



**SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL  
COLLEGE**

**RISK FACTORS AND TREATMENT OUTCOMES OF MDR TB  
PATIENTS IN ST. PETER TB SPECIALIZED HOSPITAL IN  
THE LAST 5 YEARS**

**BY – ESAYAS GOREMS (INTERN)**

**A PROPOSAL SUBMITTED TO DEPARTMENT OF PUBLIC  
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**February, 2018**

**Addis Ababa, Ethiopia**



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**Addis Ababa, Ethiopia**

## **ACRONYM/ABREVIATION**

**WHO:** World Health Organization

**TB:** Tuberculosis

**DR-TB:** Drug Resistance Tuberculosis

**MDR:** Multi Drug Tuberculosis

**XDR:** Extensive Drug Resistance

**RR-TB:** Rifampicin Resistance Tuberculosis

**MTB:** Mycobacterium Tuberculosis Bacilli

**HIV:** Human Immunodeficiency Virus

**AIDS:** Acquired Immunodeficiency syndrome

**DM:** Diabetes Mellitus

**INH:** Isoniazid

**RIF:** Rifampicin

**CFR:** Case Fatality Rate

**CI:** Confidence Interval

**AOR:** Adjusted Odds Ratio

**FSU:** Former Soviet Union

**BMI:** Body Mass Index

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## SUMMARY

**Background:** TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB). It is the ninth leading cause of death worldwide and the leading cause from a single infectious agent, ranking above HIV/AIDS. Beside this, MDR TB is defined as TB that is resistant to both isoniazid (INH) and rifampicin (RIF), two of the first-line drugs used in treating pulmonary tuberculosis. Both TB and MDR TB are the global threats that really need a special attention on the prevention and treatment. As part of the globe, Ethiopia is one of the high TB burdened country in the world. Therefore, the objective of this study will encompass in revealing the risk factors and treatment outcomes of MDR TB.

**METHODS AND MATERIALS:** The source population for this study is patients who are admitted and had follow up to St. Peter TB specialized hospital as a case MDR TB in the past 5 years. An institution based retrospective Cohort study design and a systematic random sampling procedure will be conducted to select a fair representative sample from the hospitalized patients. 374 subjects will be selected for the study. To collect data, a self-administered questionnaire will be used as a check-list to extract data's from the medical records. After data is collected, it will be entered into a computer and analyzed using SPSS version 21.0 statistical software. Multivariable logistic regression with 95% CI at  $P \leq 0.05$  will be used to determine factors associated to acquisition of MDR TB. Finally result will be presented in text and graphs and communicated to all concerned bodies.

**WORK PLAN AND BUDGET:** Total cost of the research project is estimated to be 4924.00 birr. Proposal work and field preparation will be completed till Feb 2018, data will be collected Feb-Jun 2018 and analysis, compilation and report write up will be July 2018.

**KEY WORDS:** TB, MDR-TB

# Chapter one

## Introduction

### Background of the problem

TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB). The disease is spread when people who are sick with pulmonary TB expel bacteria into the air, for example by coughing. Overall, a relatively small proportion (5–15%) of the estimated 1.7 billion people infected with *M. tuberculosis* will develop TB disease during their lifetime. However, the probability of developing TB disease is much higher among people infected with HIV, and also higher among people affected by risk factors such as under-nutrition, diabetes, smoking and alcohol consumption. (2)

