countries with good treatment facilities and a secured supply of drugs free of charge for patients, treatment results have not reached the targets set by WHO (14). The global burden of TB is highest in the Sub-Saharan Africa region and this can be attributed to the high prevalence of human immunodeficiency virus infection (HIV) which is known to increase the risk of developing TB (15).

The Ethiopian Federal Ministry of Health (FMOH) hospital statistics data has shown that tuberculosis is the leading cause of morbidity, the third cause of Hospital admission (after deliveries and malaria), and the second cause of death in Ethiopia, after malaria (5). According to the WHO Global TB report 2011, Ethiopia ranks 8<sup>th</sup> in the list of 22 high burden countries, and 3<sup>rd</sup> in Africa, with an estimated prevalence of all forms of TB in 394 per 100,000 populations (3). Treatment success measured by a standardized process of treatment outcome monitoring is one of the pillars of TB control. The most important intervention for the control of TB is effective treatment of infectious cases. Failure to complete treatment poses a significant public health risk through disease reactivation, increased transmission, and development of drug-resistance (16).

Therefore, there has been limited research into this phenomenon in the current study area, and investigation is required to determine the underlying factors for poor tuberculosis treatment outcome so that implementation measures might be required for addressing it. Thus, the primary aim of this study is to assess patients' specific treatment outcomes of tuberculosis and identifying risk factors related to poor treatment outcomes of tuberculosis patients.

### 1.3. Literature Review

According to WHO report, the rate of treatment success for 2.6 million new cases of sputum smear-positive pulmonary TB who were treated in the 2009 cohort was 87%. The treatment success rate was poor in 81% African Region. The seven countries that had lower rates of treatment success were; Brazil 72%, Ethiopia 84%, Nigeria 83%, the Russian Federation 55%, South Africa 77%, Uganda 67% and Zimbabwe 78% (3).

Routine recording and reporting of TB cases, that are diagnosed and treated by national TB control program and monitoring the outcomes of treatment is one of the core elements to stop TB treatment strategy (2). The total number of TB cases that occur each year can be estimated globally and for regions and individual countries but with uncertainty. This uncertainty reflects the fact that national surveillance systems do not capture all cases in most countries. The number of people diagnosed and treated for TB and associated treatment outcomes are routinely reported by NTPs in almost all countries. These data are reported in turn to WHO in annual rounds of global TB data collection (2).

The study from Ibadan, Nigeria in (2009) on treatment outcomes among pulmonary tuberculosis patients found that Poor treatment outcome has serious consequences, including ongoing infectivity and development of drug-resistant *Mycobacterium tuberculosis* (17).

The risk factors associated with poor outcome are likely to be different in low- and middle-income countries, information is sketchy these seem however, due to include lack of information about the disease, poor communications between health staff and patients, delays in seeking health care and lack of care and support at the clinic, and patients at high risk of an unfavorable treatment outcome should be identified early and given additional follow-up and social support. (18 -19).

According to the South Ethiopia finding in (2005) reported that evaluation of the outcome of anti-tuberculosis treatment in DOTS programe is one of the major indicators for the assessment of the performance of national TB program (20).

### **Socio-demographic and patient related factor associated with poor treatment outcome**

In industrialized settings, poor outcome is associated with male sex, lack of education, and age accessibility of health facilities, low socio-economic status and the side effects of anti-tuberculosis treatment.

According to the study conducted in northeastern Thailand in (2005) found that treatment interruption, age over 60years and male gender was associated significantly with poor treatment outcome (21). Other study from Finland in (2007) conducted on risk factors for poor tuberculosis treatment outcome the study showed that; non-HIV-related immunosuppression has significant association with unfavorable treatment outcome (14).

The study conducted in China in (2010), new smear positive TB cases in 30 provinces showed that treatment outcomes resulted in a cure rate less than 85% for elderly subjects who are aged over 60 years. Being illiterate, not having a job, loss of appetite as initial symptoms, co-morbidity, not having a treatment observer, missing more doses of the TB drugs, interrupted treatment, having side effects during treatment, long distance from the patients' house to the medical center and having no irregular sputum examinations were statistically significant association with a lower cure rate. The population over 60 years old had a significantly higher prevalence of co-morbidity. Also, in aged patients side effects were more frequent (22). Other similar study showed that being male and older age are risk factors for poor treatment outcome of tuberculosis (4, 6, 17).

According to the study conducted in the Southern Region of Ethiopia in 2010 a study found that age >55 years, male sex, treatment, being on retreatment, having a positive smear after 2 months of treatment and a diagnosis of smear-negative PTB were independently associated with a poor treatment outcome (19). In addition other study from Tigray region in (2012) evaluated that unemployment, family size greater than 5 persons increased the risk for unfavorable treatment outcome (18).

The study conducted in South west Ethiopia in (2010) found that individuals who could read and write were more likely to be aware about TB and more likely to know

that TB is caused by a microorganism than non-educated individuals. There was little knowledge about TB in rural communities around Gilgel Gibe outcomes also affected by level of education. It is reported that knowledge gap is predictor of poor tuberculosis treatment outcomes (23, 24).

### **Co-morbid disease associated with poor treatment outcomes**

In 2011, 1.1 million (13%) of the 8.7 million people who developed TB worldwide were HIV-positive. Seventy-nine percent of these HIV-positive TB cases were in the African Region. Globally, there were an estimated 0.4 million HIV-associated TB deaths in 2011. Seventy-nine percent of TB patients known to be HIV-positive were provided with co-trimoxazole preventive therapy (CPT) and 48% were started on ART. Antiretroviral therapy significantly reduces the risk of morbidity and mortality from TB. A meta-analysis published in 2012 found that ART reduces the individual risk (2).

The study conducted in Brazil from (2003-2008) on outcomes of TB treatment with HIV status the study showed that treatment outcomes were best for those with HIV negative cases and worst for those known HIV positive patients (cure rate of 85.7% and 55.7% respectively). Risk of having an unfavorable outcome (all outcomes except cure) was 3.09 times higher for those HIV positive compared with those HIV negative. The risk of death and default also increased with HIV positivity (25). Similar studies showed that HIV status played an important role in TB treatment outcomes (26-28).

According to the study conducted in Uganda Mbarara Hospital in (2009) showed that the problem of TB is made worse by the concurrent infection with HIV. It is estimated that 50% of TB patients are co-infected with HIV. Both diseases place a big social, economic and health burden on the country. Patients with HIV and TB are likely to face more challenges because they have to get HIV care in addition to the TB care. This may lead to poorer adherence among these patients and yet because of their immune suppression, are likely to get more severe forms of TB (26).

A retrospective cohort study in (2006) was conducted among HIV infected TB patients showed that, patients were categorized into ART+ group (received ART)

and ART group (did not receive ART) and they demonstrated that the substantial increase of survival in patients co infected with HIV and TB who received ART. Initiation of ART within 6 months of TB diagnosis is associated with greater survival (29). Other retrospective cohort study conducted in Giang province, Vietnam (2001-2004), on the factors associated with unsuccessful TB treatment outcomes on HIV infected TB patients study found that patients who used co-trimoxazole prophylaxis therapy effective in preventing HIV Patients from opportunistic infection and helpful in reducing mortality among HIV-infected TB patients (4, 30).

According to the study from a district of South India in (2011) showed that non initiation of ART has emerged as a high risk factor for unfavorable treatment outcome and mortality as well as for overall mortality. ART initiation in HIV infected TB patients has effective in preventing and improving Patients the survival and quality of life of patients with HIV and TB (31).

