FACTORS ASSOCIATED WITH TUBERCULOSIS TREATMENT INTERRUPTION IN IGEMBE SOUTH, MERU COUNTY, KENYA

BY

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MOI UNIVERSITY

2020

DECLARATION

Declaration by Candidate

This thesis is my original work and has not been presented for examination in any other university. No part of this thesis may be reproduced without prior written permission of the author and or Moi University.

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DEDICATION

This work is dedicated to my parents Hussein Golicha and Saida Gufu, my siblings

and friends who supported me during my studies.

ACKNOWLEDGEMENT

ABSTRACT

Background: Kenya has TB prevalence of 426/100,000 population, and national treatment interruption rate of 4.7%. Treatment Interruption involves not taking TB medication for 2 consecutive days or more. Treatment interruption will lead to treatment completion failure and increase potential for drug resistance which has higher financial implication. In 2016, Meru County reported treatment interruption rate of 5.9% with the highest rate recorded in Igembe South Sub-County. This study determined factors associated with treatment interruption among TB patients in Igembe South in 2015-2016.

Methodology: Treatment registers were reviewed to determine proportion of treatment interrupters among TB patients. A case control study was conducted among 306 participants (153 cases, 153 controls). A case was a failure to adhere to prescribed TB medication for two consecutive days or more among patients on treatment in 2015-2016 while a control was adherence to prescribed medication among patients on treatment in 2015-2016. All cases in register were selected and equal numbers of controls were selected by systematic random sampling. Both cases and controls were interviewed after obtaining written consent and data collected using structured questionnaire. Three focus group discussion (FGD) sessions (n=26) were conducted among cases. We calculated crude and adjusted odds ratios (aOR) at 95% confidence interval (CI) and factors with p-value of ≤0.05 in the final logistic regression model were considered statistically significant. The FGDs responses were recorded and later transcribed and analyzed using Nvivo 10 software. Data was coded into themes and emerging themes from the qualitative study was presented with the quantitative study results.

Results: Of the 1461 registered TB patients, 1046 (72%) were male, majority 1289 (88%) had pulmonary TB, 1430 (98%) were new patients, 279 (19 %) had HIV coinfection and 180(12%) have interrupted treatment. Among the ones who interrupted their treatment, 109 (61%) were male, 145 (81%) had pulmonary TB and 70 (39 %) had HIV coinfection. Factors that were statistically significant for treatment interruption were; waiting time at the health facility for≥1 hour(aOR3.9, CI2.1-7.1), income ≤3000 shillings (aOR2.5, CI1.4-4.2), taking alcohol (aOR2.3 CI1.2-4.4), cost of transport to health facilities of ≥150 shillings (aOR2.0, CI1.3-3.4) and not disclosing ones' TB status to relatives (aOR2.9, CI1.1-7.5).Poverty, staying far from health facilities, high transport costs and long waiting time at hospital was common concerns raised in FGD.

Conclusions: The interruption rate among TB patients of Igembe south was double the national average. Waiting time ≥1-hour, high transport cost to health facility, income ≤3000 shillings and not disclosing ones' TB status to relatives were risk factors for treatment interruption.

Recommendation: Health facilities to improve triage and TB status disclosure of TB. Consider innovative ways to minimize financial costs associated with seeking TB treatment like using community health workers to deliver drugs at home.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

OPERATIONAL DEFINITIONS

Treatment default/loss to follow up- patients on TB treatment who interrupt treatment for two consecutive months or more during the treatment period.

Treatment interruption- is not taking treatment for two consecutive days or more.

Transfer out - is moving to another health facility from the facility where one was being treated to continue with treatment.

Treatment completion- is finishing the prescribed course of TB treatment as required.

ABBREVIATIONS/ ACRONYMS

AIDS   Acquired Immune Deficiency Syndrome

ART   Anti-Retroviral Therapy

CCC   Comprehensive Care Clinic

DOTs   Directly Observed Therapy-short course

FDC   Fixed Dose Combination

FGD   Focus Group Discussion

HIV   Human Immunodeficiency Virus

IREC   Institutional Review and Ethical Committee

HCW   Health Care Worker

LTBI   Latent Tuberculosis infection

NASCOP   National Aids and STI Control Program

NTLDP   National Tuberculosis, Leprosy and Lung Disease

PLWHIV   Persons Living with HIV and AIDS

TB   Tuberculosis

WHO   World Health Organization

CHAPTER ONE

INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium Tuberculosis*. Transmission is from person to person through droplets released through coughing, spitting, sneezing or talking.(DLTLD2013, WHO & The World Health Organization, 2010). Globally, 9.6 million new TB cases occurred in the year 2014 and 28% of this was from Africa. Africa has the most severe burden relative to population with 281 cases for every 100,000 people, which is more than double the global average of 133 per 100,000 cases. In the same year, 1.5 million patients died due to active TB disease, out of which 400,000 had Human Immunodeficiency Virus (HIV) (WHO 2015). Kenya is ranked 15th among the twenty-two highest TB burden countries and 7th in Africa. Tuberculosis (TB) is a disease of major public health concern in Kenya. It is the fourth leading cause of death, presenting an enormous economic burden to the nation and negatively impacting the lives of its citizens(Prevalence Report 2016).

In the year 2014, TB cases notified were 89,294 with a male to female ratio: 1.5. Of the total cases notified, 8448 (9%) were children <15 years of age (WHO,2015).In the year 2015, TB cases notified were 81,518. Of the total cases notified, 6968 (8.5%) were children <15 years of age Tuberculosis (TB) remains one of the world's deadliest communicable diseases and one of the commonest opportunistic infection among people living with HIV (PLWHIV).

Treatment involves taking anti-TB medication for a minimum of six months. Kenya has adopted the World Health Organization (WHO) treatment guidelines of recommended fixed dose combinations (FDCs). Use of FDCs is thought to prevent acquisition of drug resistance due to monotherapy. The FDCs have also the advantage of reducing prescription errors since the recommended doses are easy to administer.

Progress in TB control has greatly been enhanced through the Directly Observed Therapy short-course (DOTs). This is greatly observed in high TB burden countries.(TB DOTS Strategy Coordination, 2014).

Kenya adopted the DOTS strategy for TB control in 1993 and several approaches were put in place to enhance DOTS. These approaches included community based TB care, collaboration between HIV and TB program, elaborate advocacy, public-private mix, communication and social mobilization to enhance communities to seek early care and adherence to medication. (DLTLD, 2013)(TB DOTS Strategy Coordination, 2014). Studies in DOTS programs showed benefits of FDCs in regards to resistance but limited evidence in relation to adherence. Directly observed therapy (DOTS) should therefore be enhanced always .(TB DOTS Strategy Coordination, 2014,WHO & The World Health Organization, 2010).

Interruption of treatment or non-adherence refers to not taking medication as prescribed which includes not taking medication for a day or more. Interruption of more than two months is known as defaulting or lost to follow up(World Health Organization, 2013). Due to varying reasons, some patients don't take their medication as prescribed and they interrupt their treatments for short periods or default (two months and above). Non-adherence or treatment interruption poses a great challenge in TB control and it's a problem for both developing and industrialized countries.

In Kenya, the recommended first line treatment for drug susceptible TB is two months of Rifampicin (R), Isoniazid (H), Pyrazinamide (Z), Ethambutol (E),(2RHZE) under DOTS followed by four months of Rifampicin and Isoniazid (4RH). Interruption of anti-TB medication can cause prolonged infectious period, treatment failure or

emergence of drug resistant TB. (Muture et al., 2011b; WHO & The World Health Organization, 2010).

Several studies on treatment default, which refers to not taking medication for two consecutive months, have been conducted in various parts of the world. In a study to assess adherence to TB medication in Iran, 30% of the study participants did not adhere to medication. (Khalili *et al.,* 2008). In a similar study among pulmonary TB patients in China, the rate of non-adherence was 12.2%.(Xu *et al.*, 2009). In Peru, a study was done to determine risk factors for defaulters in Multi-drug resistant TB patients which showed 10% of the study participants had defaulted. (Franke *et al.*,2008). In a study in South India, 17% of the participants who were treated in a DOTS program defaulted from treatment (Santha *et al.,* 2002). In Nigeria, a study conducted in Benin City showed that 23.8% of the respondents defaulted on DOTS (Adolphus *et al.*, 2012). A study on treatment interruption in Plateau State of Nigeria showed that 19% of the participants had interrupted their treatment (Akhimien *et al.*, 2014). In Uganda, a study done in Mbarara Hospital showed that the prevalence of non-adherence was at 25% among TB-HIV co-infected patients (Amuha *et al*, 2009). In Kenya a case control study done in Nairobi showed that 22.7% of the patients defaulted during the first month of the treatment and 20.4% during the second month of the treatment. This is known as the intensive phase of the treatment (Muture *et al*., 2011b).However, there are limited studies about patients who interrupt for few days or weeks but do not qualify to be called defaulters.

1.1 Problem Statement

Tuberculosis (TB) remains one of the world's deadliest communicable diseases and one of the commonest opportunistic infection among people living with HIV (PLWHIV). Kenya is ranked 15th among the twenty-two highest TB burden countries and 7th in

Africa. In the year 2014, TB cases notified were 89,294 with a male to female ratio: 1.5. Of the total cases notified, 8448 (9%) were children <15 years of age (WHO,2015).