TB is the ninth leading cause of death worldwide and the leading cause from a single infectious agent, ranking above HIV/AIDS. In 2016, there were an estimated 1.3 million TB deaths among HIV negative people (down from 1.7 million in 2000) and an additional 374 000 deaths among HIV-positive people.(2who) An estimated 10.4 million people (90% adults; 65% male; 10% people living with HIV) fell ill with TB in 2016 (i.e. were incident cases). Globally, the TB mortality rate is falling at about 3% per year. TB incidence is falling at about 2% per year; this needs to improve to 4–5% per year by 2020 to reach the first milestones of the End TB Strategy. Regionally, the fastest decline in TB incidence is in the WHO European Region (4.6% from 2015 to 2016). The decline since 2010 has exceeded 4% per year in several high TB burden countries, including Ethiopia, Kenya, Lesotho, Namibia, the Russian Federation, the United Republic of Tanzania, Zambia and Zimbabwe. Globally, the proportion of people who develop TB and die from the disease (the case fatality ratio, or CFR) was 16% in 2016. This needs to fall to 10% by 2020 to reach the first milestones of the End TB Strategy. There is considerable country variation in the CFR, from under 5% in a few countries to more than 20% in most countries in the WHO African Region. This shows considerable inequalities among countries in access to TB diagnosis and treatment that need to be addressed. Between 2000 and 2016, TB treatment averted an estimated 44 million deaths among HIV-negative people. Among HIV-positive people, TB treatment supported by ART averted an additional 9 million deaths. Drug-resistant TB is a persistent threat, with 490 000 million cases of multidrug-resistant TB (MDR-TB) emerging in 2016 and an additional 110 000 cases that were susceptible to isoniazid but resistant to rifampicin (RR-TB), the most effective first-line anti-TB drug. The countries with the largest numbers of MDR/RR-TB cases (47% of the global total) were China, India and the Russian Federation. (1)

The WHO –recommended rapid diagnostic test for detection of TB and rifampicin resistance currently available is the Xpert MTB/RIF® assay. The number of cartridges procured by

countries eligible for concessional prices was 6.9 million in 2016. Of the 48 countries in at least one of the lists of high burden countries, 28 had adopted national algorithms positioning Xpert MTB/RIF as the initial diagnostic test for all people suspected of having pulmonary TB by the end of 2016. (1)

The latest treatment outcome data show treatment success rates of 83% for TB (2015 cohort), 78% for HIV-associated TB (2015 cohort), 54% for MDR/RR-TB (2014 cohort) and 30% for extensively drug-resistant TB (XDR-TB) (2014 cohort). At least 35 countries in Africa and Asia have introduced shorter regimens for treatment of MDR/RR-TB, with high treatment success rates (87–90%). As part of efforts to improve outcomes for MDR/XDR-TB, 89 countries and territories had started using bedaquiline and 54 had used delamanid by June 2017. Regarding the treatment outcome, the proportion of MDR/RR-TB patients in the 2014 cohort who successfully completed treatment (i.e. cured or treatment completed) was 54%: in 8% the treatment failed, 16% died, 15% were lost to follow-up and 7% had no outcome information. (1)

MDR-TB is difficult to cure. Therefore, special emphasis should be given to control the spread of MDR-TB. Lack of control efforts may lead to the increased resistance to both first- and second-line drugs. A well supported and controlled special treatment unit, which uses both first-line and second-line drugs is required for a proper management of these cases and for effective control of the spread of MDR-TB. (7)

### Statement of the problem

The emergence of drug-resistant tuberculosis is a critical threat to tuberculosis (TB) control and is a major public health concern in several countries. Multidrug-resistant TB (MDR-TB), defined as resistant to at least isoniazid and rifampicin, is emerging as a major clinical and public health challenge in areas of sub-Saharan Africa.

Ethiopia is one of the high TB burdened countries in sub-Saharan Africa which ranks 7th among the 22 high TB burden countries in the world (2). According to the WHO 2013 report, the prevalence and incidence rates of TB in the country were 224/100,000 and 247/ 100,000 populations, respectively. The rate of MDR-TB was estimated to be 1.6 % and 12 % of new and retreatment cases, respectively (2). The overall burden of MDR-TB is exceptionally high in resource limited countries, where health resources, finances, and the skilled personnel required for diagnosis and management are limited, making containment and the prevention of further spread more difficult (2). In Ethiopia, the low socioeconomic status of the population, high prevalence of infectious diseases, poor treatment outcomes, longer treatment time (about two years), higher treatment costs, and many more complications make MDR-TB a more complex disease than TB (3). Based on a WHO 2015 report again, Ethiopia is ranked as 15th among 27 countries with high burden drug resistant TB with an estimated 5200 cases occurring each year. Beside this, According to the 2016 WHO global TB report, in Ethiopia an estimated 2.7% and 14% of new and previously treated TB cases had MDR-TB. Although MDR-TB is a growing concern in resource limited