A retrospectively reviewed data on all patients with tuberculosis reported from the San Francisco Tuberculosis Control Program in (2007) found that duration of treatment was extended to 10.2 months for HIV-infected patients and HIV uninfected patients received 6 months of Rifamycin-based therapy. HIV-infected individuals who received a standard 6-month Rifamycin-based regimen were more likely to relapse. The relapse rate among HIV infected was 9.3 per 100 person-years versus 1.0 in HIV-uninfected. The use of highly active antiretroviral therapy was associated with more rapid conversion of smears and cultures and with improved survival of HIV-infected patients. Standard 6-month therapy may be insufficient to prevent relapse in patients with HIV (32).

### **Type of tuberculosis related to poor treatment outcomes**

Among the countries reporting to WHO in 2010, 162 reported data showed smear-negative and extrapulmonary cases had poor treatment outcome than smear positive cases of pulmonary Tuberculosis (3).

According to study conducted in Addis Ababa in (2011) showed that survival status was significantly different between patient categories as well as across treatment centers. The death rate of pulmonary positive, pulmonary negative and extra

pulmonary TB was 2.7%, 3.6%, and 4.3%, respectively. Body weight at initiation of anti-TB treatment <35 kg low body weight patient category, year of enrollment and treatment center were independent predictors for time to death and also retreated TB patients were 1.74 times more likely to die compared to new TB patients (33).

Other study from Southern Region of Ethiopia on the Factors associated with poor tuberculosis treatment outcome. The result showed that being on retreatment, having a positive smear at the second month follow-up, and having smear-negative pulmonary TB were independent risk factors for poor outcome (18). Similarly one study from Gondar University Teaching Hospital from September 2003 to May 2008 showed that smear negative pulmonary tuberculosis patients had significantly low treatment success rate of all patients (6).

## **2. SIGNIFICANCE OF THE STUDY**

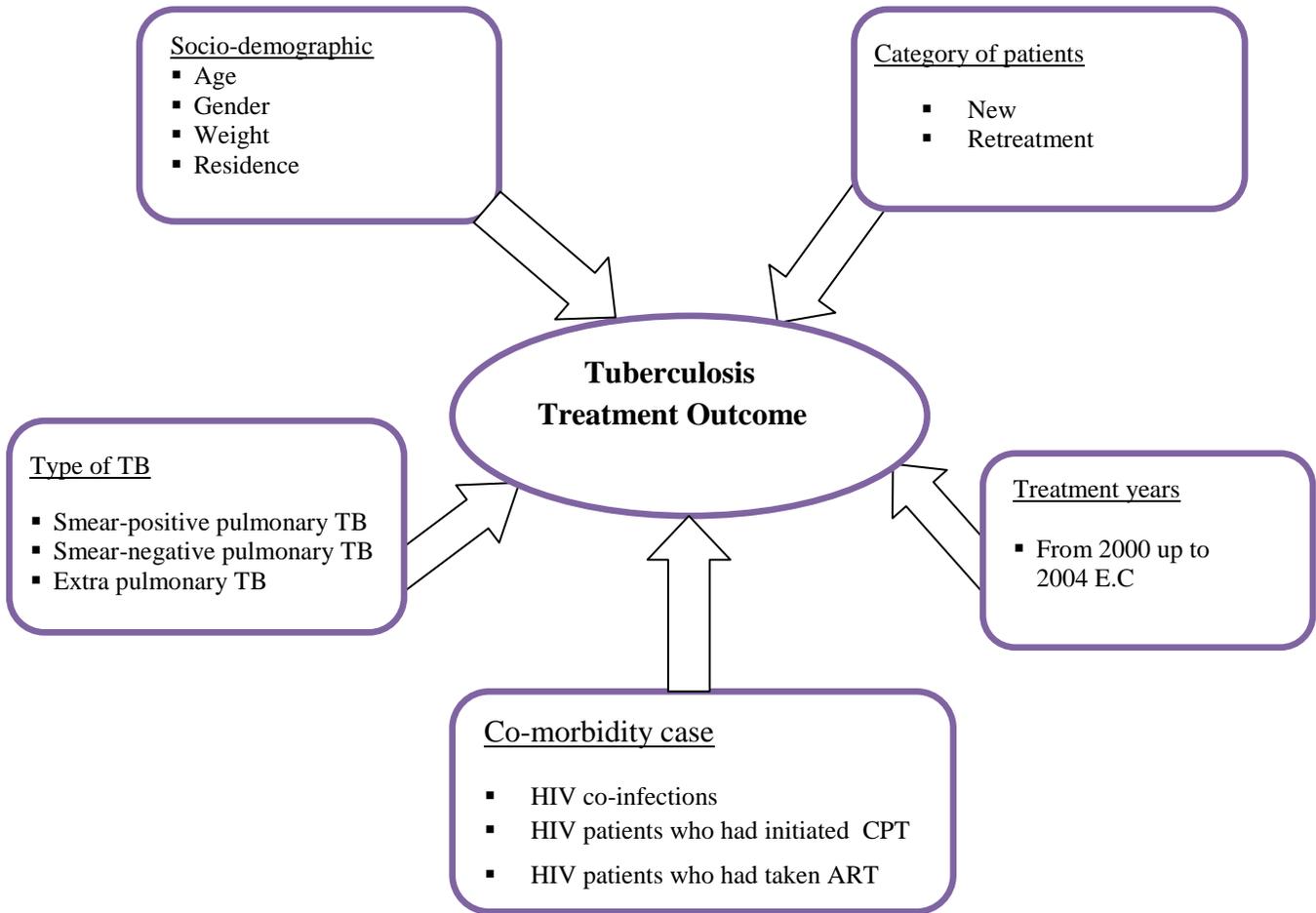
This study was designed to evaluate patient specific treatment outcomes of tuberculosis and describe the barriers for successful treatment outcomes of tuberculosis patient in Jimma University Specialized Hospital and Omonada Training Health Center. Monitoring the outcome of treatment is essential in order to evaluate the effectiveness of treatment outcomes. Furthermore, understanding the specific reasons for unsuccessful outcomes is important in order to improve treatment systems, although treatment outcomes data are needed to evaluate TB control program.

The findings of this study may in general help the health management at a higher level and the health institutions in particular to understand the extent of the problem in the study community and health institutions.

Besides, the study will enhance the capacity to look for possible alternative solutions to health service with regard to associated factors with poor TB treatment outcome in collaboration with the health centers, hospitals and relevant stake holders. It will also contribute to increase in the knowledge about associated factors with poor TB treatment outcome in the areas by concerned bodies including the health center and hospital staffs so as to develop strategies to alleviate this problem. Moreover, these surveillance data are essential in describing morbidity and mortality, monitoring trends in tuberculosis incidence and prevalence, detecting potential outbreaks, and defining high-risk groups.

In addition, the finding may be useful to other researchers as springboard while conducting further studies on similar problems. Identification of associated factors with poor TB treatment outcome is also essential in order to guide program planning, and organizing health service. It is expected that identifying those risk factors will enable to improve treatment outcome and increase success rate in Ethiopia particularly in Oromia region, Jimma University Specialized Hospital and Omonada Training Health Center.

### 3. CONCEPTUAL FRAME WORK



**Figure1.** Conceptual framework for factors associated with tuberculosis treatment outcome.

Tuberculosis treatment outcome is affected by socio-demographic, TB/HIV co-infections, TB patient category, Type of TB and treatment year difference.

