# PREDICTORS OF TB TREATMENT ADHERENCE AMONG PATIENTS AGED ABOVE 18 YEARS ATTENDING TB CLINIC IN KISUMU EAST SUB-COUNTY

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A Research Thesis submitted in partial fulfillment of the requirements for the award of Master of Science in Nursing (Community Health) degree of Masinde Muliro University of Science and Technology

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# DECLARATION

This thesis is my original work prepared with no other than the indicated sources and support and has not been presented elsewhere for a degree or any other award.

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# **Approval by Supervisors**

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# **DEDICATION**

I dedicate this thesis to my family for the moments taken out of family time and for their support to do so.

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## ABSTRACT

Tuberculosis (TB) contributes 2.7% of total Disability Adjusted Life Years (DALY) in low income countries. It is also the leading infectious cause of mortality and morbidity in these countries. Kenya is one of the countries with the highest burden of tuberculosis globally. The country still has poor treatment outcomes in a significant number of patients. These poor treatment outcomes have been considerably linked to TB treatment adherence problems. The study area, Kisumu East sub-County, had the lowest TB treatment cure rates (81%) in the country versus the recommended 85%. This can be linked to treatment adherence problems. Therefore, a cross sectional descriptive study was conducted to establish the predictors of TB treatment adherence among patients aged above 18 years attending TB clinics in Kisumu East sub-County. A total of 250 respondents were interviewed. Random numbers were used to assign respondents to the study from TB permanent register. An interviewer administered structured questionnaire was used to collect data from the respondents on the social, demographic, behavioral, biological, treatment and health system predictors of TB treatment adherence. The data was analyzed using descriptive statistics for sociodemographic variables and bivariate analysis as the selection criteria for inclusion in the binary logistic regression analysis. A p values ( $p \le 0.05$ ), Odds Ratios and 95% confidence interval (CI) were used to demonstrate association between selected variables. Adherence among the respondents was at 90.5% (226 respondents). Number of family members (OR: 6; 95%CI: 2-19;p=0.005), having a family member to remind the patient when to take the drugs (OR:4; 95%CI:2-13;p=0.007) and time taken before seeking health care (OR: 3.7; 95%CI: 2.2-6.7; p<0.001) were significantly associated with adherence. This study is the first to estimate adherence level in the study area. Patients' sociodemographic predictors of adherence should form basis for flagging some patients for adherence counseling, psychosocial support and community follow-up. The information generated from this study could be used by local TB programs for their Advocacy Communication and Social Mobilization (ACSM) in targeting the specific adherence predictors in the region.

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# LIST OF ABBREVIATIONS

AAFB	Active Acid Fast Bacteria
ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immunodeficiency Syndrome
CDC	Center for Disease Control and Prevention
DALY	Disability Adjusted Life Years
DH	District Hospital
DLTLD	Division of Leprosy, Tuberculosis and other Lung Diseases
НС	Health Center
HIV	Human Immunodeficiency Virus
IERC	Institutional Ethics Review Committee
IMB	Information Motivation Behavior model
INH	Isoniazid
JOOTRH	Jaramogi Oginga Odinga Teaching and Referral Hospital
KDHS	Kenya Demographic and Health Survey
KNBS	Kenya National Bureau of Statistic
MDR – TB	Multi-Drug Resistant Tuberculosis
MMUST	Masinde Muliro University of Science and Technology
МоН	Ministry of Health
NACOSTI	Nation Commission for Science Technology and Innovation
SGS	School of Graduate Studies
SPSS	Statistical Package for Social Sciences
SSA	sub-Saharan Africa
ТВ	Tuberculosis
TBMAS	TB Medication Adherence Scale
VAS	Visual Analogue Scale
WHO	World Health Organization

#### **CHAPTER ONE**

## **INTRODUCTION**

## **1.1 Overview**

The following have been presented in this chapter: background, statement of the problem, research questions, objectives, operational definition of terms and conceptual framework.