countries like Ethiopia, it is largely underreported, compromising control efforts. Information concerning the true extent of the problem of MDR-TB in the African Region is limited. Since, there are significant gaps in surveillance, and lack of standards for methodology, data sharing and coordination. The overall epidemiology of drug resistant TB is not well understood in Ethiopia. Hence, understanding the burden of the most prevailing infections like MDR-TB is urgently required to guide public health interventions that are both specific and effective. Furthermore, identifying the possible risk factors like HIV, smoking, TB contact history, diabetes, fasting, history of prison and BCG vaccination status will be helpful in halting the transmission and development of MDR TB. As part of the sustainable development goal 3 and its 3rd target among the 13 targets (Ensure healthy life and promote well-being for all at all ages; By 2030, End the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water borne diseases and other communicable diseases) it's the area of concern to all countries in the world. (3) Therefore, the aim of this research is to determine the magnitude of MDR TB patients admitted in St. Peter TB specialized Hospital in the past 5 years and identifying the possible risk factors that makes the patients vulnerable to acquire the infection and also reveals the treatment outcomes.

### Significance of the study

Despite many researches done on different aspects of MDR TB, The disease entity is still a great threat in the current medical world. It has a multitude of impacts mainly in the developing countries like Ethiopia. This research will provide an understanding on the major risk factors and treatment outcomes of MDR TB. This know-how will be helpful in drawing conclusions on the possible area of intervention and to give recommendation to the concerned body. Moreover, the research will be conducted in one of the big TB center in Ethiopia that makes it the research conclusive at the end of the day.

## Chapter two

### Literature review

Tuberculosis is one of the major pandemic public health problems in the history of mankind. Before the era of Antibiotics, it was the number one killer of all diseases. After so many years of research, human beings developed a curative weapon against the causative agent of the disease but nowadays the mysterious Mycobacterium Tuberculosis started to develop resistance against the most potent and effective medications. The resistance developed by the infective agent is a night mare for the world scientists. They are restlessly doing researches to describe the prevalence, risk factors and outcomes of treatment in patients with Mono- or Multi drug resistance Tuberculosis world widely.

## Researches in Ethiopia

One of the studies done in pulmonary tuberculosis patients attending two public hospitals in East Gojjam zone showed that the prevalence of MDR TB was 1.29% for newly diagnosed and 16.67% for retreatment cases. Resistance to at least one drug was 15.58 % among newly diagnosed and 50.0 % among previously treated cases. Resistance among newly diagnosed patients was most common for streptomycin 5.19 % and ethambutol 5.19 % followed by rifampicin 3.89 % .Among retreatment cases, isoniazid resistance was most frequent in which 33.33 % (4/12) of the isolates were resistant.. In addition to this, the research revealed, age group of 25–34 years and previous history of treatment were independently associated with anti-TB drug resistance. (4).

Another research which was done in districts of metema and west armachiho stated that the overall prevalence of MDR-TB was 5.7 % (2.3 % among new cases and 13.9 % among previously treated cases). Beside this, History of previous treatment was significantly associated risk factor for MDR-TB. Among the research participants, 94.4 % were susceptible to Rifampicin, while 5.7 % were confirmed to be resistant to Rifampicin and Isoniazid.(5)

The research which was published with a title of Multidrug resistant tuberculosis in Ethiopian settings and its association with previous history of anti-tuberculosis treatment: a systematic review and meta-analysis revealed that as they found an overall prevalence of MDR-TB among newly diagnosed and previously treated TB patients to be 2% (95% CI 1% - 2%) and 15% (95% CI 12% - 17%), respectively. The observed difference was statistically significant ( $P < 0.001$ ) and there was an odds ratio of 8.1 (95% CI 7.5–8.7) for previously treated TB patients to develop a MDR-MTB infection compared to newly diagnosed cases. Furthermore, they said for the past 10 years (2006 to 2014) the overall MDR-TB prevalence showed a stable time trend in Ethiopia.(5)

Another hospital based retrospective showed that the prevalence of MDR-TB was 174 (46.3%). Trend in resistance rate among re-treatment cases from 2004 to 2008 showed a significant increase for any drug as well as for INH, RIF, and MDR resistance ( $P < 0.05$  for trend).(6)