## **4. OBJECTIVES**

### **4.1. General objective**

To assesses treatment outcome of tuberculosis and associated factors for treatment outcomes at Jimma University Specialized Hospital (JUSH) and Ommo-Nada Training Health Center (ONTHC).

### **4.2. Specific objectives**

- ❖ To assess the outcomes level of patients registered for anti-tuberculosis treatment in JUSH and ONTHC.
- ❖ To identify factors associated with treatment outcomes of tuberculosis at JUSH and ONTHC
- ❖ To identify predictors for poor treatment outcomes of tuberculosis at JUSH and ONTHC

## 5. METHOD AND PATIENTS

### 5.1. Study area and Period

The study was conducted at Jimma University Specialized Hospital and Ommonada Training Health center, Jimma Zone, Oromia region, Ethiopia. The hospital possesses basic facilities for tuberculosis treatment and serves Jimma town and the surrounding population close to 15 million and Ommo-nada district is one of the 12districts found in Jimma zone and 68km east from Jimma town and has population of 26,175. In JUSH and ONTHC TB clinic, directly observed treatment short cores (DOTS) is operating under the National tuberculosis control programme of Ethiopia. The data were collected from March 03 to April 7/2013.

### 5.2. Study Design

Health facility based general retrospective cohort study among TB patients

### 5.3. Source population

All tuberculosis patients undergoing treatment at Jimma University Specialized Hospital and Ommo-nada Training Health center between 1<sup>st</sup>September2000 to august 2004E.C.

### 5.4. Study participants

All Tuberculosis patients who were under regular follow up in the TB clinic and had treatment outcome of tuberculosis in selected health facilities that fulfill the inclusion criteria were included between 1<sup>st</sup>September2000 to august 2004E.C.

#### **Inclusion Criteria**

- All tuberculosis patients who were registered on TB patient standard registration book with all follow up parameters and
- Patients who had treatment outcomes result in the follow up periods.

#### **Exclusion criteria**

- Patients' data that had not full information on treatment outcomes record.
- Illegible records

## 5.5. Sampling Technique

All tuberculosis patients who had fulfilled the inclusion criteria in both study areas during the period of 1<sup>st</sup> September 2000 to August 2004 E.C. were included.

## 5.6. Study Variables

### 5.6.1. Dependent Variables

- ❖ Treatment outcomes of tuberculosis

### 5.6.2. Independent Variables

- ❖ Socio-demographic factors
  - ✓ Age
  - ✓ Gender
  - ✓ weight
  - ✓ Residence
- ❖ Type of TB
  - ✓ Smear positive Pulmonary TB
  - ✓ Smear negative Pulmonary TB
  - ✓ Extra-pulmonary TB
- ❖ Category of patient
  - ✓ New
  - ✓ Re treatment
- ❖ Co-morbidities:
  - ✓ HIV status
  - ✓ HIV patients who had initiated CPT
  - ✓ HIV patients who had taken ART
- ❖ Treatment\_years
  - ✓ From 1<sup>st</sup> September 2000 to last August 2005 E.C.

### 5.7. **Data collection and Data quality assurance**

Data was collected through medical record reviews of patients using a prepared standard checklist from TB clinic. The content of the checklist include socio-demographic characteristics, HIV status and tuberculosis type. In order to assure the quality of data the following measures were undertaken:-

- ✓ Pre-test was done before 3 days of the research conducted and accordingly modifications were made.
- ✓ Data were collected by trained 2 nurses working in the JUSH and ONTHC.
- ✓ The data collectors were trained for 2 days on the data collection format and techniques of data retrieval.
- ✓ The principal investigator and supervisors strictly monitored data collectors daily to assure the completeness of filled formats.

### 5.8. **Plan for data analysis**

Data were coded and then checked for its completeness and consistency. The collected data were entered and analyzed using SPSS for windows version 16.0 statistical soft ware program. A descriptive analysis was conducted to check for outliers, consistencies and to identify missed values for independent variables. Bivariate analysis was employed to see the association between independent variables and treatment outcomes. To control the effect of confounding factors or to determine independently associated variables, each variables that are statistically significant at  $p\text{-value} < 0.25$  in bivariate analysis was entered in to backward stepwise multiple logistic regression model as the independent variable.  $P < 0.05$  was considered as statistically significant for all the independent variables in the final model.

### 5.9. **Ethical consideration**

Ethical clearance to carry out this study was obtained from institution review board, Jimma University (Ref.No.RPGC/148/2013). The patient data from medical charts were accessed upon the approval of the research proposal by research committee. Also, official letter was taken to clinical director of Jimma university specialized

hospital and head of the ONTHC to carry out the research. Confidentiality was secured during the data collection, thus name and address of the patient was not recorded in the data collection format.

#### 5.10. **Dissemination plan**

The result of the study will be disseminated to responsible bodies such as Jimma University community, Federal Ministry of Health, Ethiopian Food, Medicines and Health care Administration and Control Authority (FMHACA), Oromia Regional Health Bureau, Zonal and district health offices and district administration of the study area. The study finding will also be submitted to professional journal for publication to serve as base line for further studies.

### 5.11. Definitions of terms

**Treatment outcome was divided into seven categories according to NTLCP guideline. These categories are:**

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

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

**Treatment failure:** A patient who remains or becomes again smear-positive at the end of 5 “month” or later during treatment; or a patient who was PTB-negative at the beginning and turned out smear-positive at the end of the intensive phase.

**Died:** A patient who died for any reason during the course of treatment.

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

**Transfer out:** A patient who started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of treatment results. In this study, transfer out is not considered in the analysis for outcome, which was categorized as good and poor.

**Treatment success:** The sum of patients who are declared “cured” and those who have “completed” treatment.

**According to WHO criteria, treatment outcomes were categorized in to two:**

**Successful outcome-** if TB patients were cured (i.e., negative smear microscopy at the end of treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms.

**Poor outcome-** if treatment of TB patients resulted in treatment failure (i.e., remaining smear-positive after 5 months of treatment), or default (i.e., patients who interrupted their treatment for two consecutive months or more after registration), or death.

However, patients who transferred out to other districts were excluded from the treatment outcome evaluation as information on their treatment outcome was unavailable.

**Tuberculosis (TB):** is a patient in whom tuberculosis has been confirmed bacteriologically or diagnosed by a clinician

**Smear-positive Pulmonary TB:** A patient with at least two sputum specimens which were positive for acid-fast bacilli (AFB) by microscopy, or a patient with only one sputum specimen which was positive for AFB by microscopy, and chest radiographic abnormalities consistent with active pulmonary TB.

**Smear-negative pulmonary TB:** A patient with symptoms suggestive of TB, with at least two sputum specimens which were negative for AFB by microscopy, and with chest radiographic abnormalities consistent with active pulmonary TB

**Extra-pulmonary TB (EPTB):** This included tuberculosis of organs other than the lungs, such as lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges, etc

**New case (N):** A patient who never had treatment for TB, or has been on previous anti-TB treatment for less than four weeks.

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

**Not evaluated:** a patient whose treatment outcome is not known.

## 6. RESULTS

### 1. Socio-demographic and clinical characteristics of TB patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center

A total of 2107 patients were treated for tuberculosis in Jimma University Specialized Hospital and Ommo-Nada Training Health Center, from September 2000 to August 2004 E.C. From total of TB patients 1248 (59.2%) were males. The mean age of the patients was  $29.5 \pm 1.31$  year, ranging from 1-74 years. About one third of the patients were in the age range of 15- 24.9 (32.3%) year and urban dwellers (72.3%)(Table1).