With the high TB burden in Kenya, adherence to medication is very important to increase treatment completion, treatment success and avoid drug resistance which comes with cost implication. Understanding reasons why a patient does not take medication for even a day can help the healthcare workers and the national program in preventing a patient from defaulting. Sometimes patients fail to adhere to the prescribed treatment; some may interrupt their medication for some few days then continue while others default from treatment. Failure to adhere to the prescribed medication can cause prolonged infectious period, treatment failure (Sawadogo *et al*., 2015) or progression to drug resistance form of TB (Hirpa *et al*., 2013; Mulu *et al., 2015)*. According to the Kenya Drug Resistance Survey (KDRS) of 2015, the prevalence of multi-drug resistant TB (MDR TB) among the previously treated and new cases was 2.1 % and 0.7 % respectively (Ministry of Health, NTLD-Program, 2016). Non-adherence to TB treatment comes with cost implication for the country because the management of drug resistance TB is exorbitant.

Strategies to promote adherence include enhancing DOTS to include community based care, and improving counseling and communication to patients(TB DOTS Strategy Coordination, 2014).

Rate of lost to follow up (interruption of two consecutive months or more) has been gradually increasing in Kenya and also in Meru County. The figure below (figure 1.1) shows the trends of interruption of more than two months nationally and at the county.
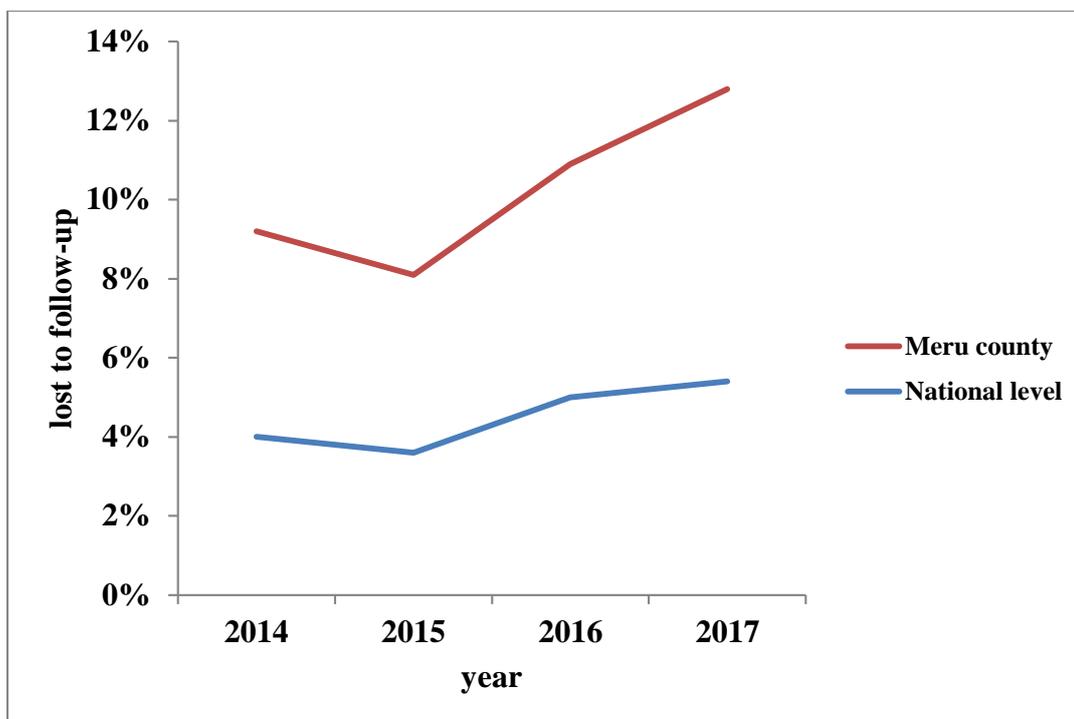
Figure 1.1: Distribution of loss to follow up proportions at National level and Meru County, 2014-2017

Knowing factors associated with treatment interruption can help in strengthening patients' adherence to medication and possibly prevent treatment interruption. Factors that have contributed to the burden include the high burden of HIV; low income levels with consequent socio-economic deprivation (Ministry of Health, NTLD-Program, 2016) and since these factors can affect the use of medication, understanding why patients interrupt their medication for few days or weeks can be useful in preventing the patient from interrupting for longer period (defaulting). This will also help to minimize development of antimicrobial resistance.

1.2 Justification

Non-adherence to TB treatment can eventually lead to defaulting or even drug resistant TB. Though there are studies on defaulters/lost to follow (interruption for two consecutive months or more) in Nairobi (Muture *et al*., 2011b) and non-adherence in Baringo (Obwoge *et.al*., 2016), however, these studies did not look at patients' who interrupted treatment for less than 2 months. A study on using survival analysis to

identify risk factors for treatment Interruption among new and retreatment TB patients in Kenya found that many patients interrupted their treatment during the intensive phase and also recommended for more research to understand this risk factors in depth so as to improve medication adherence (Masini *et al*., 2016).

Meru County had a higher risk of interruption compared to the national average (Masini *et al*., 2016). Unpublished report from the national TB program showed that in 2016, Meru County had an interruption rate of 5.9%, above the national rate of 4.7%. Twenty six percent of interrupters in Meru County were from Igembe South Sub-County. There are no published studies on factors associated with treatment interruption in Igembe South Sub-County despite high rates of interruptions reported. Studies on factors associated with defaulting done in Nairobi (Muture *et al*., 2011b) and Baringo (Obwoge *et.al., 2016* Counties could not be generalized to Igembe sub County.

Understanding factors associated with TB treatment interruption for less than 2 months will provide Igembe South Sub-county health department, Meru County and the National TB program useful information that will help improve strategies and policy guidelines on TB patients' treatment completion and outcomes.

1.3 Research Questions

This study aims at answering the following questions

1. What is the proportion of TB patients who interrupted treatment for more than 2 days or more in Igembe South 2015-2016?

2. What are the factors associated with TB treatment interruption for 2 days or more in Igembe South 2015-2016?

1.4 Objectives

1.4.1 Broad objective

The main objective of the study was to determine proportion of TB treatment interrupters and factors associated with treatment interruption among TB patients registered in Igembe South sub County in 2015-2016.

1.4.2 Specific objectives

1. To determine the proportion of TB patients who interrupted treatment

2. To determine socio-economic, patient related, health system and therapy related factors associated with TB treatment interruption

CHAPTER TWO

LITERATURE REVIEW

2.1 Etiology of TB

TB is caused by a bacillus belonging to a group of bacteria grouped in the *Mycobacterium tuberculosis complex.* The most common agent is *Mycobacterium tuberculosis.*

Other agents include *Mycobacterium bovis* (transmitted through contaminated milk and milk products) and *Mycobacterium africanum.* The bacillus is transmitted from person-to-person through aerosolized droplet nuclei (WHO , 2010).

2.2 Pathogenesis of TB

Droplet nuclei containing tubercle bacilli are inhaled enter the lungs and travel to the alveoli. Tubercle bacilli multiply in the alveoli. A small number of tubercle bacilli enter the bloodstream and spread throughout the body. The bacilli may reach any part of the body, including areas where disease is more likely to develop such as the lungs, kidneys, brain, or bone (DLTLD, 2013; WHO , 2010).

Within 2-10 weeks the immune system produces special immune cells that surround the tubercle bacilli. The cells form a hard shell that keeps the bacilli contained and under control, this is known as TB Infection. If the immune system cannot keep the bacilli under control; the bacilli begin to multiply rapidly, this is known as TB disease**.** This process can occur in different places in the body, such as the lungs, kidneys, brain, or bone (DLTLD, 2013; WHO, 2010).

Risk factors for TB disease include, HIV, poorly treated previous TB, sex(males more than females), malnutrition, diabetes, alcoholism, tobacco smoking, other conditions

e.g. immunosuppressing therapy (The Stop TB, 2013; WHO, 2010). In Kenya, the most common risk factor is for TB disease is HIV infection (DLTLD, 2013).

2.3 Classifications and Diagnosis

The diagnosis of PTB is based on one or more of the following: History of presenting complaints for example history of cough is a key symptom. Diagnosis can also be based on past medical history for example Diabetes, HIV. Diagnosis can also be based on history of contact with TB, Physical examination, Sputum AFB microscopy, Other supportive investigation Chest x-ray (Supportive for smear negative TB) and Specialized bacteriological examination like Culture, Molecular tests, and Drug Susceptibility Test (DST) for Anti-TB drugs (DLTLD, 2013).

Clinically TB is classified as pulmonary or extra pulmonary or classified on patient group or previous history (DLTLD, 2013; WHO , 2010).

2.4 TB Treatment

TB treatment is guided by following principles; using FDCs, never to use single drugs, the dosages should always be based on the weight of the patient and medication should be given under direct observation to ensure adherence and completion (DLTLD, 2013; TB DOTS Strategy Coordination, 2014; WHO , 2010).

The first line drugs are Rifampicin, Isoniazid, Ethambutol and Pyrazinamide(DLTLD, 2013). For Drug Resistant TB, second line drugs are used. Second line drugs used in Kenya include Kanamycin injection, prothionamide tablets, levofloxacin tablets, cycloserine tablets and pyrazinamide tablets (programmatic management of drug resistant turberculosis (pmdt)-kenya, 2014). These second line drugs are considered toxic and may not be readily available making it very costly for the Country to manage Drug Resistant TB (DLTLD, 2013).

To enhance adherence to medication, DOTS should be provided using a treatment supporter who is acceptable and accountable to the patient. The supporter could be a HCW, a family member, a friend or volunteer. DOTS can take place at the health facility, at home or even workplace (The Stop TB,2013; (WHO , 2010).