## **1.2 Background of the study**

Tuberculosis (TB) contributes 2.7% of total DALY in low income countries and is the leading infectious disease in these countries (WHO, 2015b). Kenya has been ranked 10<sup>th</sup> among the 22 high burden TB countries in the world, and the 3rd country with the highest TB burden in Africa (WHO, 2014a). According to the World Health Organization's Global TB control report, Kenya had approximately 120,000 new TB cases in 2012. The disease remains the single leading cause of death (6.3% of total deaths) and DALY (4.8% of total DALYs) in the country (DLTLD, 2010; WHO, 2014b).

There has been concerted effort to make reverse these adverse TB trends in the country. These efforts have been through highly effective TB treatment regimens recommended by WHO treating and preventing TB. However, there is growing recognition that if the target of reducing TB cases and cases of adverse treatment outcome is to be realized, the aspect of adherence to anti-TB medication is to be addressed innovatively (Tesfahuneygn et al., 2015). Adherence to treatment determines individual health outcomes and has far reaching ramifications on health expenditure. Tuberculosis (TB) and the Human Immunodeficiency Virus (HIV) have been known to rapidly develop drug resistant disease strains especially when

medications are not adhered to as required. Multidrug resistant tuberculosis (MDR-TB) emerged largely because of widespread non-adherence to treatment for TB disease. This form of TB has become a public health issue in reemergence of TB. MDR-TB has great financial implications when it comes to treatment, length of stay in the hospital and overall morbidity associated with tuberculosis (WHO, 2014a).

The efforts to improve adherence have focused primarily on therapeutics involved in the treatment of TB. Public health prioritization of adherence to TB treatment is important because: TB has a high risk of transmission, non-adherence prolongs TB's infectious phase, non-adherence enhances the emergence and spread of drug-resistant organisms and the labor and financial expenses of treating drug-resistant TB are immense (DiStefano & Schmidt, 2016; Tesfahuneygn et al., 2015). The factors associated with adherence to TB treatment are demographics, social status, culture, patient characteristics and behaviour, the relationship between healthcare provider and the patient, the treatment regimen, health care seeking practices and the health care setting (Suwankeeree & Picheansathian, 2014). These predictors are known to be diverse from one setting to another. There are differences in the way the predictors interplay with each other in determining adherence (Hugtenburg, Timmers, Elders, Vervloet, & van Dijk, 2013; Méda et al., 2014).

## **1.3 Problem statement**

Tuberculosis therapy requires a high adherence rate of over 90% to facilitate cure (WHO, 2014a). Identifying predictors to adherence can go a long way in facilitating the development of effective and appropriate interventions. Measuring and improving adherence is fundamental. A standardized approach for TB adherence to treatment is not likely to succeed across all settings. Quantifying adherence in a specific setting

can inspire future TB program interventions and suggest solutions to resolve the problems adherence (Nieuwlaat et al., 2014; Ong'ang'o, Mwachari, Kipruto, & Karanja, 2014)

Outcomes of TB treatment and care like cure rate, reduced transmission within the community (reduced incidence), treatment completion, defaulting and treatment can be linked to adherence (Gebrezgabiher et al., 2016). Therefore, if prioritized and handled innovatively, adherence can enhance better treatment outcomes (DiStefano & Schmidt, 2016).

Kisumu East sub-County has some of the leading adverse outcomes of care with 81.2% cure rates as opposed to the recommended 85% by the WHO (Gondi & Malika, 2010; WHO, 2015b). The cases of retreatments and drug resistance in this area are 36.3% which is higher than the national rate of 35%. Equally, the sub-county has the highest incidence of TB (10.1%) regionally (DLTLD, 2010; Gondi & Malika, 2010). These egregious adverse outcomes can be associated with adherence to TB treatment in the region (Dolma et al., 2013; WHO, 2015b)

Anecdotal evidence from clinical interviews of some of the TB clients seeking treatment at Kisumu District Hospital by the researcher, the patients individually reported great challenges in complying with treatment requirements due to several reasons. Some of the reasons elicited during the clinical interviews are; pill burden especially when taking TB medications with other drugs, lack of food, travelling, hospitalization and forgetting.