Among patients for whom disease category were documented, 1023 (48.6%), 619 (29.4%) and 465 (22.1%) of them had smear-positive, smear-negative pulmonary TB (PTB) and extrapulmonary TB (EPTB) respectively. The highest number of patients (1569 (74.5%)) were from Jimma University Specialized Hospital and 1770(84%) number of patients were new cases. With regard to HIV status, 1175(84.2%) and 178(8.4%) of patients were HIV negative and positive respectively. Of those HIV-positive, 122(68.5%) and 104(58.4%) were initiated co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART) respectively (Table 2).

**Table1:** Socio-demographic and general characteristics of TB patients (N=2107) in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Characteristics		JUSH and ONTHC		JUSH		ONTHC	
		Frequency	Percent	Frequency	Percent	Frequency	Percent
Gender	Male	1248	59.2	916	58.4	332	61.7
	Female	859	40.8	653	41.6	206	38.3
Age (years)	0-14.9	186	8.8	140	8.9	46	8.6
	15-24.9	681	32.3	541	34.5	140	26.0
	25-34.9	578	27.4	417	26.6	161	29.9
	35-44.9	349	16.6	255	16.3	94	17.5
	45-54.9	199	9.4	142	9.1	83	15.4
	55-64.9	88	4.2	59	3.8	3	.6
	>= 65	26	1.2	15	1.0	11	2.0
Residence	Urban	1523	72.3	1134	72.3	389	72.3
	Rural	508	24.1	359	22.9	149	27.7
	Prison	76	3.6	76	4.8	0	0
Weight (Kg)	7-14.9	47	2.2	36	2.3	46	8.6
	15-19.9	44	2.1	33	2.1	140	26.0
	20-20.9	76	3.6	55	3.5	161	29.9
	30-39.9	135	6.4	110	7.0	94	17.5
	40-54.9	1303	61.8	975	62.1	57	10.6
	55-75	502	23.8	360	23.0	29	5.4

**Table 2:** Clinical characteristics of T.B patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Characteristics		JUSH		ONTHC	
		Frequency	percent	Frequency	percent
Tuberculosis type	Smear positive	755	48.1	268	49.8
	Smear negative	460	29.3	159	29.6
	Extrapulmonary	354	22.6	111	20.6
HIV status	Positive	116	7.4	62	11.5
	Negative	1385	88.3	390	72.5
CPT initiated? for Sero-positive TB patients	Yes	82	44.6	40	27.0
	No	34	18.5	22	14.9
ART initiated? for Sero-positive TB patients	Yes	69	37.5	35	23.6
	No	47	25.5	27	18.2
Smear result at 2 <sup>nd</sup> month for PTB positive patients	Positive	77	4.9	26	4.8
	Negative	254	16.2	85	15.8
	Not tested	1238	78.9	427	79.4
Smear result at 5 <sup>th</sup> month for PTB positive patients	Positive	6	4	0	0
	Negative	268	17.1	105	19.5
	Not tested	1295	82.5	433	80.5
Smear result at 7 <sup>th</sup> month for PTB positive patients	Positive	0	0	0	0
	Negative	269	17.1	105	19.5
	Not tested	1300	82.9	433	80.5

## **2. Treatment outcome of TB patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center**

Among all TB patients (2107), 1135 (53.9%) and 369 (17.5%) of them were completed the treatment and cured respectively. Among 1751 number of patients evaluated for treatment outcome, 1504 (85.9%) and 247 (14.1%) number of them had successful and unsuccessful treatment outcome respectively. Among a total of 42 numbers of deaths, 32 of them were males.

Among 1248(59.2%) male patients, 617(49.4%) and 230 (18.4%) of them completed the treatment and transferred out respectively while 518 (60.3%) and 157 (18.3%) of females completed the treatment and cured respectively

Highest number of patients, 1135(53.9) completed the treatment for whom TB type was documented, completed treatment and cured patients among smear positives constituted the second highest number on the other hand transferred out in both smear negative and extra pulmonary TB constituted the highest number of patients. (Table3).

**Table 3:** Treatment Outcome of TB patients by socio-demographic and clinical characteristics of TB patients, in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Characteristics		Cured N (%)	Completed treatment N (%)	Transferred out N (%)	Default N (%)	Failure N (%)	Death N (%)
Gender	Male	212(17.0)	617(49.4)	230(18.4)	128(10.3)	29(2.3)	32(2.6)
	Female	157(18.3)	518(60.3)	126(14.7)	41(4.8)	7(0.8)	10(1.1)
Total		369(17.5)	1135(53.9)	356(17.0)	169(8.0)	36(1.7)	42(2.0)
Residence	Urban	289(19)	913(62)	212(13.9)	78(5.1)	19(1.2)	12(0.8)
	Rural	73(14.4)	182(35.8)	127(25.0)	81(15.9)	17(3.3)	28(5.5)
	Prison	7(9.2)	40(52.6)	17(22.4)	10(13.2)	0(0.0)	2(2.6)
Total		369(17.5)	1135(53.9)	356(17.0)	169(8.0)	36(1.7)	42(2.0)
Age group (years)	0-14.9	28(15.0)	95(51.1)	23(12.4)	26(14.0)	6(3.2)	8(2.3)
	15-24.9	165(24.2)	354(52.0)	148(21.7)	11(1.6)	2(0.2)	1(0.1)
	25-34.9	135(23.4)	318(55.0)	91(15.7)	28(4.8)	4(0.7)	2(0.4)
	35-44.9	34(9.7)	196(56.2)	50(14.3)	49(14.1)	8(2.3)	12(3.4)
	45-54.9	6(3.0)	110(55.0)	30(15.0)	35(18.0)	7(3.5)	11(5.5)
	55-64.9	1(1.1)	48(54.5)	11(12.5)	18(20.5)	5(5.7)	5(5.7)
	>65	0(0.0)	14(54.0)	3(12.0)	2(8.0)	4(15.0)	3(11.0)
Total		369(17.5)	1135(53.9)	356(17.0)	169(8.0)	36(1.7)	42(2.0)
TB Type	Smear positive PTB	369(36.0)	484(47.0)	128(13.0)	31(3.0)	7(0.7)	4(0.3)
	Smear negative PTB	–	371(60.0)	128(20.6)	81(13.1)	19(3.1)	20(3.2)
	EPTB	–	280(60.2)	100(21.5)	57(12.3)	10(2.4)	18(3.8)
Total		369(17.5)	1135(53.9)	356(17.0)	169(8.0)	36(1.7)	42(2.0)

**3. Treatment outcome and TB type across the years for all cases of tuberculosis in Jimma University Specialized Hospital and Ommo-Nada Training Health Center**

The trends of TB treatment through September 2000 to August 2004 E.C showed that the percentage of patients cured showed improvement, whereas the percentages of defaulters 13(3.1), treatment failures 2(0.5) and death were 3(0.7) decreased through the indicated time gap. Most of the patients in each year completed the treatment while cured number of patients constituted the second highest number in each year except in 2003 and 2004 (transferred out had highest number). In 2004 E.C Smear positive pulmonary TB patients were 251(60.2) constituted highest number of patients and in 2000 E.C Smear negative pulmonary TB 161(32.4) and extra pulmonary TB 126 (25.4) were constituted the highest number (Table 4).