In Kenya, TB treatment is now provided in individualized patient packs (DLTLD, 2013: The Stop TB). Patient packs are also available to private health care providers irrespective of the source of drugs (GoK or otherwise). About 10% of registered TB patients in Kenya live in the arid and semi-arid areas making patient follow-up and support to be difficult (DLTLD, 2013) . DLTLD has now standardized treatment all over the country. To improve adherence and treatment success, the national TB program recommends patients education about TB and the medication. Patient education should be offered during every visit.(DLTLD, 2013; The Stop TB).

2.5 Factors Affecting Treatment Compliance

Many factors have been shown to be associated with treatment outcomes. These factors are also determinants for treatment interruption. They include socio and economic factors, health system/service provider factors, patient related factors and therapy related factors.(Adolphus *et al.,* 2012; TB DOTS Strategy Coordination, 2014; The World Health Organization, 2010).

2.5.1 Socio and economic factors

Being male gender was associated with poor adherence to treatment (Balbay *et al.*, 2005; Nabil *et al.*, 2013). TB has always been associated with the poor and poverty has been shown to greatly affect adherence (Long *et al.*, 2011). This may mean poor housing conditions, overcrowding and even malnutrition (Franke *et al*., 2008). As much as TB treatment is free, the patients may incur some extra costs e.g. money for

transport to the health facility to pick drugs, ancillary drugs or money for other tests. If the money is not available, the patient will not likely go to the clinic to refill the pills (Amuha *et al*., 2009). A patient may not have money for transport or too weak to walk hence will miss medication (Akhimien *et al*., 2014). Patients have interrupted treatment due to the unbearable financial conditions (Tadesse *et al*, 2013). This study done in Ethiopia showed that some patients had to relocate to towns where the treatment site is located so as to reduce the travel distance hence incurring additional costs of relocation and rent. Financial burden is more for MDR patients who have to stay in isolation for some time. If TB patient is a family breadwinners, the economic burden is worse (Baral *et al.*, 2014). Patients with strong religious beliefs and faith have been shown to adhere very well with medication (Nabil *et al.,* 2013;(Bieberly & Ali, 2008).

2.5.2 Patient related factors

Drinking alcohol, cigarrete smoking/tobacco use and use of marijuana or mandrax were associated with treatment interruption (Peltzer & Louw, 2014; Rajagopaul *et al*., 2014). Health education before initiation and during treatment is recommended (Holtz *et al.,* 2006; Gelmanova *et al.,* 2007). Studies have shown that patients who have little or no knowledge about the disease and its control are more likely to interrupt (Mutinda *et al*., 2014; Nezenega *et al*., 2013).Support from community, relatives or friends has been associated with treatment adherence and better outcome(Mutinda *et al*., 2014; Ong 'ang 'o J.R *et al.,* 2014).

In Ethiopia a study showed that patient who got counselling were more comfortable and open to discuss about their illness. The patients reported that it felt better to have someone who listens to them without any discrimination (Baral *et al*., 2014).Due to fear of discrimination, some patients may not disclose their status to their families or friends.

They will therefore not like to be seen taking medication hence non adherence (Fallis, 2013; Tabatabai *et al*., 2014).

2.5.3 Health system factors

Friendly healthcare staff has been shown to motivate patients and helps in adherence to medication (Baral *et al*., 2014;Widjanarko *et al*., 2009), while some patients who defaulted treatment complained of health care workers bad attitudes (Holtz *et al.*, 2006). TB patients have also interrupted or default due to ignorance or poor knowledge about TB treatment (Amuha *et al*., 2009; Santha *et al*., 2002; Jakubowiak *et al*., 2007).Long distance to health facilities and associated cost of public transport is associated with TB treatment interruption (Akhimien *et al*., 2014; Amuha *et al*., 2009; Suganthi *et al*., 2008; Woimo, Yimer, Bati, & Gesesew, 2017). In some instances, patients have complained of long waiting time before they get service at the health facilities or communication breakdown from service providers is also associated with treatment interruption (Akhimien *et al*., 2014; Gugssa Boru, Shimels, & Bilal, 2017).

2.5.4 Therapy related factors

These are factors about the disease and the medication. Co morbidity with other infection is a major problem in TB infection especially HIV and Diabetes. A co-infected TB patient has complex medication regimen to use for all his infections.(Amuha *et al.*, 2009; Muture *et al*., 2011b).

Adverse drug reaction was associated with treatment interruption (Breen *et al*., 2006; Gebremariam *et al*., 2010). ARVs drug toxicity and drug-to-drug interaction between anti-TBs and ARVs can lead to adverse reactions (Naidoo *et al*., 2013; WHO , 2010). TB medication is over a period of six months or more (WHO , 2010). The long period

of treatment has been shown to be associated with treatment interruption or default (Akhimien *et al*., 2014; Franke *et al*.,2008).

Some studies have shown that patients with pulmonary TB tend to have better adherence than those with extra-pulmonary TB. Also patients who had coughing and hemoptysis had better adherence (Balbay *et al*., 2005; Gebrezgabiher *et al*., 2016).

2.6 Conceptual Framework

This study will adopt the following framework where factors like socioeconomic factors, Patient related factors, therapy related factors and health system factors can make a TB patient on medication to interrupt their TB treatment.

Independent Variable   Outcome

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┌─────────────────────────────┐
│  Socio economic factors     │
│                             │
│  E.g. Income, occupation    │
└─────────────────────────────┘

┌─────────────────────────────┐
│  Health system factors      │
│                             │               ┌──────────────┐
│  E.g. waiting time,         │               │ Treatment    │
│  counselling                │               │ Interruption │
└─────────────────────────────┘               └──────────────┘

┌─────────────────────────────┐
│  Therapy related factors    │
│                             │
│  Medication side effects,   │
│  knowledge                  │
└─────────────────────────────┘

┌─────────────────────────────┐
│  Patient related factors    │
│                             │
│     -   Alcohol , disclosure│
└─────────────────────────────┘
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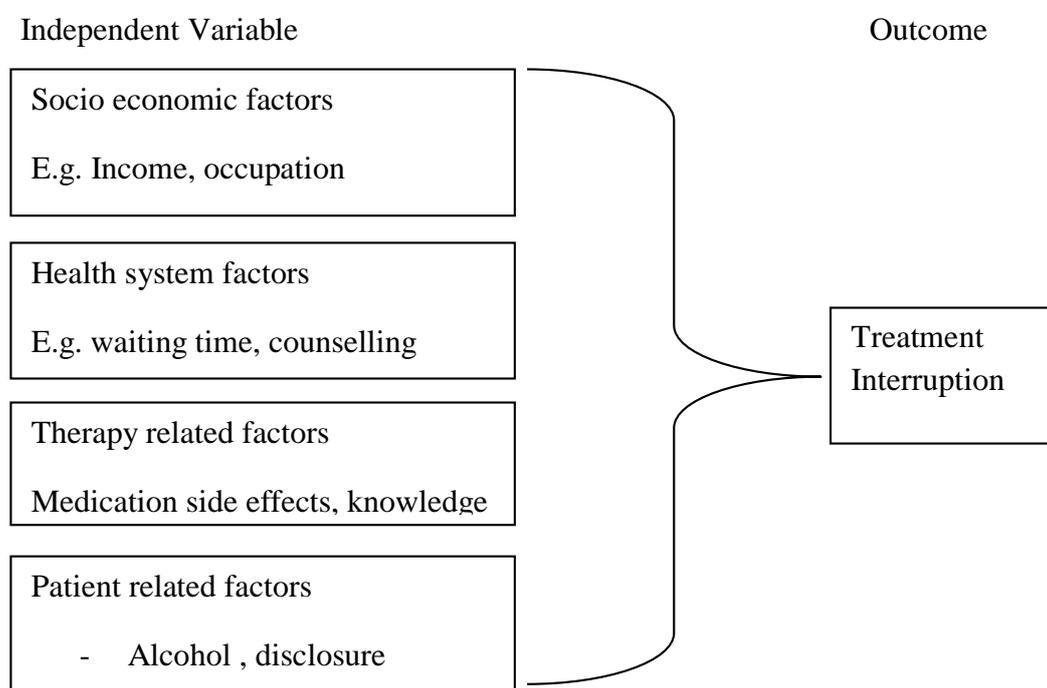
CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