One of the research done at St. Peter TB specialized hospital on the predictors of MDR TB among adult patients showed that the mean age among cases and controls was 30.5 ( $\pm 9.26$ ) and 34.73 ( $\pm 11.28$ ) years, respectively. The likelihood of having MDR-TB was 20.3 times higher among those who had a any previous history of TB treatment (AOR=20.3 [CI 5.13, 80.58]), 15.7 times higher among those who had TB more than once (AOR=15.7 [CI 4.18, 58.71]) compared those who had once, 6.8 times higher among those who had pulmonary TB (AOR=6.8 [CI 1.16, 40.17]) and 16.1 times higher for those who had experienced treatment with a Category II regimen (AOR=16.1 [CI 2.40, 108.56]). (10)

A research which was done in oromia region found that an occupation of farming, known TB contact history, alcohol use, HIV infection, previous known TB history, and previous TB treatment outcome were predictors of MDR-TB. (11) Another research done in Amhara region revealed that Patients who had TB treatment failure (AOR=13.5,CI=2.69-70), cavitations on chest x-ray (AOR=1.9,CI=1.1-3.38) and contact with MDR-TB patients (AOR=1.4,CI=0.19-0.39) were more likely to be MDR-TB patients. Low monthly income (AOR=1.1,CI=0.34-0.47),alcohol consumption (AOR=1.5,CI=0.2-0.98) and young age (AOR=2.9,CI=1.07-7.68) were the other risk factors of MDR-TB. (12)

In one of the research done at 2 MDR TB treatment initiation hospitals in SNNPR, among out of 154 patients, 13 (8.44%) patients were died making an overall incidence density rate of 7 (95% CI=5.62-8.84) per 100 Person year.(17) Survival at the end of 1st, 2nd, 3rd, and 4th month was 98%, 97%, 95% and 92% respectively. Presence of medical complication [AHR=4.3, 95% CI =2.3-8.71], drug side effect [AHR=2.6, 95% CI =1.7-3.5], seropositivity [AHR=3.15, 95% CI =2.21-6.67], and baseline weight [AHR=0.9, 95% CI =0.82-0.98] were predicted mortality. (18,19,20,21)

In another systemic review and meta-analysis of published studies done on the treatment outcome of MDR TB revealed that the pooled prevalence, 63.5% (95% CI: 58.4–68.5%) successfully completed full treatment (cured or treatment completed) with a pooled cure rate of 55.6%, whereas 12.6% (95% CI: 9.0–16.2%) of the patients died, 14.2% (95% CI: 11.6–16.8%) defaulted from therapy, and 7.6% (95% CI: 5.6–9.7%) failed therapy. Overall 35. 4% (95% CI: 30–40.8%) of patients had unsuccessful treatment outcomes. An unsatisfactorily high percentage 43% (95% CI: 32–54%) of unsuccessful treatment outcomes was observed among patients who were enrolled in standardized treatment regimens. (22,23,24,25)

## **Research done beyond Ethiopia**

A research done in Portugal on the topic of MDR TB risk factors stated that Diabetes mellitus [adjusted odds ratio (OR): 3.54; 95% CI: 1.45 - 8.66], intravenous drug use (OR: 4.77; 95% CI: 1.24 - 18.32) and previous TB treatment (OR: 2.48; 95% CI: 1.12 - 5.49) were found to be risk factors for drug-resistant disease development. (13)

A retrospective study done in Israel from 1999-2010 showed the prevalence of MDR TB 5.8% and the risk factors include being male, age 30–59 years, migrants (mainly from the former Soviet Union [FSU]) who had stayed in Israel for 2 years, and having pulmonary TB, human immunodeficiency virus (HIV) infection and sputum smear positivity. Of all MDR-TB patients, 71.0% achieved treatment success, while 19.8% died. (14,26)