Table 4: Trends of treatment outcome and tuberculosis type across the years for all cases of tuberculosis in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Treatment outcome and TB type		Years					Total
		Sept.2000 - Aug. N (%)	Sept.2001 - Aug. N (%)	Sept.2002 - Aug. N (%)	Sept.2003 - Aug. N (%)	Sept.2004 - Aug. N (%)	
Treatment outcomes	Cured	76(15.3)	64(15.0)	58(17.0)	89(21)	82(19.7)	369(17.5)
	Completed treatment	280(56.3)	218(51.2)	179(52.2)	242(57.1)	216(51.8)	1135(53.9)
	Transferred out	73(14.7)	74(17.4)	46(13.4)	62(14.6)	101(24.2)	356(16.9)
	Defaulted	43(8.7)	51(12)	39(11.3)	23(5.4)	13(3.1)	169(8.0)
	Failure	10(2.0)	10(2.3)	11(3.2)	3(0.7)	2(0.5)	36(1.7)
	Died	15(3.0)	9(2.1)	10(2.9)	5(1.2)	3(0.7)	42(2.0)
Total		497(100)	426(100)	343(100)	424(100)	417(100)	2107(100)
TB Types	Smear positive pulmonary TB	210(42.2)	194(45.5)	165(48.4)	203(47.9)	251(60.2)	1023(48.6)
	Smear negative pulmonary TB	161(32.4)	137(32.2)	105(30.6)	121(28.5)	95(22.8)	619(29.4)
	EPTB	126(25.4)	95(22.3)	73(21)	100(23.6)	71(17.0)	465(22.0)
Total		497(100)	426(100)	343(100)	424(100)	417(100)	2107(100)

**4. Unadjusted logistic regression analysis showing association of factors affecting treatment outcome among Tuberculosis patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center**

Unadjusted logistic regression analysis was carried out for all patients who had outcome except transferred out. All of the variables (age, gender, weight, residence, patients category, TB type

HIV Status, CPT initiation for HIV positive, ART initiation for HIV positive, Smear result at 2<sup>nd</sup> month for Smear positive PTB, year of treatment and treatment Centre) in the bivariate logistic regression analysis were candidate for multiple logistic regressions analysis, as all of them had P-value less than 0.25. Thus, from the above variables, age, gender, weight, residence, patients category, TB type, HIV Status, CPT initiation for HIV positive, ART initiation for HIV positive, Smear result at 2<sup>nd</sup> month for Smear positive PTB, and year of treatment have significant association with treatment outcome as it is indicated by P-value of <0.05 (Table5).

Table 5: Bivariate logistic regression analysis of factors affecting treatment outcome in TB patients in Jimma University Specialized Hospital and Ommo-Nada Training Health from 2000 - 2004 E.C

Characteristics		Treatment success		P-value	COR	95% CI	
		Successful N (%)	Unsuccessful N (%)			Lower	Upper
Age group (yrs)	0-14.9	123 (75.5)	40 (24.5)	<0.001	12.06	6.36	22.85
	15-24.9	519 (97.4)	14 (2.6)		1		
	25-34.9	453 (93.0)	34 (7.0)	0.002	2.78	1.47	5.25
	35-44.9	230 (77.0)	69 (23.0)	<0.001	11.12	6.13	20.16
	45-54.9	116 (68.6)	53 (31.4)	<0.001	16.93	9.09	31.56
	55-64.9	49 (63.6)	28 (36.4)	<0.001	21.18	10.46	42.88
	=/>>65	14 (60.9)	9 (39.1)	<0.001	23.83	8.84	64.23
Gender	Male	829(81.4)	189(18.6)	<0.001	2.65	1.94	3.62
	Female	675(92.0)	58(8.0)		1		
Weight (Kg)	7-14.9	31(70.5)	13 (29.5)	0.013	2.33	1.19	4.54
	15-19.9	32 (76.2)	10 (23.8)	0.139	1.73	0.84	3.59
	20-29.9	48 (75.0)	16 (25.0)	0.041	1.85	1.03	3.33
	30-39.9	99 (90.0)	11 (10.0)	0.141	0.62	0.32	1.17
	40-54.9	915 (84.7)	165 (15.3)		1		
	55-75	379 (92.2)	32 (7.8)	<0.001	0.47	0.32	0.69
Residence	Urban	1202(91.7)	109(8.3)		1		
	Rural	255(67.0)	126(33.0)	<0.001	5.45	4.08	7.28
	Prison	47(79.7)	12(20.3)	0.002	2.82	1.45	5.47
Patients Category	New	1294(89.3)	155(10.7)		1		
	Retreatment	210(69.5)	92(30.5)	<0.001	3.66	2.72	4.92
TB Type	Smear positive pulmonary TB	853(95.3)	42(4.7)		1		
	Smear negative pulmonary TB	371(75.6)	120(24.4)	<0.001	6.57	4.53	9.53
	EPTB	280(76.7)	85(23.3)	<0.001	6.17	4.16	9.14
HIV Status	Positive	90(55.9)	71(44.1)		1		
	Negative	1317(91.0)	130( 9.0)	<0.001	0.13	0.09	0.18
	Unknown	97(67.8)	46(32.2)	0.033	0.60	0.38	0.96

**(Continue) Table 5:** Bivariate logistic regression analysis of factors affecting treatment outcome in TB patients in Jimma University Specialized Hospital and Ommo-Nada Training Health from 2000 -2004 E.C

Characteristics		Treatment success		P-value	COR	95% CI	
		Successful N (%)	Unsuccessful N (%)			Lower	Upper
CPT initiation for HIV positive	Yes	87(77.7)	25(22.3)	<0.001	1	15.29	186.19
	No	3(6.1)	46(93.9)		53.36		
ART initiation for HIV positive	Yes	76(79.2)	20(20.8)	<0.001	1	6.41	29.89
	No	14(21.5)	51(78.5)		13.84		
Smear result at 2 <sup>nd</sup> month for Smear positive PTB	Positive	68(74.7)	23(25.3)	<0.001	1	0.001	0.07
	Negative	323(99.7)	1(0.3)		0.01		
	Not tested	462(96.2)	18(3.8)		0.12		
Year of treatment	2000	356(84.0)	68(16.0)	<0.001	3.16	1.84	5.44
	2001	282(80.0)	70(20.0)	<0.001	4.11	2.39	7.07
	2002	237(79.8)	60(20.2)	<0.001	4.19	2.41	7.29
	2003	331(91.4)	31(8.6)	0.153	1.55	0.85	2.83
	2004	298(94.3)	18(5.7)	<0.001	1		
Treatment Centre	JUSH	1095(88.3)	145(11.7)	<0.001	0.53	0.40	0.70
	ONTHC	409(80.3)	102(19.7)		1		

**ART**-Antiretroviral therapy

**EPTB**- Extra-pulmonary Tuberculosis

**CPT**-co-trimoxazole prevention therapy

**PTB**- Pulmonary Tuberculosis

**COR**- Crude Odds Ratio,

**5. Adjusted logistic regression analysis showing factors independently associated with treatment outcome among Tuberculosis patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center**

Multi-variate logistic regression analysis showed that patients aged between 35-44.9, 45-54.9, and 55-64.9 and greater than or equal to 65 years of old were 6.54, 12.41, 26.97 and 25.93 times more risky to develop poor treatment outcome compared to patients aged 15-24.9 years of age respectively. Being male is 2.99 times more likely to have poor treatment outcome than females. Rural residence and prisoned patients were 3.1 and 2.7 times more likely to develop poor treatment outcome compared to urban resident patients respectively. TB patients on retreatment were 1.9 times more likely to develop poor treatment outcome compared to new patients. Smear negative and EPTB patients were 6.6 and 5.2 times more likely to develop poor treatment outcome compared to patients with smear positive TB respectively.