The study was conducted in Igembe South sub-county, Meru County. Igembe South is the largest in Meru County with an area of 6936 square kilometers and population density of 1.356 million. (Figure 2.1). It has the highest population density of 616 persons per km^2 and main occupation is farming. The high density in Igembe south is attributed to high fertile land which is good for farming. The most common diseases in the region are upper respiratory tract infection, arthritis/joint pains, intestinal worms, skin diseases and other diseases of the respiratory system. Igembe South has 44 health facilities (thirty five level 2 facilities, seven level 3 facilities and two level 4 facilities) and twelve TB treatment sites. Igembe South has highest burden of treatment interruption in Meru County, thus why we choose it for the study.
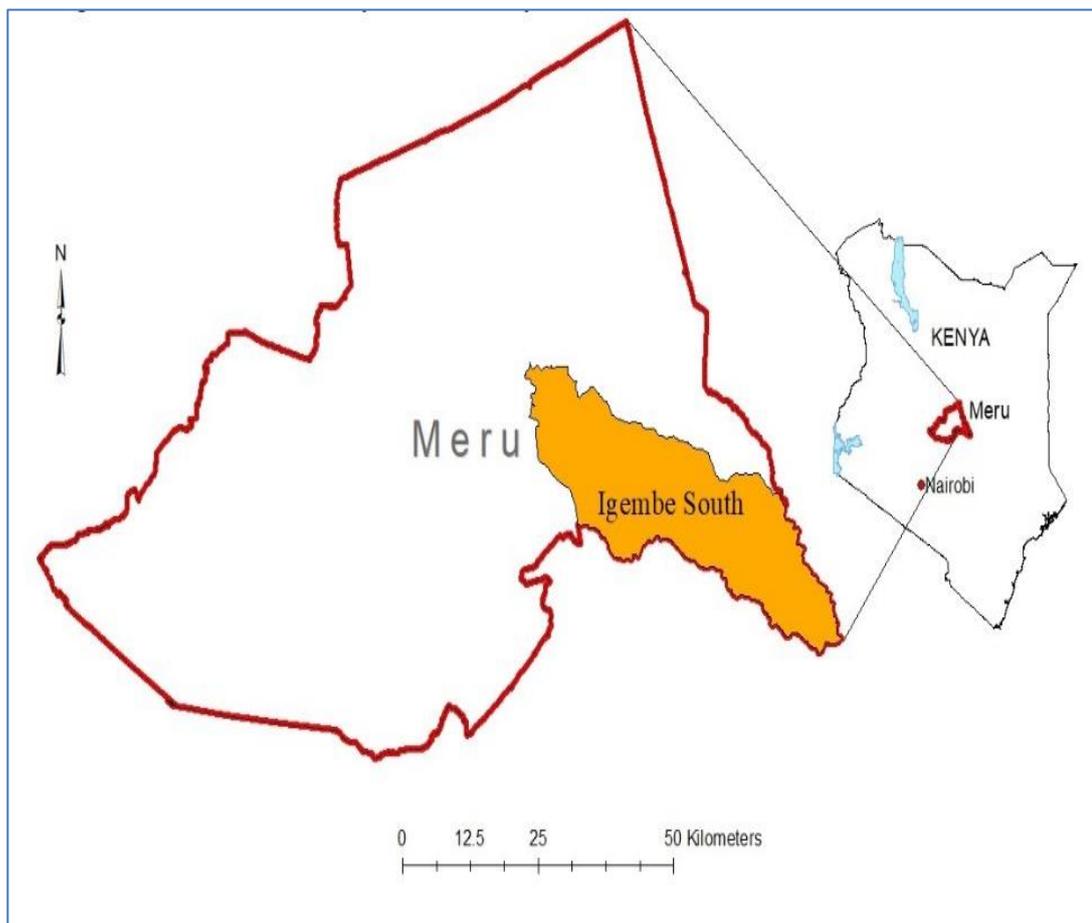
Figure 2.2: Map of Igembe South, Meru County, Kenya

3.2 Study Population

The study was conducted among TB patients who were enrolled on anti-TB treatment between January 2015 and December 2016.

3.3 Study Design

This was a mixed methods study.

Review of both electronic and manual TB treatment registers were conducted to identify total TB patients enrolled in 2015 and 2016 and those who interrupted treatment.

A case control study was conducted to determine factors associated with TB treatment interruption using patients who interrupted treatment as cases and those who adhered to treatment as controls.

Focus group discussions were also carried out among patients who interrupted treatment (cases) to further understand the reasons for TB treatment interruption.

3.3.1 Records review

Electronic treatment registers were reviewed to obtain number of patients who were registered (census) for TB treatment in 2015-2016. Then, TB facility hard copy register were reviewed to identify TB patients who interrupted treatment.

3.3.2 Case control study

3.3.2.1 Definitions of cases and controls

Case: failure to adhere to prescribed TB medication for a period of two days or more in TB patients who were enrolled on treatment in Igembe South in 2015 and 2016.

Control: adherence to prescribed TB medication in any TB patient who was enrolled on treatment in Igembe South, in 2015 and 2016.

3.3.2.2 Inclusion criteria

- TB patient who had interrupted their treatment for a period of two days or more regardless of their return to therapy or DOTs afterwards.
- TB patient enrolled into TB treatment in 2015-2016

  TB patient who consent to participate

3.3.2.3 Exclusion criteria

- TB patient that had transferred out to another sub-county or county
- TB patient lost to follow up

- TB patient who died

- TB patient enrolled into TB treatment earlier than 2015 and later than 2016

3.3.2.4 Identification and selection of cases and controls

Cases

We identified cases by going through the facility TB treatment registers to pick those who had interrupted their treatment. Those who met the eligibility criteria for cases were selected.

Controls

All patients who met the criteria as controls were identified from the facility TB treatment register and used as a sampling frame. The interval (K) was calculated by dividing the total number of patients in the sampling frame by the sample size. We randomly selected a starting point and there after every 7th patient enrolled as control. Deceased TB patients in TB register or those who declined to participate were replaced by the next participant on the list.

For minors, information was acquired from the legal guardians.

3.4 Sample Size Calculation

3.4.1 Case control study

Case control study sample size for the study was calculated using Fleiss JL formulae. The following assumptions were made for calculating the sample size:

- The power of the study was set at 91%

- The odds ratio 2.3

- Confidence limits of 95%

- Ratio of cases to control 1:1

- Percentage of controls exposed was set at 18.2 % for waiting time of $\geq$ 1 hour at facility as a risk factor(Muture *et al.*, 2011)

Formula 1981:

$$n_1 = \frac{\left[z_{\alpha/2} \sqrt{(r+1)\overline{p}\,\overline{q}} + z_{1-\beta} \sqrt{rp_1q_1 + p_2q_2} \right]^2}{r(p_1 - p_2)^2}, \quad n_2 = r \times n_1$$

Variable	Case – Control	
$z_{\alpha/2}$	Two-sided confidence level(1-alpha)	95
$z_{1-\beta}$	Power (% chance of detecting)	91
R	Ratio of Controls to Cases	1
p1	Hypothetical proportion of controls with exposure (Muture *et al.*, 2011b)	18.2
q1	1-p1	81.8
p2	Hypothetical proportion of cases with exposure:	34.2
q2	1-p2	65.8
	Odds Ratio to be detected (Muture *et al.*, 2011b)	2.3

Fleiss Formula (1981):

$$n_1 = \frac{\left[z_{\alpha/2} \sqrt{(r+1)\overline{p}\,\overline{q}} + z_{1-\beta} \sqrt{rp_1q_1 + p_2q_2} \right]^2}{r(p_1 - p_2)^2}, \quad n_2 = r \times n_1$$

$$n_1 = \frac{\left[1.96\sqrt{2 \times 0.23 \times 0.8} + 0.91\sqrt{0.182 \times 0.818 + 0.342 \times 0.658} \right]^2}{(0.182 - 0.658)^2}$$

This gave a sample size of 182 cases and 182 controls giving a total of 364 samples.

3.4.2 Focus group discussion (FGD)

Participants for the FGD were cases that participated in the case control study interviews. At the end of questionnaire administration in the case control study, cases

were asked if they would be willing to participate in FGD. Both male and female who agreed to participate were invited for FGD. Three FGD groups of 8-10 people were conducted.

3.5 Data Collection

3.5.1 Records review

Hard copy facility registers and electronic register was used to identify TB treatment interrupters. Number of patients registered for treatment during the period was obtained from the electronic register. Variables collected included socio-demographic characteristics (patient age, sex, weight), date started on treatment, refill dates, type of diagnosis, type of TB, sputum results and HIV status.

3.5.2 Case control study

Interviewers were identified and trained on how to conduct the interviews. We used a semi structured validated questionnaire which was written in English and back-translated to Swahili and pre-tested in the community before the main study. With the help of community health workers, we traced back cases and controls to their residence in the community for questionnaire administration. We explained the study objectives clearly to the participants and requested them to sign the consent forms before administering questionnaire.

A semi structured validated questionnaire (Adolphus *et al*., 2012) was administered to the participants by trained interviewers through one on one interviews.

Variables collected included in case control study; social-demographic characteristics (patient age, sex, marital status, occupation, education, household size and family income), TB treatment details (date of diagnosis, date started on treatment, symptoms and type of diagnosis), patient related factors(patient's access to treatment site, money

spent on visit to clinic, if patient travelled and if stopped medication, substance use), service provider factors(This includes patient's waiting time at the facility, privacy offered, education and counselling about TB), and patients' perception attitude and beliefs about TB(cultural and religious belief about TB, community members' attitude and disclosure to family or friends) .

3.5.3 FGD

A meeting was set up with cases who agreed to participate on the FGD. An FGD interview guide (appendix 5) was used during the discussion. Questions in the guide included knowledge on TB and its risk factors, knowledge on TB treatment, reasons for interruption and how to prevent interruption. No real names were used during the discussion. The discussion was tape recorded and notes taken too.

3.6 Data Management and Analysis

3.6.1 Records review and case control study

We analysed data using epi info 7 (CDC, Atlanta, GA, USA). We carried out descriptive analysis where we calculated proportions for categorical variables and means/medians for continuous variables. We conducted bivariate analysis to determine risk factors by using odds ratio as measure of association at 95% confidence interval. Chi square test and Fishers exact was used as the test of significance and any factors with P-values < 0.05 was considered significant.

We conducted Multivariate analysis where factors from bivariate analysis with p-value < 0.20 were entered into multiple logistic regression model. Factors with p-value <0.05 in final model were considered statistically significant.