## **1.4 Research question**

1. What is the prevalence of adherence to treatment among TB patients attending clinic in Kisumu East sub-County.

- 2. What are the predictors of TB treatment adherence among TB patients attending clinic in Kisumu East sub-County.
- 3. What is the effect of the predictors on adherence

## 1.5 Main objective

To evaluate the predictors of TB treatment adherence among patients attending TB clinic in KDH

# **1.6 Specific Objectives**

- To determine the prevalence of adherence among TB patients attending clinic in Kisumu East sub-County.
- 2. To establish the predictors of TB treatment adherence among TB patients attending clinic in Kisumu East sub-County.
- 3. To analyze the effect of the predictors on adherence among TB patients attending clinic in Kisumu East sub-County

# **1.7 Justification**

Most studies on TB treatment outcomes have attributed high prevalence of TB treatment adverse outcomes to problems with adherence to TB treatment (Dolma et al., 2013; Dooley et al., 2011). The study region sees some of the highest cases of poor outcomes of treatment like loss to care, TB related deaths and drug resistance. These treatment outcomes can be linked to problems with adherence to TB treatment (DLTLD, 2010; Gondi & Malika, 2010). The researcher established that no study has been published to estimate the prevalence of adherence and the predictors of the same in this region. This survey, therefore, will be a groundbreaker in estimating the prevalence and predictors of adherence in the study region.

The results of this study will be shared with local and national TB programs for their Advocacy Communication and Social Mobilization (ACSM) in targeting the specific

aspects determining adherence or non adherence in the region thus improving overall outcomes of the programs.

# 1.8 Operational definition of variables

**Behavioral Predictors** – observable or self reported conduct of the respondent that predicts treatment adherence. Included in the study were alcohol and drug abuse, sexual conduct and health care seeking.

**Personal factors** – Individual perceptions and attitudes that influence adherence **Predictors** – factors that determine TB treatment adherence

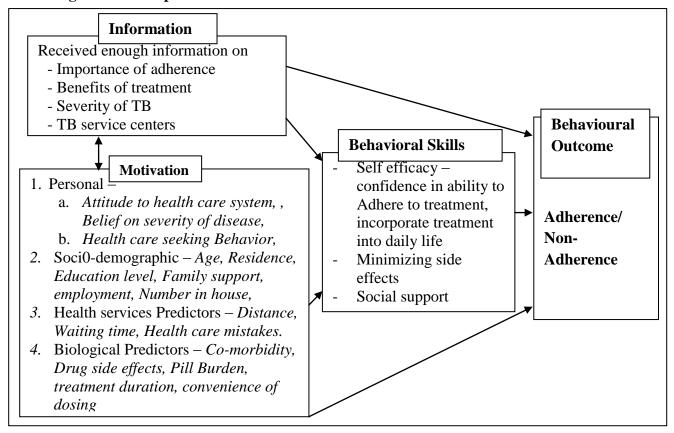
**Socio-economic and demographic Predictors** – patients' social, financial and population structure aspects that affect adherence e.g. family support, level of education, social status, employment status, age, sex, residence, housing and family size.

**TB treatment adherence** – the patient being able to take 90 % of their medication as per the prescription. This was self reported as the patient was asked the number he/she missed in the last 7 days and in the last one month.

**Treatment and Disease factors** – these were factors related to TB medication modalities aspects of TB co-morbidity that can predict adherence. Examples of these were: pill burden, length of treatment, drug side effects, drug interactions and co-morbidities of TB and other health conditions or diseases e.g. HIV/AIDS, diabetes and mental illnesses

# **1.9 Conceptualization of Theoretical Framework**

The researcher adapted Information Motivation Behaviour (IMB) Model (see appendix 10) in the study (Iribarren et al., 2014). This model demonstrates that information, motivation and behavioural skills interact to predict individual's behaviour. Figure 1 below therefore illustrates the conceptualization of the IMB framework. Knowledge on TB and its care and how that knowledge was acquired forms the information part of the framework. Information or lack of it can influence patient's behaviour (adhering to treatment). Under motivation there are the following predictors of TB treatment adherence: individual, socio-demographic, health service and treatment related predictor. Behavioural skills are: minimizing side effects, keeping reminders or diaries and acquiring social support moderate the effects of the information and motivation in predicting TB treatment adherence (Iribarren et al., 2014).