TB patients with HIV negative were 0.06 times less likely to develop poor treatment outcome compared to HIV positive TB patients. Among HIV positive patients, who didn't start co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART) were 58.6 and 10.5 times more likely have poor treatment outcome compared to patients who start CPT and ART respectively. Patients started their anti-TB medication in 2001 and 2002 E.C were 2.26 and 2.67 times more likely to have poor treatment outcome compared to patients who started their medication in 2004 (Table 6).

Table 6: Adjusted logistic regression analysis of factors that independently affect treatment outcome among tuberculosis patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Characteristics	Treatment success			P-Value	AOR	95% CI	
	Successful N (%)	Unsuccessful N (%)				Lower	Upper
Age group (yrs)	0-14.9	123 (75.5)	40 (24.5)	0.376	2.19	0.385	12.49
	15-24.9	519 (97.4)	14 (2.6)		1		
	25-34.9	453 (93.0)	34 (7.0)	0.170	1.69	0.79	3.62
	35-44.9	230 (77.0)	69 (23.0)	<0.001	6.54	3.20	13.35
	45-54.9	116 (68.6)	53 (31.4)	<0.001	12.41	5.88	26.19
	55-64.9	49 (63.6)	28 (36.4)	<0.001	26.97	11.34	64.17
	=/>65	14 (60.9)	9 (39.1)	<0.001	25.93	6.85	98.25
Sex	Male	829(81.4)	189(18.6)	<0.001	2.99	1.99	4.48
	Female	675(92.0)	58(8.0)		1		
Weight (Kg)	7-14.9	31(70.5)	13 (29.5)	0.257	3.09	0.44	21.79
	15-19.9	32 (76.2)	10 (23.8)	0.059	6.55	0.93	46.02
	20-29.9	48 (75.0)	16 (25.0)	0.055	5.97	0.96	37.04
	30-39.9	99 (90.0)	11 (10.0)	0.143	1.98	0.79	4.92
	40-54.9	915 (84.7)	165 (15.3)		1		
	55-75	379 (92.2)	32 (7.8)	0.001	0.44	0.27	0.72
Residence	Urban	1202(91.7)	109(8.3)		1		
	Rural	255(67.0)	126(33.0)	<0.001	3.07	2.08	4.53
	Prison	47(79.7)	12(20.3)	0.028	2.66	1.11	6.37
Patients Category	New	1294(89.3)	155(10.7)		1		
	Retreatment	210(69.5)	92(30.5)	0.003	1.90	1.25	2.89
TB Type	Smear positive PTB	853(95.3)	42(4.7)		1		
	Smear negative PTB	371(75.6)	120(24.4)	<0.001	6.67	4.15	10.73
	EPTB	280(76.7)	85(23.3)	<0.001	5.20	3.12	8.68
HIV Stats	Positive	90(55.9)	71(44.1)		1		
	Negative	1317(91.0)	130(9.0)	<0.001	0.06	0.03	0.09
	Unknown	97(67.8)	46(32.2)	<0.001	0.29	0.14	0.58

**(Continue) Table 6:** Adjusted logistic regression analysis of factors that independently affect treatment outcome among tuberculosis patients in Jimma University Specialized Hospital and Ommo-Nada Training Health Center from 2000-2004 E.C

Characteristics		Treatment success		P-Value	AOR	95% CI	
		Successful N (%)	Unsuccessful N (%)			Lower	Upper
CPT initiation for HIV-positive	Yes	87(77.7)	25(22.3)		1		
	No	3(6.1)	46(93.9)	<0.001	58.58	6.76	507.84
ART initiation for HIV-positive	Yes	76(79.2)	20(20.8)		1		
	No	14(21.5)	51(78.5)	0.021	10.48	1.42	77.46
Smear result at 2 <sup>nd</sup> month for Smear positive PTB	Positive	68(74.7)	23(25.3)		1		
	Negative	323(99.7)	1(0.3)	<0.001	0.008	0.001	0.08
	Not tested	462(96.2)	18(3.8)	<0.001	0.12	0.04	0.34
Year of treatment	2000	356(84.0)	68(16.0)	0.166	1.64	0.82	3.29
	2001	282(80.0)	70(20.0)	0.028	2.26	1.09	4.66
	2002	237(79.8)	60(20.2)	0.007	2.67	1.31	5.47
	2003	331(91.4)	31(8.6)	0.553	0.79	0.37	1.72
	2004	298(94.3)	18(5.7)		1		

## 7. DISCUSSION

Assessment of anti-tuberculosis treatment outcome and identifying factors responsible for poor treatment outcome is one of the major indicators for the evaluation of the performance of a national TB program.

In the study area, treatment success rate was 85.9%, which is addressing the WHO international target of 85 % (3). Therefore, the treatment was satisfactory. Most of the patients at both study area had higher number of patients who completed the treatment; on the other hand, higher number of cured patients were from urban residence.

The treatment success rate of this study (85.9%) is higher than previous studies conducted in some parts of Ethiopia including Gondar University Teaching Hospital, which is 29.5% (6); Felege Hiwot Referral Hospital, which is 26%.9 (34); and Southern region, which is 74.8% (17). However, it is lower than study in Tigray region (89.0%) (18). The difference could be due to variation in DOTS performance in the various study areas, difference in duration of study period, sample size and setting, knowledge deficit, patient awareness about TB, inappropriate health seeking behavior and stigma towards TB. For example, the study in Southern Ethiopia was conducted over a longer period (2002–2007) with sample size of 6547 patients.

In this study among patients with poor treatment outcome, about (8%) of them was defaulters, 2% was died and very few (1.7%) had treatment failure. Such poor treatment outcome result was comparatively lower than study conducted in Gondar University Teaching Hospital, with 18.3% and 10.1% of defaulters and deaths respectively (6) and in Tigray region with failure rate of 3.7% (18). probably this indicates that patient follow up procedures and patient awareness about TB treatment was good and higher than other study area.

In multivariable logistic regression model, poor treatment outcome was significantly associated with patients' age group of 35-44.9, 45-54.9, and 55-64.9 and greater than or equal to 65 years compared with the age group of 15-24.9 years. Large number of the patients in any age group completed the treatment while defaulters in 45-64.9 year age range constituted the next higher number of patients. This showed that as

age increases the occurrence of poor TB treatment outcome out ways. These could be due to presence of co-morbidity, more side effects as well as general physiological deterioration which is higher than younger patients. Similarly, a retrospective survey conducted in Northeastern Thailand showed that the risk of treatment failure/death were significantly associated with the patients' age greater than 60 years (21) while others showed poor treatment outcomes with age(4, 19).

Being male was independent risk factor for poor treatment outcome in the present study. Similar findings were reported from other studies (17, 20-21). This might be due to males are highly exposed to cigarette smoking and alcohol consumption, which might contribute to poor treatment outcomes.

Weight (at initiation of anti-TB treatment) greater than 55 Kg was significantly associated with good treatment outcome as compared to age range of 40-54.9 Kg. As body weight increases, the patients' general conditions are also increases in anti TB treatment. The study in Addis Ababa revealed that body weight at initiation of anti-TB treatment less than 35 kg was a significantly associated with poor treatment outcome (33). This variation could be due to difference in weight classifications and sample size in both groups of studies.