3.6.2 FGD

The focused group discussions were tape recorded and written observations made during data collection. Data was later transcribed and later translated into English. All transcripts and recordings were read out several times by investigators separately to bring out the main themes. Data was analysed using thematic content analysis, where various sub themes were gathered, coded and compared with each other to classify common recurring themes in the set. The process captured emerging themes and enabled us to continue making discoveries about deeper realities in the data that was referenced by codes so as to identify connections between the themes and the respondents in relation to factors and attitudes associated with TB treatment and interruptions.

It was then combined into broader categories, and ordered, summarized and finally interpreted.

3.7 Ethical Approval and Considerations

Approval

Ethical approval was sought and obtained from Moi University Institutional Review and Ethical Committee (IREC), approval number **IREC/2016/FELP/N, Approval number 000 1800** and permission to conduct the study secured from Meru County Health office.

Informed Consent

A written Informed consent was sought and obtained from the cases and controls before interviews were conducted.

CHAPTER FOUR

RESULTS

4.1 Records Review

4.1.1 Characteristics of study participants

TB patients from Igembe South Sub-County enrolled in 2015 and 2016 were 1461.

Males were 1046/1461 (72%), majority of patients, 1289/1461 (88%) had pulmonary

TB, 1430/1461 (98%) were new patients, 279/1461 (19 %) had HIV co infection and

(Table 4.1).

A hundred and eighty patients (12%), 95% confidence interval (10.7-14.1) interrupted

TB treatment (Figure 4.1).

**Table 4.1: Characteristics of TB patients in Igembe South, Meru County, 2015-
2016**

Characteristic	n (%)
Gender	
Male	1046 (72)
Female	415 (28)
HIV status	
Positive	279(19)
Negative	1136 (61)
Type of TB	
Pulmonary	1289 (88)
Extra-pulmonary	171 (12)

TB treatment interruption in Igembe South, Meru County, 2015-2016

■ **TB patients registered for treatment** ■ **TB patients who interrupted treatment**
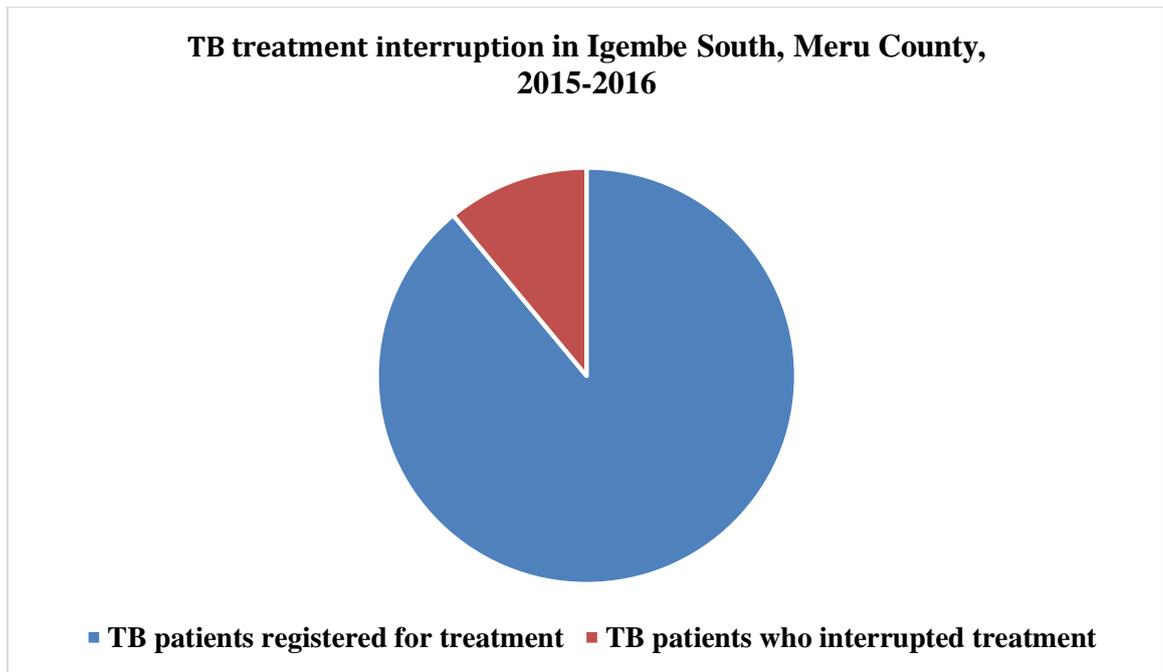
Figure 4.1: Proportion of patients who interrupted treatment, Igembe North sub County, Mery, 2015-2016

4.2 Case Control study

From records review, 180 TB patients had interrupted treatment for 2 or more days. Among the 180 who interrupted treatment, 17 patients were dead and 10 were lost to follow up. Therefore, 153 cases and 153 controls were enrolled for case control study (Table 4.2).

Sex

Total number of males enrolled for the case control study was 188/306 (61%) while females were 118/306 (39%). Among the cases, 90/153(59%) were male and 63/153 (41%) were female (Table 4.2).

Education

Most of the study participants 257/306 (84%) had formal education. Among those who had informal education, 23/153 (15%) were cases and 26/153 (17%) were controls. (Table 4.2).

Marital status

More than half of the study participants 175/306 (57%) were married with 86/153(56%) among the cases and 89/153 (58%) among the controls. (Table 4.2).

Family size

Most of the households visited 260/306 (85%) had a family size of a maximum of four people with 132/306 (86%) among the cases and 128/306 (84%) among controls. (Table 4.2).

Occupation

More than half of the study participants 163/306 (53%) were unemployed. Unemployment was high among the controls 58 % while employment was slightly high 51% among the cases. (Table 4.2).

Income

Many of the study participants 190/306 (62%) had a household income of less than three thousand Kenya shillings with 106/153 (69%) among the cases. (Table 4.2).

Table 4.2 : Demographic characteristics of case control study participant, Igember South, Meru County, Kenya 2015-2016

Characteristic	Case n (%)	Control n (%)	Total n (%)
Sex			
Male	90 (59)	98 (64)	188 (61)
Female	63 (41)	55 (36)	118 (39)
Education			
Informal	23 (15)	26 (17)	49 (16)
Formal	130 (85)	127 (83)	257 (84)
Marital status			
Single	67 (44)	64 (42)	131 (43)
Married	86 (56)	89 (58)	175 (57)
Family size			
1-4	132 (86)	128 (84)	260 (85)
5-8	21 (14)	25 (16)	46 (15)
Occupation			
Employed	78 (51)	65 (42)	143 (47)
Unemployed	75 (49)	88 (58)	163 (53)
Income			
≤3000	106 (69)	84 (55)	190 (62)
>3000	47 (31)	69 (45)	116 (38)

Age

Distribution of cases by age-group and distribution of controls by age group were similar. Both cases and controls had higher number of patients in the age group of 20-39 (Figure 4.2)
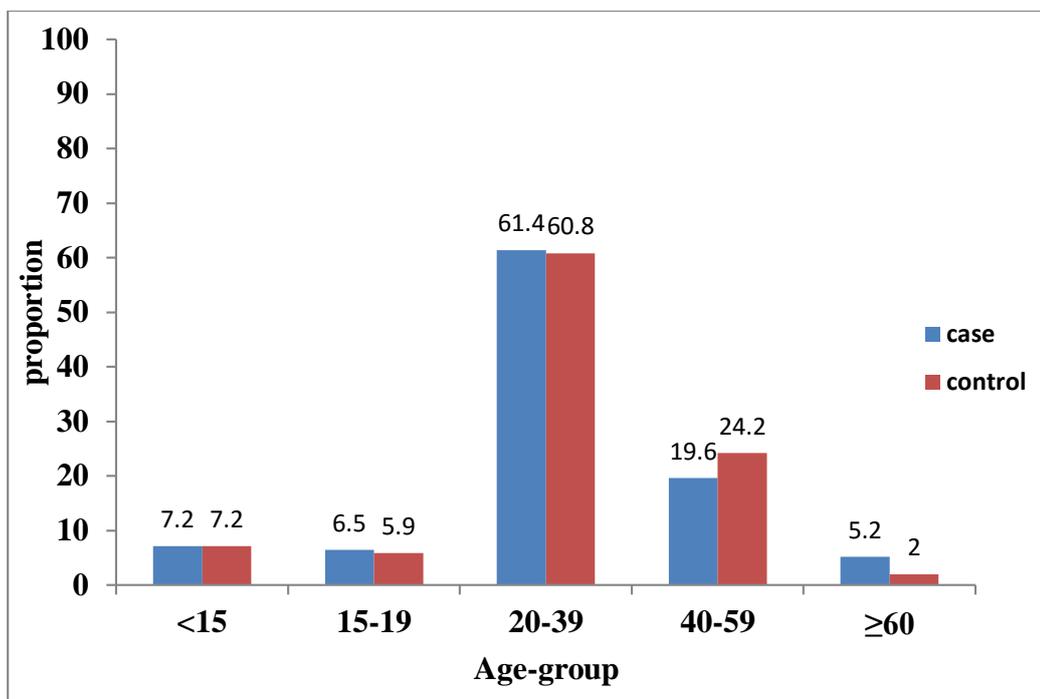
Figure 4.2 : Distribution of cases and controls by age-group, Igembe South, Meru County, Kenya 2015-2016

4.2.1 Factors associated with TB treatment interruption

Several factors were associated with TB treatment interruption. These were grouped into social and economic factors, patient related factors, therapy related factors and health system factors.