A hospital base case control study conducted in Henan province in China from 2012-2013 stated that previous TB treatment (AOR = 4.51, 95 % CI: 3.55–5.56), male sex (AOR = 1.09, 95 % CI: 0.24–1.88), high school or lower education degree (AOR = 1.87, 95 % CI: 1.27–2.69), unemployment (AOR = 1.30, 95 % CI: 0.78–2.52), long distance of residence from the health facility (AOR = 6.66, 95 % CI: 5.92–7.72), smoking (AOR = 2.07, 95 % CI: 1.66–3.19), poor knowledge regarding MDR-TB (AOR = 2.06, 95 % CI: 1.66–2.92), traveling by foot to reach the health facility (AOR = 1.85, 95 % CI: 1.12–3.09), estimated amount of time to reach the health facility was greater than 3 h (AOR = 1.42, 95 % CI: 0.51–2.35), social stigma (AOR = 1.17, 95 % CI: 0.27–2.03), having an opportunistic infection (AOR = 1.45, 95 % CI: 0.58–2.4), more than 3 TB foci in the lungs (AOR = 1.98, 95 % CI: 1.49–3.25), total time of first treatment was more than 8 months (AOR = 1.39, 95 % CI: 0.65–2.54), adverse effects of anti-TB medication (AOR = 2.39, 95 % CI: 1.40–3.26), and more than 3 prior episodes of anti-TB treatment (AOR = 1.83, 95 % CI: 1.26–2.80) are the risk factors for MDR TB. (15,27)

A retrospective-prospective cohort study conducted in England, Wales and Northern Ireland from 2004-2007 G.C showed that a total of 70.6% (144/204) of patients successfully completed treatment at 24 months or more. For those with unsuccessful outcomes 6.9% (14/204) had their treatment stopped, 6.4% (13/204) died where TB was recorded as a causative or contributory factor or the relationship between the two was unknown, 7.8% (16/204) were lost to follow up, 2.9% (6/204) completed treatment within 12 months and 0.5% (1/204) completed treatment but relapsed. Ten of the 204 (4.9%) patients had neutral outcomes: nine were transferred overseas and mainly referred to clinics in resource poor countries in Asia and Africa and one died where TB was incidental to death. (16)

Another retrospective cohort analysis on the treatment outcomes of MDR TB patients in Brazil done from 2007-2013 stated that the overall success proportion was 60%. Success was more likely in non-HIV patients, sputum-negative at baseline, with unilateral disease and without prior DR-TB.

A retrospective study conducted in Hunan province of China on the outcome of treatment of MDR and XDR TB reported that For the entire cohort, treatment success was 57% (n = 275); 58% (n = 272) for MDR-TB and 30% (n = 3) for XDR-TB. Overall, 27% were lost to follow-up (n = 130), 27% (n = 126) for MDR-TB and 40% (n = 4) for XDR-TB; and 16% had a poor treatment outcome (n = 76), 15% for MDR-TB and 30% (n = 3) for XDR-TB. Of the 10 XDR-TB patients, 3 (30%) completed treatment, 3 (30%) died and 4 (40%) were lost to follow-up. Of the 471 MDR-TB patients, 258 (57%) were cured, 16 (3%) completed treatment, 13 (3%) died, 60 (13%) experienced treatment failure, and 126 (27%) were lost to follow-up.

## **CHAPTER THREE**

### **Objectives of the study**

#### **A. General objectives**

To assess Risk factors and Treatment outcomes of MDR TB patients in St. Peter TB specialized hospital in the last 5 years

#### **B. Specific objectives**

- To identify possible risk factors of acquiring MDR TB
- To assess the treatment outcomes of patients with MDR TB treated in St. Peter TB specialized hospital in the last 5 years
- To describe the relationship between risk factors and the treatment outcomes of the disease in the past 5 years

## **CHAPTER FOUR**

### **METHODS AND MATERIALS**

#### **STUDY DESIGN**

Institution based Retrospective; cohort study will be conducted to carry out this research.

#### **STUDY AREA**

The study will be conducted in St. Peter TB specialized Hospital. Saint peter TB specialized hospital is one of the prestigious medical institute in Ethiopia. It has been given a due emphasis on the prevention, treatment and rehabilitation of TB patient's since long time ago. Since 2009 E.C, the hospital in collaboration with global Health committee started to provide an inpatient treatment for patients with MDR TB. In this regards, it's the pioneer hospital in Ethiopia. The hospital has an isolation room for MDR TB patients. It's found around Intoto mountainous area next to Shiro Meda. Currently, the service provided by the institution is rapidly increasing.