Patients on retreatment had poor outcome than newly diagnosed and treated cases. As the patients were exposed to anti-TB medication frequently, sub-optimal therapy and drug resistance might occur. Similar findings also reported that re-treatment was significantly associated with poor outcome treatment (17, 31, 33).

Being at rural residence and prison was significantly associated with poor treatment outcome higher number defaulters were from rural residence and higher number transferred out were from prisoned patients when compared to patients who lived in urban areas. This variation might be due to low DOTS performance, inadequate health seeking behavior, stigma towards TB, lower patient awareness about TB treatment and the long distance between their homes and the treatment center. One study conducted in a rural community in Southwest Ethiopia showed that there was little knowledge about TB transmission and prevention (23). On the other hand, the study conducted among prisoners in eastern Ethiopian showed that prisoners have a moderate level of knowledge and practice about TB, which reveals misconceptions

about its causes, control, prevention and treatment (35). Close monitoring and health education for rural residence and prisoned patients is great importance.

In this study, the type tuberculosis was associated with poor treatment outcome. Smear negative and extra pulmonary TB were significantly associated with poor treatment outcome compared to smear positive PTB patients. This probably due to low rate of identification of illness, delay to start treatment and treatment outcome monitoring of smear-negative and extra pulmonary TB is only clinical condition but smear-positive pulmonary TB patients are by testing sputum result at 2<sup>nd</sup>, 5<sup>th</sup> and 7<sup>th</sup> in addition to clinical progression of the patients (17, 6, 34). Among smear positive PTB patients, smear result at 2<sup>nd</sup> month negative and not tested patients were 0.008 and 0.12 times less likely to develop poor treatment outcome than 2<sup>nd</sup> month positive smear result this indicate that smear result after completing initiation phase highly associated with treatment outcome. In this study the number of smear positive PTB cases were highest 1023(48.6%) compared to smear negative and extrapulmonary tuberculosis cases over the years.

The current study showed that HIV-negative TB patients have good treatment outcomes compared to HIV-positive TB patients. Being TB patients alone might be with low pill burden, minimum adverse effects, mild drug-drug interaction and good immunity compared to TB/HIV co-infected patients. This is similar with other published reports, in which TB/HIV co-infection was significantly associated with poor treatment outcome (24, 28.).The problem of TB is worse by the concurrent infection with HIV. It is estimated that 50%of TB patients are co-infected with HIV (26). Both diseases place a big social, economic and health burden on the country Patients with HIV and TB are likely to face more challenges because they have to get HIV care in addition to the TB care. This may lead to poor adherence among these patients (12).

This study indicated that, patients who initiated antiretroviral therapy timely for those sero-positive TB patients are a contributory factor for good treatment outcome. Similar studies stated that TB- HIV co-infection without the use of ART resulted in poor treatment outcome (28-29). HIV-infected patients who received ART during

tuberculosis treatment converted their sputum smears and cultures to negative significantly faster than those not treated with ART (25).

The treatment success rate of TB from 2000 to 2004 E.C became improved subsequently, which is explained as patients started their anti-TB medication in 2001 and 2002 treatment years were more likely to have poor treatment outcome compared to patients started their medication in 2004 treatment years. This difference might be due to improvement in patient awareness about TB transmission and treatment as a result of health education and promotion, health extension workers involvement in the community mobilizations and improvements in DOTS performance in the subsequent year of treatment. Similar study reports from South Ethiopia showed that introduction and expansion of DOTS significantly increased treatment success rate and decreased in defaulters and failure rates (20).

### **Strength and limitation of the study**

#### **❖ Strength of the study**

- ✓ This is a five year study and large number of patients included
- ✓ No research was conducted previously on assessment of tuberculosis treatment outcome and its associated factors at JUSHL and ONTHC.

#### **❖ Limitation of the study**

- ✓ Being retrospective
- ✓ Secondary data
- ✓ Large number of patients transferred out

## **8. CONCLUSIONS**

Treatment outcome among tuberculosis patients was satisfactory in the study area.

Male gender, age greater than 35 years, smear negative and extra-pulmonary tuberculosis, retreatment with anti-tuberculosis medications, rural residence, being at prison, TB-HIV co-infection without co-trimoxazole preventive therapy and antiretroviral therapy, and treatment years of 2001 and 2002 were known to be independent predictors of poor treatment outcome among tuberculosis patients in the study area.

## **9. RECOMMENDATION**

Based on the study finding the following recommendations are drawn:

- ✓ HIV testing is strongly recommended for all patients before commencing treatment for TB and initiated co-trimoxazole preventive therapy, antiretroviral therapy timely for those sero-positive TB patients.
- ✓ Specific measures (appropriate and sustainable health education) should be considered by health policy makers, hospital and health center administrators to reduce the rate of poor treatment outcome among high-risk groups, such as the male patients, elderly patients, retreated patients, patients who lived in rural area, prisoned patients and HIV Co-infected patients.
- ✓ Enhanced supervision and adequate TB monitoring and follow up of treatment outcome of patients all over the country, in all TB treatment centers.
- ✓ Other Prospective study involving both chart review and patient interview should be performed.

## REFERENCES

1. World Health Organization. WHO report. Global tuberculosis control: epidemiology, strategy, financing. WHO/HTM/ TB/2008.393. Geneva, Switzerland: WHO, 2008.
2. World Health Organization. WHO report. Global tuberculosis control: epidemiology, strategy, financing. WHO/HTM/ TB//2012.6.). Geneva, Switzerland: WHO, 2012.
3. World Health Organization. WHO report. Global tuberculosis control: epidemiology, strategy, financing. WHO/HTM/ TB/2011.16. Geneva, Switzerland: WHO, 2011.
4. Castelnuovo B. A review of compliance to anti tuberculosis treatment and risk factors for defaulting treatment in Sub Saharan Africa. *African health sciences*. 2010 Dec;10(4):320-4.
5. Ministry of Health of Ethiopia (MOH): Tuberculosis, Leprosy and TB/HIV Prevention and Control Programme Manual. Addis Ababa: MOH 4th edition. 2008,29-33.
6. Tessema B, Muche A, Bekele A, Reissig D, Emmrich F, Sack U. Treatment outcome of tuberculosis patients at Gondar University Teaching Hospital, Northwest Ethiopia. A five year retrospective study. *BMC Public Health*. 2009;9:371.
7. Jianzhao H, van den Hof S, Lin X, Yubang Q, Jinglong H, van der Werf MJ. Risk factors for non-cure among new sputum smear positive tuberculosis patients treated in tuberculosis dispensaries in Yunnan, China. *BMC Health Serv Res*. 2011;11:97.
8. Maher D, Nunn P. Evaluation and determinants of outcome of tuberculosis treatment. *Bull World Health Organ*. 1998;76(3):307-8.
9. Collins BN. Assessing the outcome of tuberculosis treatment in the Cameroon Baptist convention health board tuberculosis treatment centers. Sweden: Umea; 2011,27-29.
10. Pefura Yone EW, Kengne AP, Kuaban C. Incidence, time and determinants of tuberculosis treatment default in Yaounde, Cameroon: a retrospective hospital register-based cohort study. *BMJ Open*. 2011;1(2):e000289.
11. Lawrence M. Tuberculosis Treatment Outcomes in Adult TB Patients Attending a Rural HIV Clinic In South Africa Bushbuckridge: Witwatersrand, Johannesburg; 2009,6:8.