4.2.1.1 Social and economic factors at bivariate level

Socio-economic factors associated with treatment interruption at bivariate level were female gender (OR=1.46, p=0.096), being employed (OR=1.41, p=0.14) and having an income ≤3000 (OR=1.85, p=0.01).(Table 4.3)

Table 4.3: Bivariate social economic factors associated with treatment interruption, Igembe South, Meru County, Kenya 2015-2016

Characteristic	Case n (%)	Control n (%)	OR	95 % C.I	p -value
Age <15	11 (50)	11 (50)	ref		
15-19	10 (53)	9 (47)	0.9	0.26-	0.87
20-39	94(50)	93 (50)	0.99	3.07	0.98
40-59	30 (45)	37 (55)	1.23	0.41-	0.67
≥60	8 (73)	3 (27)	0.38	2.39	0.21
Sex				0.47-	
Male	90 (59)	98 (64)	0.80	3.24	0.347
Female	63 (41)	55 (36)		0.08-	
				1.80	
				0.51-	
				1.27	
Education					
Informal	23 (15)	26 (17)	0.86	0.47-	0.640
Formal	130 (85)	127 (83)		1.60	
Marital status					
Single	67 (44)	64 (42)	1.08	0.69-	0.729
Married	86 (56)	89 (58)		1.70	
Family size					
1-4	132 (86)	128 (84)	1.23	0.65-	0.522
5-8	21 (14)	25 (16)		2.30	
Occupation					
Employed	78 (51)	65 (42)	1.41	0.90-	0.136
Unemployed	75 (49)	88 (58)		2.21	
Income					
≤3000	106 (69)	84 (55)	1.85	1.16-	0.010
>3000	47 (31)	69 (45)		2.96	

4.2.1.2 Health system/service provider factors at bivariate level

At bivariate analysis, waiting time of more than one hour (OR=3.75, P=<0.0001) at the facility for either treatment refill, patient review, or food supplement and counselling on use of medication on each visit (OR=0.53, P=0.21) was associated with interruption (Table 4.4).

Table 4.4: Health system and service provider factors associated with treatment interruption, Igembe South, Meru County, Kenya 2015-2016

Characteristic	Case n (%)	Control n (%)	OR	95% C.I	P -value
Waiting time					
>1 hour	51 (23)	18 (12)	3.75	2.07-6.80	<0.0001
< 1 hour	102 (67)	135 (88)			
Counselling					
frequency	6 (4)	11(7)	0.53	0.19-1.46	0.212
Each visit	147 (96)	142 (93)			
1st/once while					

4.2.1.3 Patient related factors/patient knowledge

When asked about causes of TB, majority of the respondents' stated overcrowding, malnutrition and poor hygiene as the major causes of TB (Table 4.5).

Table 4.5: Response on causes of TB by cases and controls in Igembe South, Meru County, Kenya 2015-2016

Factor	Case n (%)	Control n (%)	Total
Overcrowding	104 (46)	122 (54)	**226**
Malnutrition	89 (48)	98 (52)	**187**
Poor hygiene	68 (41)	99 (59)	**167**
Use of Alcohol	37 (58)	27 (42)	**64**
Chewing Miraa	23 (43)	31(57)	**54**
Poverty	14 (26)	39 (74)	**53**

In the FGD, when asked to define what TB is, most of the respondents cited TB as an airborne disease that affects the chest. Some respondents went further into pointing out malaise and fever as some of the key symptoms associated with TB disease.

We found some *patient related factors* associated with interruption though some were not significant at bivariate. These factors were travelling from residential place (OR= 0.53, P=0.055), incurring hospital bills/self-bearer of cost (OR=1.48, P=0.0098), spending more than 150 Kenya shillings for transport to and from the health facility (OR=1.89, P=0.007), using alcohol (OR=1.74, P=0.060), not disclosing one's status to family (OR=2.96, P=0.014). (Table 4.6)

Table 4.6: Bivariate Patient related factors associated with treatment interruption, Igembe South, Meru County, Kenya 2015-2016

Characteristic	Case n (%)	Control n (%)	OR	95 % C.I	p - value
Use of Miraa					
Yes	59 (39)	63 (41)	0.90	0.57-1.42	0.64
No	94 (61)	90 (59)			
Use of					
Alcohol	36 (24)	23 (15)	1.74	0.97-3.11	0.060
YesNo	117 (76)	130 (85)			
Cost bearer					
Self	103 (67)	89 (58)	1.48	0.93-2.36	0.098
relative	50 (33)	64 (42)			
Transport to					
clinic	72 (47)	49 (32)	1.89	1.19-3.00	0.007
≥150	81 (53)	104 (68)			
<150					
Status Disclosure					
No	19 (12)	7 (5)	2.96	1.21-7.26	0.014
Yes	134 (88)	146 (95)			
Use of other drugs					
Yes	35 (23)	26 (17)	1.45	0.82-2.55	0.198
No	118 (77)	127 (83)			

Those who had not disclosed their TB status to anyone about their condition gave the following reasons given for not disclosing their condition (table 4.7).

Table 4.7: Reasons for non-disclosure of disease status among cases and controls in Igembe South, Meru County, Kenya 2015-2016

Reason	Case n (%)	Control n (%)	Total
Fear of divorce	10(91)	1(9)	11
Fear of isolation	19 (76)	6 (24)	25
Fear of eviction	2 (67)	1 (33)	3
Fear of losing job	1 (33)	2 (67)	3

4.2.1.4 Therapy related factors associated with treatment interruption

From the case control study, medicine related reasons given by the cases were: feeling better 69 (45%), medication side effects 42 (27%), and not seeing any improvement 17 (11%). Side effects associated with TB drugs may also result in non-adherence to treatment. Among the side effects are malaise and headache. The aftermath is more unbearable if the patient is not well advised on the medication and the possible side effects to expect. Another challenge is the general feeling of well-being associated with taking drugs. Among the changes associated with taking drugs is the subsidence of common symptoms such as coughs and night fevers. This might be misconstrued by the patient as having attained full healing hence resulting in non-adherence.

4.2.1.5 Multivariate factors associated with TB treatment interruption in Igembe South, Meru County, Kenya 2015-2016

All factors with p-value less < 0.20 in bivariate analysis were entered into multiple logistic regression model. Factors independently associated with treatment interruption were; patient waiting time of more than one hour at the health facility (aOR= 3.9, p=<0.0001), income <3000 (aOR=2.5, p=0.001), drinking alcohol (aOR=2.3, p=0.017),

not disclosing ones' TB status to relatives or friends (aOR=2.9, p=0.034)and transport

cost of more than 150 Kenya shillings to and from health facility (aOR=2.0, p=0.005)

(Table 4.8).

Table 4.8: Multivariate factors associated with TB treatment interruption in Igembe South, Meru County, Kenya 2015-2016

Factors	aOR	95% CI	p-value
Waiting time ≥1 hour	3.9	2.1─7.3	<0.0001
Income ≤3000 Kshs	2.5	1.4─4.2	0.001
Drinking Alcohol	2.3	1.2─4.4	0.017
Transport cost≥150 Kshs	2.0	1.3─3.4	0.005
TB Status non-disclosure	2.9	1.1─7.5	0.034

Low income emerged as one of key factor for not adhering to medication. Respondents

argued that one may lack money for transport to and from the facility where they collect

their drugs. Poverty also emerged in the form of inadequate and inappropriate nutrition.

Respondents said that they, occasionally, fail to take medication due to lack food. They

argued that it would be impossible to take medication on an empty stomach.

> *"One may lack money to go to the clinic (to pick the drugs)"* (female, FGD 3)

> *"Failing to take good (sufficient and balanced) food ... because you cannot take drugs when you haven't fed well (not safe)" (*male, FGD 1).

> *"They should be given food aid, money (fare to go) get the drugs"* (male, FGD 1).

Alcohol consumption and the presence of other diseases was also mentioned as one of

the reasons why some people contact the disease while others do not. The respondents

said that the latter weakens the body (immunity) system making one prone to the

infection. The respondents also pointed out that the disease is more severe in patients

with compromised immunity compared to the rest. It was also thought that alcoholism causes poor feeding which eventually weakens an individual hence making him susceptible to the infection.

> *"Those who contract the disease are mostly weak. Maybe they have grown weak due to other diseases. The (TB) bacteria easily infect the body when it is weak"* (Female, FGD 3)

> *"If the body's immune system is weak and one gets infected, the disease will be more severe than on someone whose immune system is strong or takes a balanced diet (feeds well)"* (Female, FGD 3)

> *"Those who take alcohol without feeding well grow weak hence they can get infected" (*Male, FGD 1)

Stigmatization also seemed to cut across all patients irrespective of the social class. A student reported that a section of the people who knew he had contracted the disease would discourage him by telling him that the disease was untreatable. Those who didn't know his condition would be too inquisitive. This made him to contemplate taking his medication in public. Stigma seems to be big challenge more so to patients who are co-infected.

> *"Sometimes people tell you that you have TB and it is not curable hence you lose morale"* (Female, FGD 1)

> *"People (other passengers) may become too inquisitive when you expose the drugs"* (Male, FGD 2).

The element of stigma popped up once more i.e. the subjects who made an effort to lend money from their friends still found it challenging to state to the lender that the money was meant to facilitate the collection of anti TB drugs. This owes to the fear that TB patients are likely to face stigma if their status is known.

> *"If I borrow money (from someone) I never specify that I intend to use it to get medication for my kid"*

The respondents also acknowledged that the patients have a role to play in the journey to medication compliance. The patients need to accept their status because it helps in

adhering to medication. They also need to perform some duties to generate income. Patients can also work with close relatives or friends who will remind them of when and how to take medication. These people can also collect the drugs from hospital on their behalf.