#### **SOURCE POPULATION**

Patients admitted as a case of MDR TB and got treatment in St. Peter TB specialized hospital.

### **1.1. STUDY UNITS AND PERIOD**

All patients admitted as a case of MDR TB and got treatment in Saint Peter TB specialized hospital in the past 5 years.

#### **SAMPLE SIZE DETERMINATION**

To calculate the sample size a single population proportion formula,  $[n = (Z \alpha/2)^2 p (1-p) / w^2]$ , was employed. Proportion of satisfaction (P) value of 58% was taken from the finding of a study done in Hunan province of China on the outcomes of treatment of MDR TB. In addition, 95% confidence level with margin of error 5% ( $w = 0.05$ ) were used. Hence, the sample size was calculated as

$$\begin{aligned} n_o &= (Z\alpha/2)^2 p (1-p) / w^2 \\ &= (1.96)^2(0.58)(0.42)/(0.05)^2 = 374 \end{aligned}$$

Since the total population (N) is not large in comparison to  $n_o$ , the finite population correction will be calculated as

$$\begin{aligned} N &= n_o / (1 + n_o/N) \\ &= 374 / (1 + 374/N) = \end{aligned}$$

Considering 10 % non- response rate (incomplete data), the final sample size obtained will be\_\_\_\_\_.

#### **SAMPLING PROCEDURES**

*Source of data:* Medical records of patients

*Sampling:* Systematic random sampling will be used (after giving a unique serial code to each medical record and determining the sampling interval by using this formula:  $K = N/n$ )

## DATA COLLECTION INSTRUMENTS

A well designed check-list of questions will be used for data collection. The data collection will be done by the investigator himself or by a well-informed person.

## STUDY VARIABLE

### *Dependent*

MDR TB treatment outcomes

### *Independent*

Socio demographic factors (age, sex, marital status, educational level, occupation, ethnicity, religion), previous TB treatment history, comorbid illnesses like DM, HIV), contact history with a known MDR TB patient, alcohol consumption, cigarette smoking, BMI, Drug adherence during previous treatment, intravenous drug use, sputum smear positivity

## 1.2. DATA MANAGEMENT AND ANALYSIS

The completed check list will be checked for completeness and consistency by the principal investigator. Code will be given to the completed check lists. The coded check lists will be categorized by health institution (health service delivery points). The principal investigator with an experienced data clerk will enter the data using EPI info version 6.0 and SPSS 21 statistical packages. Data cleanup will be performed to check for, accuracy, consistencies, & values. Any error will then be identified and corrected. Central tendency & dispersion will be used, analyzed and described in the form of frequency tables & depicted graphically. Internal comparison will be made.

## 1.3. STANDARD DEFINITIONS according to WHO

**MDR:** Multidrug-resistant tuberculosis (MDR-TB) is defined as TB that is resistant to both isoniazid (INH) and rifampicin (RIF), two of the first-line drugs used in treating pulmonary tuberculosis.

**Pre-XDR:** Pre-XDR TB is defined as TB that is resistant to both isoniazid and rifampicin (RIF)

and either a fluoroquinolone or second-line injectable agent but not both.

**XDR:** Extensively drug-resistant tuberculosis (XDR-TB) is defined as MDR-TB with additional resistance to any fluoroquinolone (FQ) and to at least one of three injectable second-line anti-tuberculosis drugs used in treatment (capreomycin [CPM], kanamycin [KM] or amikacin [AMK])

**New patients:** A case of TB that has never had Anti-TB treatment

**Previously treated:** Patients that have received 1 month or more of anti-TB drugs in the past, may have

positive or negative bacteriology and may have disease at any anatomical site.

**Relapse:** 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 acid fast bacilli smear positive or culture positive.

**Treatment failure:** - A patient who is sputum smear or culture positive at 5 months or later during treatment.

**Defaulter:-** A patient whose treatment was interrupted for 2 consecutive months or more.

**Presumptive MDR-TB:** Those TB patients who had any TB treatment failure, symptomatic close contact of confirmed MDR-TB cases, return after relapse, return after default and previously treated cases that remain smear positive at the end of intensive phase.