**Figure 1: Conceptualization of Theoretical Framework** 

#### CHAPTER TWO

## LITERATURE REVIEW

## 2.1 Overview

This section has been organized as per the objectives. It has literature on prevalence of TB treatment adherence and the predictors of TB treatment adherence. The predictors have been desegregated into earlier conceptualized broad categories. These are: behavioural, socio-demographic, biological and health system predictors of adherence.

#### 2.2 Epidemiology of Tuberculosis

Tuberculosis is caused by Mycobacterium tuberculosis bacteria. The disease essentially spreads from one person to another via airborne transmission with a large reservoir within the human population, latent and active cases. People living with HIV are 20-30 times more likely to develop active TB. The common symptoms of active lung TB are cough with sputum and blood, chest pains, weakness, weight loss, fever and night sweats. Diagnosis of TB is by several methods namely: Active Acid Fast Bacteria microscopy (AAFB), chest xray, rapid genexpert test, rapid molecular tests for MDR-TB. Tuberculosis is a leading cause of morbidity and mortality. Several core issues influence the global trends of TB. These issues are: drug resistance, HIV pandemic, social determinants of health and adherence (CDC, 2014a; Fogel, 2015; Montales, Beebe, Chaudhury, & Patil, 2015; Pai et al., 2016).

WHO estimates that there are 10.4 million new cases of TB worldwide and 1.7 million died of the same disease (including 0.4 million among people with HIV). One million children aged 0-14 years fell ill with TB and 250000 of them died of TB in 2016. Tuberculosis mostly affects adults in their most productive age even though all age groups are at risk (WHO, 2016; Zumla et al., 2016)

Although sub-Saharan Africa (SSA) has 12% of the world's population it generated 29% of the 9 million TB cases and had 254,000 TB related deaths. SSA bears the highest global TB/HIV burden and over 50% of TB cases in SSA are co-infected with HIV<sup>-</sup> An estimated 1.7 million died from TB globally in 2016, of which a large majority of the 360,000 HIV-positive TB cases who died were from sub-Saharan Africa (Zumla et al., 2016)

Kenya is one of the 22 high burden TB countries that together account for more than 80% of the world's TB cases. WHO estimated that there were 120,000 new cases of TB in Kenya in 2012 (WHO, 2014b). The estimated 9,500 (5,400-15,000) deaths due to TB make it the fourth leading cause of mortality in the country and the leading infectious cause of mortality (NLTLD, 2015).

# 2.3 Treatment of tuberculosis

This disease is a treatable and curable. Active TB that is drug-susceptible is treated with a standard six month course of four antimicrobial drugs that are provided. These antimicrobials are: Isoniazid, rifampicin, pyrazinamide and ethambutol. If provided with information, supervision and support to the patient by a health worker or trained volunteer and social support, cure of TB can be guaranteed. Without such support, treatment adherence can be difficult and the disease can spread. The vast majority of TB cases can be cured when medicines are provided and taken properly (CDC, 2014b).

Poor adherence can lead to drug resistance. Drug resistant TB needs other much more expensive drugs for treatment. First line drugs for MDR-TB are high-dose isoniazid, pyrazinamide, and ethambutol. The second line is the high-dose levofloxacin. The third line comprises the injectable drugs, which should be used in the following order: capreomycin, kanamycin, then amikacin. The fourth group are called the second-line drugs and should be used in the following order: thioamides, cycloserine, then aminosalicylic acid (Lange et al., 2014)

# 2.4 Tuberculosis Treatment Adherence

Adherence to treatment is defined as following the recommended course of treatment by taking all the prescribed medications for the entire length of time necessary (Vrijens et al., 2012). The adverse outcomes of TB treatment can be reversed if TB treatment adherence problem is innovatively handled (Tesfahuneygn et al., 2015). The documented benefits of adherence are; reduced periods of severe illness, shortened infectivity period and reduced chances of developing drug resistance (DiStefano & Schmidt, 2016).