> *"Even though one is weak, he should try to perform light duties to be able to get something to eat to avoid being affected by the drugs"* (Female, FGD 3)

> *"You need to acknowledge you are sick so that you complete the medication"* (Male, FGD 2)

> *"You can inform someone who is close to you, e.g. a desk mate if you are a student, to remind you to take medication"* (Male, FGD 2)

One also needs to avoid negative comments from friends and peers. Moreover, one should take an initiative to monitor his health rather than being compelled to take his medication.

> *"You need to block your ears from the outside world. Continue taking your medication irrespective of what they say. Try the much you can to get the drugs. If you get the drugs then adhere to the medication"* (Female, FGD 2)

From the FGDs, as a solution to some of the stated challenges, the respondents' fronted openness with key players within the school administration as a way of ensuring students obtained their drugs on time. Communication to the school by the doctor would also help in obtaining appropriate diet for infected students.

> *"I had to reveal my situation to my class teacher. After which I would easily leave the school whenever I ran out of drugs"* (Male, FGD 2)

It is also one's responsibility to make it to hospital within the stipulated working hours to avoid missing refills.

> *"Try to be early for the clinic to avoid quarreling with the doctors"* (Female, FGD 3)

> *"You should monitor your health at the hospital. You should not be force to take medication all the time"*(Female, FGD 1)

CHAPTER FIVE

DISCUSSION

The study-determined proportion of patients whose TB treatment was interrupted and factors associated with the interruption. The independent factors statistically associated with TB treatment interruption were either patient-related, health system-related, socio-economic factors or treatment related.

5.1 Proportion of Interrupters

Twelve percent of TB patients interrupted treatment at some point during the course of treatment. A case control study done in Nairobi, Kenya, reported that most of the TB patients interrupted treatment during the first and second month of the treatment (Muture *et al*., 2011).Other studies elsewhere in African continent reported higher interruption rates. A retrospective case control study conducted among 262 participants in Benin, reported23.8 % rate of treatment interruption (Adolphus *et al*, 2012). In Plateau State, Nigeria, review of medical records and interviewing randomly selected pulmonary TB patients in their eighth month of treatment showed that 17% of the patients interrupted TB treatment (Akhimien *et al*., 2014). In Khartoum State, Sudan, a case-control study reported treatment interruption rate of 14%(Osman *et al*., 2016).

5.2 Factors Associated with Treatment Interruption

In this study, income below Kshs3000 was associated with interruption of TB treatment. TB has always been associated with the poor and poverty has been shown to greatly affect adherence (Long *et al*, 2011). Low or no income can lead to poverty (Pettit *et al*., 2013) that may result to poor housing conditions, overcrowding and even malnutrition (Franke *et al*., 2008) or lack of food (Fallis, 2013). When a patient does not have food, they may fail to take medicine because maybe they are scared of side

effects. In some studies, low income has been shown to be associated with drug resistance TB (Mulu *et al.*, 2015). A study done in Ethiopia showed that some patients had to relocate to towns where the treatment site is located to reduce the travel distance (Tadesse *et al*, 2013).These patients had to pay extra rent and medical expenses leading to financial constraints. Some patients therefore preferred to interrupt treatment due to the unbearable financial conditions. Our finding is similar to a case control study done in Sudan that reported that not working or low social economic status was associated with treatment interruption(Osman *et al.,* 2016).

High cost of transport to the health facilities was associated with treatment interruption. As much as TB treatment is free in Kenya, patients incur transport cost to health facilities for reviews and to collect their drugs. These may pose a challenge to those with no or low income. TB patients may miss their refill date if they do not have money for transport to health facility. Some may walk to the facility but those who cannot walk due to weakness or long distance will end up missing their refill date. This is more challenging if the health facilities are far (Akhimien *et al*., 2014; Amuha *et al*., 2009). If the money for transport is not available, the patient will most likely not go to the clinic to collect their drugs (Amuha *et al*., 2009).

According to the TB patient cost survey done in Kenya in 2017, 27 % of the households with TB patients suffered catastrophic costs. Some of those costs included transport to and from health facilities and paying out of pocket for other medical expenses.

Drinking alcohol was associated with treatment interruption. Treatment interruption has been shown to be associated with use of substance such as alcohol, cigarrete smoking/tobacco use and even use of Marijuana or mandrax. A patient under the influence of any of this substances may have altered thinking or behaviour and forget

to take medication or get side effects due to alcohol drug interaction.(Rajagopaul *et al*., 2014; Holtz *et al.,* 2006; Gelmanova *et al.,* 2007). A person under the influence of alcohol may not adhere to their medication which may lead to treatment failure or progression to drug resistant TB (Finlay *et al*., 2012; Mulu *et al.*, 2015). Participants who disclosed their condition to relative and friends were not likely to interrupt their treatment. Disclosing one's disease condition might have had some advantages including, getting support from the relatives or friends. This support could have been financial or social where the relatives or friends remind the patients to take their medication, help them in some household chores or even prayers and moral support. Lack of family support has been associated with TB treatment interruption (Osman *et al.*, 2016). Support from community, relatives or friends has been associated with TB treatment adherence and better outcome (Mutinda *etal*., 2014; Ong 'ang 'o *et al*., 2014). A study in   Ethiopia reported that TB patient who got counselling were more comfortable and open to discuss about their illness (Baral *et al*., 2014). The patients' reported that it felt better to have someone who listens to them without any discrimination. A study in Andara region of Namibia reported that patients may fail to disclose their TB status for fear of discrimination (Fallis, 2013).

Waiting time of more than an hour was associated with treatment interruption. Waiting for long at the health facility when going for treatment refill may discourage some individuals making them not return for subsequent refill. Long waiting time may be associated with poor service delivery by the service provider or   high workload. Poor communication between the TB patient and the service provider has been associated with treatment interruption (Gugssa Boru *et al*., 2017). At times a patient may have to stay hungry for a long time as they waits to be attended to(Akhimien *et al*., 2014). A study done in Kenya reported that use of the community health workers (CHWs) in

monitoring patients or delivering of treatment at home has improved TB treatment adherence (Ong 'ang 'o *et al*., 2014).

5.3 Limitations

1. Data quality

Poor documentation of treatment dates of appointments in TB patients registers. Some registers had incomplete documentation or no documentation on missed dates of appointment. These could have underestimated the number of those who had interrupted treatment. We minimized this by verifying information in electronic register with hard copy facility register.

Interruption was based on the documentation in TB register only. The study did not find out if patients had interrupted their treatment at home thus might have underestimated rate of treatment interrupters.

2. The case control study did not include those who were lost to follow-up. The lost to follow-up patients could have had the same characteristics as the interrupters or not. However, this might not bias our study because of the low number of the lost to follow up (5.5%)

3. The study was conducted among participants who had already completed their TB treatment course and this might have led to recall bias.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Twelve percent of TB patients enrolled for treatment in Igembe South Sub-County had their treatment interrupted. The factors significantly associated with treatment interruption were waiting time of more than one hour at the health facilities when going for refills or appointments, high cost of transport incurred when going to the health facilities, having an income of less than 3000 Kenya Shillings, not disclosing ones' TB status to family/relatives, and consumption of alcohol during the treatment course.

6.2 Recommendations

To help in reducing number of TB patients who interrupt treatment for 2 days or more, the following recommendations were given:

1. TB patients should be given counselling before initiation of treatment and during every visit to enhance adherence to medication

2. The NTLD-P should do monitoring of interruptions of less than two months so that interrupters can be identified early enough and prevent them from being defaulters/lost to follow-up.

To help in controlling the factors that can lead to treatment interruption, the following were recommended

1. Sub-County TB coordinator to sensitize the clinicians on documentation of missed appointments for the purpose of patient monitoring. The coordinator should also strengthen service delivery and consider waiting waivers for those who come for refill only so as to reduce waiting time at the health facilities.

2. Health facilities should improve triage, ensure intensive patient counselling and education prior to initiation of treatment and also in subsequent visits to avoid alcohol intake and promote disclosure. The clinicians in collaboration with the public health team should also do community sensitization including schools to promote disclosure and avoid alcohol intake during the course of treatment.

3. The National TB, Leprosy and Lung Disease Program (NTLD-P) in collaboration with the County Government should consider innovative ways to minimize financial costs associated with seeking TB treatment like using community health workers to deliver drugs at home.

4. The NTLD-P in collaboration with the Ministry of Health should consider enrolling TB patients to existing social protection program to supplement their income and other catastrophic cost.

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APPENDICES

Appendix 1: IRB Approval Letter

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/FELP/N
Approval Number: 0001800

4th January, 2017

Qabale Hussein Golicha,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Mr. Golicha,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled: -

"Factors Associated with Tuberculosis Treatment Interruption in Igembe South, Meru County, Kenya".

Your proposal has been granted a Formal Approval Number: *FAN: IREC 1800* on 4th January, 2017. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 3rd January, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

Appendix 2: Consent form

Study title

Factors associated with TB treatment interruption in Igembe South 2015-2016

Introduction

My name is ……………….. I would like to learn about TB treatment, treatment interruption and factors that lead to interruption. TB is an infectious disease and a major public health problem.

Current control strategy involves DOTS. Interruption can progress to defaulting and also being infectious for a long period which poses a threat to the community. It is therefore essential to understand factors associated with interruption for effective control of TB.

What does the study bear?