## OPERATIONAL DEFINITION

✚ **Treatment success** means if the patients completed 2 years treatment course or declared cured.

✚ **Treatment Failure** means if the patient outcome of the treatment includes the following:

- Died of disease course or treatment complication
- Stopped treatment
- Lost to follow up
- Complete treatment within 12 months
- Complete but relapsed
- Develop XDR TB
- Severe common drug complications

✚ **Neutral outcome** means if the patient transferred to other institution before the completion of treatment.

### ***1.4.COMMUNICATION OF THE RESULT***

Since the report from this study is expected to be useful for all concerned bodies who want to develop policies, and implementation of the possible intervention to minimize the risk factors predispose the patient at acquire the disease and also to enhance the treatment outcome. The

result will also be disseminated to any organization or institution or individuals who have direct or indirect input to the project. All attempts will be made to present the results of the study on local and/or international Journals.

### **ETHICAL CLEARANCE**

Letter of ethical clearance will be obtained from SPHMMC. Letter for cooperation from each level is expected; the confidentiality of the patients' information will be maintained.

### **Inclusion & exclusion criteria**

#### ***INCLUSION CRITERIA***

- Patients who were admitted and had follow up as a case of MDR TB in St. Peter TB Specialized Hospital in the study Period
- Patients whose data are found to be completed during data collection period

#### ***EXCLUSION CRITERIA***

- Patients whose data's are found to be incomplete
- Patients who were admitted as a case of XDR from the very beginning

## Work plan

The various components of this research proposal and the time it will take are summarized in the following table.

**Table 1: Time schedule**

| S.No | Activities                                    | 2017 G.C. | 2018 G.C. |     |     |     |       |     |      |      |
|------|-----------------------------------------------|-----------|-----------|-----|-----|-----|-------|-----|------|------|
|      |                                               |           | Nov       | Jan | Feb | Mar | April | May | June | July |
| 1    | Research title selection                      | x         |           |     |     |     |       |     |      |      |
| 2    | Proposal development and submission           |           | X         | X   |     |     |       |     |      |      |
| 3    | Approval of proposal ethical clearance        |           |           | X   |     | X   |       |     |      |      |
| 4    | Data collection, analysis and report write up |           |           |     |     | x   | x     | X   | X    |      |
| 5    | First draft report submission                 |           |           |     |     |     |       |     | X    |      |
| 6    | Review and research report finalization       |           |           |     |     |     |       |     |      | X    |
| 7    | Final research report submission              |           |           |     |     |     |       |     |      | x    |
| 8    | Research report evaluation by the examiners   |           |           |     |     |     |       |     |      | x    |
| 9    | Defense                                       |           |           |     |     |     |       |     |      | x    |
| 10   | Final report/ thesis submission after defense |           |           |     |     |     |       |     |      | X    |
|      |                                               |           |           |     |     |     |       |     |      |      |

## Budget proposal

**Table 2: Personnel Costs break down:-**

| Personnel       | Activity                  | Quality                         | No | Working days | Per-time/day | Total |
|-----------------|---------------------------|---------------------------------|----|--------------|--------------|-------|
| Data collectors | Training+ Data collection | 12 <sup>th</sup> grade complete | 5  | 5            | 40           | 1000  |
| Total           |                           |                                 |    |              |              | 1000  |

**Table 3: Transport and communication cost:-**

| Description                      | Trip                | Freq. | Unit price | total |
|----------------------------------|---------------------|-------|------------|-------|
| Fuel for car                     | For local transport | ----- | -----      | 400   |
| Communication (fax, tel. e-mail) | -----               | ----- | -----      | 400   |
| Total                            | -----               | ----- | -----      | 800   |

**Table 4 : Cost of Supplies (stationary)**

| Description | Unit   | Quantity | Unit price in Birr | Total in Birr |
|-------------|--------|----------|--------------------|---------------|
| Photo copy  | each   | 2100     | 1                  | 2100          |
| CD/R        | Single | 5        | 10                 | 50            |
| Pens        | Each   | 12       | 5                  | 60            |
| Pencils     | Each   | 13       | 1                  | 13            |
| Notebook    | Each   | 12       | 10                 | 120           |
| Calculator  | Each   | 1        | 80                 | 80            |
| Marker      | Set    | 1        | 50                 | 50            |

|       |      |       |       |      |
|-------|------|-------|-------|------|
| Total | ---- | ----- | ----- | 2473 |
|-------|------|-------|-------|------|