12. Weiguo Xu, Wei Lu, Yang Zhou, Limei Zhu, Hongbing Shen, Wang. J. Adherence to anti-tuberculosis treatment among pulmonary tuberculosis patients: a qualitative and quantitative study. *BMC Health*. 2009;9(169).
13. Bronner LE, Podewils LJ, Peters A, Somnath P, Nshuti L, van der Walt M, et al. Impact of community tracer teams on treatment outcomes among tuberculosis patients in South Africa. *BMC Public Health*. 2012;12(621).
14. Vasankari T, Holmstrom P, Ollgren J, Liippo K, Kokki M, Ruutu P. Risk factors for poor tuberculosis treatment outcome in Finland: a cohort study. *BMC Public Health*. 2007;7:291.
15. Takarinda KC, Harries AD, Srinath S, Mutasa-Apollo T, Sandy C, Mugurungi O. Treatment outcomes of adult patients with recurrent tuberculosis in relation to HIV status in Zimbabwe: a retrospective record review. *BMC Public Health*. 2012;12(124).
16. M Day, A Middlemiss, J Thorpe, Okereke. E. What really happens to tuberculosis patients classified as lost to follow-up in West Yorkshire 2012:1-6.
17. Fatiregun AA, Ojo AS, Bamgboye AE. Treatment outcomes among pulmonary tuberculosis patients at treatment centers in Ibadan, Nigeria. *Ann Afr Med*. 2009 Apr-Jun;8(2):100-4.
18. Munoz-Sellart M, Cuevas LE, Tumato M, Merid Y, Yassin MA. Factors associated with poor tuberculosis treatment outcome in the Southern Region of Ethiopia. *Int J Tuberc Lung Dis*. 2010 Aug;14(8):973-9.
19. Berhe G, Enquesselassie F, Aseffa A. Treatment outcome of smear-positive pulmonary tuberculosis patients in Tigray Region, Northern Ethiopia. *BMC Public Health*. 2012;12:537.
20. Shargie EB, Lindtjorn B. DOTS improves treatment outcomes and service coverage for tuberculosis in South Ethiopia: a retrospective trend analysis. *BMC Public Health*. 2005 Jun 6;5(62).
21. Anunnatsiri S, Chetchotisakd P, Wanke C. Factors associated with treatment outcomes in pulmonary tuberculosis in northeastern Thailand. *Southeast Asian J Trop Med Public Health*. 2005 Mar;36(2):324-30.

22. Ai X, Men K, Guo L, Zhang T, Zhao Y, Sun X, et al. Factors associated with low cure rate of tuberculosis in remote poor areas of Shaanxi Province, China: a case control study. *BMC Public Health*. 2010;10:112.
23. Abebe G, Deribew A, Apers L, Woldemichael K, Shiffa J, Tesfaye M, et al. Knowledge, health seeking behavior and perceived stigma towards tuberculosis among tuberculosis suspects in a rural community in southwest Ethiopia. *Plos one*. 2010;5(10):e13339.
24. Vijay S, Kumar P, Chauhan LS, Vollepore BH, Kizhakkethil UP, Rao SG. Risk factors associated with default among new smear positive TB patients treated under DOTS in India. *Plos One*. 2010;5(4):e10043.
25. Sanchez M, Bartholomay P, Arakaki-Sanchez D, Enarson D, Bissell K, Barreira D, et al. Outcomes of TB treatment by HIV status in national recording systems in Brazil, 2003-2008. *Plos One*. 2012;7(3):e33129.
26. Amuha, M. G. Kutuyabami, P. Kitutu, F. E. Odoi-Adome, R. Kalyango, N. J. Non-adherence to anti-TB drugs among TB/HIV co-infected patients in Mbarara Hospital Uganda: prevalence and associated factors. *African health sciences*. 2009 Aug 1;9(1):S8-15.
27. Gloria Akosua Ansa JDW, Kamran Siddiqi ,Xiaolin Wei Assessing the impact of TB/HIV services integration on TB treatment outcomes and their relevance in TB/HIV monitoring in Ghana. *BioMed Central*. 2012.122-31.
28. Tansuphasawadikul S, Saito W, Kim J, Phonrat B, Dhitavat J, Chamnachanan S, et al. Outcomes in HIV-infected patients on antiretroviral therapy with tuberculosis. *Southeast Asian J Trop Med Public Health*. 2007 Nov;38(6):1053-60.
29. Manosuthi W, Chottanapand S, Thongyen S, Chaovavanich A, Sungkanuparph S. Survival rate and risk factors of mortality among HIV/tuberculosis-coinfected patients with and without antiretroviral therapy. *J Acquir Immune Defic Syndr*. 2006 Sep;43(1):42-6.
30. Thuy TT, Shah NS, Anh MH, Nghia do T, Thom D, Linh T, et al. HIV-associated TB in An Giang Province, Vietnam, 2001-2004: epidemiology and TB treatment outcomes. *PLOS One*. 2007;2(6):e507.

31. Vijay S, Kumar P, Chauhan LS, Rao SV, Vaidyanathan P. Treatment outcome and mortality at one and half year follow-up of HIV infected TB patients under TB control programme in a district of South India. *Plosone*. 2011;6(7):e21008.
32. Nahid P, Gonzalez LC, Rudoy I, de Jong BC, Unger A, Kawamura LM, et al. Treatment outcomes of patients with HIV and tuberculosis. *Am J Respir Crit Care Med*. 2007 Jun 1;175(11):1199-206.
33. Belete G, Gobena A, Sibhatu B, Girmay M. Mortality and associated risk factors in a cohort of tuberculosis patients treated under DOTS programme in Addis Ababa, Ethiopia. *BMC Infectious Diseases*.2011;11(127)
34. Fantahun B, Berhanu A, Tewodros D, Belay A, Woghata T, Belay T, et al. A retrospective study on the outcomes of tuberculosis treatment in Felege Hiwot Referral Hospital, Northwest Ethiopia. *International Journal of Medicine and Medical Sciences*. February 2013;5(2) 85-91.
35. Abebe DS, Biffa D, Bjune G, Ameni G, Abebe F. Assessment of knowledge and practice about tuberculosis among eastern Ethiopian prisoners. *Int J Tuberc lung Dis*. 2011 Feb; 15(2):228-33.

# ANNEX

## DATA COLLECTION FORM

To assess patient specific treatment outcome of tuberculosis and risk factors for poor treatment outcomes at Jimma University Specialized Hospital and Ommo-nada Training Health Center.

### Instruction

- A. Select your answer for the questions by marking “√” in the box provided  
B. If your answer is out of the choice provided; write your answer in the space provided.

1. Age of the patient \_\_\_\_\_ year
2. Weight of the patient \_\_\_\_\_ kg
3. Gender Male  Female
4. Address Urban  Rural  Prisoner
5. Category of patient New  Re treatment
6. TB Treatment Outcome  
Cured  Completed treatment   
Failure  Defaulted   
Died  Transferred out.
7. Type of TB Smear positive Pulmonary TB  Smear negative Pulmonary TB   
Extra pulmonary TB
8. HIV status of the patient HIV positive  HIV negative  not tested   
If positive CPT is initiated? Yes  No   
If positive CPT is initiated Yes  No
9. Smear result after initiation phase (2<sup>nd</sup> month) Smear positive  Smear negative
10. Smear result at 5<sup>th</sup> and 7<sup>th</sup> month Smear positive  Smear negative   
Smear positive  Smear negative