If you agree to participate, you will be asked questions about your TB treatment. Answering these questions has no risk, whatsoever.

What happens to the information about you?

The information recorded about you will only be used for the purpose of the study. All data will be kept in a computer protected with a password. Only authorized personnel involved in the project will have access to this information. The information will be deleted once the project is completed. It will not be possible to identify you with the results of the study when it is published.

Voluntary Participation

It is voluntary to participate in this study. You can withdraw your consent to participate in this study at any time without giving any reason. This will not affect your future treatment. If you would like to participate, you will give your consent using your signature or thumb print on the last page.

Criteria for participation

Participants of this study are TB Patients who interrupted their treatment at any time and those who adhered without interruption between January 2015 and June 2016.

Duration of interview

The interview may take up to 30 minutes of your time. The focus group discussion will take about an hour.

Possible benefits

Participants may not get direct benefits from the study

Participants' responsibility

The participant does not have any responsibility except providing information required for the study. The project will not cover any expenses for the participants because they participate in the study.

Privacy

The information recorded about you is only stated in the questionnaire that you have seen today. There will not be a link with other registers. Only the investigators of the study have access to personally identifiable information, and all such information is kept confidential.

Right of access and deletion of information about you

If you agree to participate in the study, you are entitled to have access to what information is collected about you. You are also entitled to correct any inaccuracies in the information we have on you. If you withdraw from the study, you can request to have the collected information about you deleted.

Appendix 3: Declaration of consent

I read and understood the purpose and benefits of the research work. I am aware that participation in the study is absolutely voluntary and also I can withdraw at any time during the course of the study without any consequences on me having access to health care services now or in the future. I am also aware that the information I give will be used strictly for research purpose and also will be kept confidential. I therefore declare that I have agreed to voluntarily participate in the study.

Name of participant…………………………… …………………….………

Signature/thumb print…………………. Date……………….……….……….

Name of investigator/research assistant………………………………………

Signature……………………………….. Date……………….…….……

Appendix 4: Questionnaire

SECTION A: bio data and demographic information

1. Age (years): 2. Sex Male =1 Female =2

2. Interviewee: 1=self 2=Proxy

3. Education:

Code	Education Level	Tick
1	No Formal Education	
2	Primary	
3	Secondary	
4	Tertiary	
5	None	

4. Marital status:

Code	Status	tick
1	Single	
2	Married	
3	Divorced	
4	Widow /widower	
5	Separated	

5. Occupation:

Student (1) ☐; Business (2) ☐ Civil servant (3) ☐; Professional (4) ☐ ; Farmer (5) ☐

Unemployed (6) ☐ ;Others (7)   ☐

7 Religion:

 Christian (1) ☐   ; Muslim (2) ☐ ; Traditionalist (3) ☐ ; Others (4) ☐

8. What is your family size? 1 (1-4) ☐ ; 2 (5-8) ☐ ; 3 (>8) ☐

9. What is your estimated income per month? KSHS_____

SECTION B: TB treatment details

1. When did you first experience the symptoms before reporting to the hospital?

1(<1month) ☐   ; 2 (1-2months) ☐   ; 3 (2-3 months) ☐   ; 4 (>3 months); ☐

2. Date of diagnosis……………….

3. Type of diagnosis X-ray (1) ☐ ; Sputum smear (2) ☐   ; Culture (3)   ☐;

4. Date treatment started: ………………

5. Type of drug: Isoniazid =1; Rifampicin =2; Ethambutol =3; Pyrazinamide =4;

   Streptomycin =5

6. What did you do when you first experienced the symptoms?

SECTION C: Patient related factors

1. How do you get to the clinic? Walked (1) ;☐   Took a vehicle (2) ☐; Took a

   bike (3) ☐   Others (☐)

2. Do you own a car or bike? Yes (1) ☐   ;No (2) ☐

3. On average, how much do you spend on transportation to the clinic and back home

   per visit? KSHS…………………….

4.Who paid the hospital bills? Self (1) ☐; Family members (2)☐ ; Husband (3) ☐;

   Wife (4);   ☐   Others (5) ☐

5. When you started the hospital treatment, did you travel outside your locality?

   1 =Yes2 =No

If yes why did you travel? ..……………………………………………………………

6. Did your drugs get finished before you returned for the next visit? 1 =Yes 2 =No

7. What did you do when your drugs got finished?

Contacted the nearest hospital (1) ▮ ;Waited till return (2) ▮ ;

 Did not return for further drugs (3) ▮ ; Returned immediately for treatment (4) ▮

8. Do you use other drugs alongside the TB drugs? Yes (1) ▮ ; No (2) ▮

If yes, which one? Pain reliever (1) ▮ ; Multivitamins (2) ▮ ; Antihypertensive ▮

drugs (3) ;

Ant-diabetic drugs (4) ▮ ;Antiretroviral drugs (5) ▮ ; Others (6) ▮

9. Did you ever stop taking the TB drugs? Yes (1) ▮No (2) ▮

 If yes, how many days did you not take medication?

10. What was your reason for stopping the treatment? (Tick the appropriate ones)

	Reason	Yes (1)	No (2)
10A	Was feeling better		
10B	Long distance to health facility		
10C	Condition worsened/did not improve		
10D	Thought hospital treatment will not cure the disease		
10E	Medication side effects		
10F	Dissatisfied by the services provided		
10G	Lack of money		
10H	Delivery/Maternal leave		
10I	Others (specify)		

11. What phase of treatment did you stop taking the TB drugs?

   1. Intensive phase (1st 2 months of treatment); ☐

   2 .Continuation phase (6 months of treatment) ☐

12. Were you informed by health workers that you must complete your treatment?

     1 =Yes ☐

     2 =No ☐

13. Do you know the consequences of not completing treatment?

   1 =Yes ☐ 2 =No   ☐

   If yes, what are the consequences?

   1 =Organisms build resistance ☐   ; 2 =Infect those around ☐

   3 =Death; ☐   4=others, please specify_____

14. Do you use any of the following?

	Substance	Tick
14 A	Tobacco	
14 B	Alcohol	
14 C	Miraa	

15 What support did your family render regarding your treatment?

	Can tick more than one	Tick
15 A	Reminded me to take my drugs	
15 B	Supported financially	
15 C	Helping in household chores	
15 D	Helping in prayers	
15 E	No support	
15 F	Others (specify)	

16. What is your main source of income? 1= small scale trader; 2= farmer; 3= casual

labor; 4=employed

SECTION D: Patient's perceptions, attitude and beliefs of TB

1. Did your family and friends knew that you were suffering from TB? 1 =Yes 2 = No

2. If No, why? (You can tick more than one)

		Tick
2A	Fear of isolation	
2B	Fear of eviction	
2C	Fear of divorce	
2D	Fear of losing your job	

3. What is the cultural and religious belief of TB in your locality?

	May tick more than one	Tick
3A	Caused by witchcraft/spiritual means	
3B	Punishment for dishonest/bad deeds	
3C	Hereditary	
3D	Can be cured by prayers only	
3E	Don't know	
3F	Others (specify)	

4. What is the attitude of your community members towards TB?

		Tick
5A	TB is associated with poverty	
5B	TB is a deadly disease thus should be feared	
5C	TB is associated with stigma	
5D	Can be cured only by traditional means	
5E	Can be treated with orthodox medicines	
5F	Others (specify)	

5. What do you think was the cause of your TB? (You can tick more than one)

		Tick
6A	Malnutrition	
6B	Poverty	
6C	Miraa	
6D	Poor hygiene	
6E	Overcrowding	
6F	Alcohol intake	
6G	Tobacco intake	
6H	Spiritual attack	
6I	Others(Specify)	

SECTION E: Service provider related factors

1. How often were you counseled about TB treatment by health care providers?

1= on the first visit; 2 = on each visit; 3 = Once a while   ; 4= Never

2. Did the health worker provided privacy while attending to you at the hospital?

1 =Yes 2 =No

3. How were you served with your drugs on each visit to the clinic?

1 =Daily dose   ; 2 =Weekly dose   ; 3 = Once in 2 weeks   ;

4 =Monthly   5=Others

4. Did the health care providers educate you on the disease condition?

1 =Yes   2 =No

5. Did the health care providers give card indicating your review date?

1 =Yes 2 =No

6. How long did you have to wait at the clinic on each visit before you were served

with your drugs?

1 = <30 minutes 2 =30mins – 1hr   , 3=1-2hrs   4 =3-4hrs   , 5 > 4hrs

Appendix 5: Focused group discussion guide

Thank you for joining us today. My name is Qabale Hussein. I am a student from Moi University. I am here today to conduct an interview to gather your thoughts and opinions about TB and TB treatment.

Before we start, I would like to let you know that this interview is for academic research purposes only. Please be assured that everything we discuss during this interview will be kept in strict confidence and your real name will not appear in any of our results. As such, please make every effort to be open and honest when responding to the questions. For data capture purposes, this interview will be recorded on audio tape. The interview will last approximately one hour.

1. What is TB? /What do you know about TB? *(moderator to Probe further on cause of TB and possible risk factors of TB)*

2. Do you think TB is treatable? How is it treated? How long should you take anti TB medicines?

3. Is it important to complete TB treatment? Why?

4. According to you, what are reasons related to you as a person that affects adherence or completion of TB treatment?

5. In your opinion what are reasons related to health systems that influence adherence or completion of TB treatment?

6. In your opinion how do you think adherence can be improved?

(Before end of the session, provide time for the participants to ask questions and clarifications)

Thank you for your time.