Table 5: Project cost summary:-

| Number | Descriptive cost                 | Total |
|--------|----------------------------------|-------|
| 1      | Personnel                        | 1000  |
| 2      | Supplies                         | 2473  |
| 3      | Transportation and communication | 800   |
| 4      | Total                            | 4273  |
| 5      | Contingency (15%)                | 641   |
| 6      | Grand total                      | 4914  |

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## ANNEX: QUESTIONNAIRE

### QUESTIONNAIRE FOR ASSESSING THE RISK FACTORS AND TREATMENT OUTCOMES OF MDR TB PATIENTS IN St. PETER TB SPECIALIZED HOSPITAL IN THE LAST 5 YEARS

Questionnaire number.....

#### SOCIO-DEMOGRAPHIC CHARACTERSTICS

1. Age of respondent.....
2. Ethnicity.....
3. Place of residence.....
4. Region .....
5. Sex    male ☐                      female ☐
6. Marital status:    Married ☐    Divorced ☐    unmarried ☐    others ☐
7. What is your religious background?
  - Orthodox Christian ☐
  - Muslim ☐
  - Protestant ☐
  - Other specify.....
8. What is your highest level of formal education attained(tick one number only)
  - illiterate ☐
  - Primary ☐
  - Secondary incomplete ☐
  - Secondary Complete ☐
  - College ☐
  - Others specify.....
9. What is your occupation? (Tick one only most relied on)
  - Casual labor ☐
  - Self employed ☐
  - Civil service ☐
  - Private sector employed (specify) ☐
  - Others specify .....
10. How Many people are living with you in your family?

#### QUESTIONS TO ASSESS THE RISK FACTORS OF MDR TB

11. Weight of the patient.....
12. Height of the patient.....
13. Has anyone in your household been previously diagnosed with TB?  
Yes ☐    No ☐

[If yes, go to next question; if no, skip to Q15]

14. Has anyone in your household been previously treated for TB?

Yes ☐  
No ☐

15. Have you ever had a close contact with a known MDR TB patient?

Yes ☐  
No ☐

16. Did you have a previous history of TB treatment?

Yes ☐  
No ☐

(If yes, answer the next three consecutive questions; if no, skip to Q20)

17. How was the diagnosis of TB made?

Sputum smear positivity ☐  
Sputum culture ☐  
Chest X-ray ☐  
Clinical suspicion ☐

18. How do you rate your drug adherence?

Excellent ☐  
Good ☐  
Fair ☐  
Poor ☐

19. How many times did u get treated for TB?

Once ☐  
Twice ☐  
Thrice ☐  
More ☐

20. Have you previously tested positive for HIV?

Yes ☐  
No ☐

(If yes, answer the next question; if not skip to Q20)

21. Are you currently on ARVs?

Yes ☐  
No ☐

22. Have you had a cigarette smoking Habit previously?

Yes ☐  
No ☐

(If yes, answer the next question; if not skip to Q22)

23. How many cigarettes do you smoke per day? .....

24. Did you have alcohol drinking habit?

Yes ☐

No

☐

(If yes, answer the next question; if not, skip to Q24)

25. How long have you been drinking alcohol? .....

26. Have you diagnosed to have Diabetes Mellitus?

Yes

☐

No

☐

27. Have you ever had a history of an intravenous drug use?

Yes

☐

No

☐

### QUESTIONS TO ASSESS THE TREATMENT OUTCOMES OF MDR TB

28. Have you completed the treatment successfully?

Yes

☐

No

☐

(If no, answer the next question)

29. What happened to the patient during the course of treatment?

Stopped treatment before completion

☐

Lost to follow up

☐

Complete treatment but relapsed

☐

Severe common drug complications

☐

Develop XDR TB

☐

Death

☐

30. Did the patient transferred to other institution for treatment completion?

YES

☐

NO

☐

.....

.....

.....