Adherence is important because TB is nearly always curable if patients adhere to their TB treatment regimen. Adherence to anti TB medications is a strong determinant of treatment outcomes. In Papua, those on Directly Observed Therapy (DOT) in the community said they never missed their doses and the outcome was 95% cure rate compared to 75% among the overall population on TB treatment (Diefenbach-Elstob et al., 2017). In another study in Nigeria where adherence was estimated at 79.5% the cure rates were only 78% (Alobu, Oshi, Oshi, & Ukwaja, 2014).

# 2.5 Prevalence of adherence to TB treatment

In Argentina, a study in a region with the highest prevalence of TB estimated prevalence of adherence to be 88% which was lower than the critical basic minimum of 90% recommended by the WHO (Herrero et al., 2015; WHO, 2014a). This study, however, utilized convenience sampling which could lead to selection bias. A South

African study established TB treatment adherence to be 89%. This study was among patients attending TB/HIV clinic (Mazinyo et al., 2016).

In a 2012 study in Homabay, Kenya, overall adherence was estimated at 95.2% using Isoniazid (INH) urine test in a conveniently sampled group of patients attending clinic at the time of the study. These findings were similar to those in Tanzania, 95.7% adherence, where the same methodology and test were used to estimate adherence in patients on home based TB care (Mkopi et al., 2012). However INH urine test has been shown to be indicative of adherence in the recent past (up to 72 hours of the last dose) as opposed to cumulative compliance over a period of time. Self reported adherence has better panorama of behavioural aspects that should not be left out when referring to adherence (Yin et al., 2012).

## 2.6 Predictors of TB treatment adherence

The predictors of TB treatment adherence have been widely studied and the researcher classified them into broad categories as behavioural, biological, social, demographic and health system factors.

## 2.6.1 Sociodemographic Predictors

Social aspects such as employment status, family support, number of people living in one house, low status occupation were found to predict adherence to TB medications (Anaam, Ibrahim, & Aldobhani, 2013; Méda et al., 2014). Lower education or illiteracy and lack of money to pay for transport and treatment of drug side effects were a major socioeconomic factor contributing to poor adherence (Nissen et al., 2012; Peltzer & Pengpid, 2013). Social support like family supervision, assistance with child care, transportation and shelter were shown to be associated with improved adherence to care(Orr, 2011). In Brazil, incidences of partial completion of

treatment were shown to have significant association with living away from home family, overcrowding at home and lack of family support (Aquino et al., 2015). Some of the demographic predictors of adherence identified from previous studies are male gender, older age, rural residence and not being married (Alobu et al., 2014; Elbireer, Guwatudde, Mudiope, Nabbuye-Sekandi, & Manabe, 2011; Ifebunandu & Ukwaja, 2012). A study in Estonia demonstrated urban residence as a factor leading to non-adherence to TB medication (Kliiman & Altraja, 2010)

## **2.6.2 Behavioural Predictors**

Several studies have demonstrated that behavioural aspects like alcoholism (Naidoo, Peltzer, Louw, Matseke, McHunu, et al., 2013), drug abuse (Anaam et al., 2013; Méda et al., 2014) and cigarette smoking (Tachfouti et al., 2013) as predictors of adherence to TB treatment. In a study in Burkina Faso, intravenous drug usage was independently associated with poor adherence (Méda et al., 2014). In study among newly diagnosed TB patient, being a female sex workers was an absolute risk factor for non-adherence to TB treatment (Kulkarni et al., 2013). Common among these studies was the mode selection of participants by convenience sampling. Equally, possible confounders for the effect of these predictors were not adjusted for at the data analysis level.

#### 2.6.3 Treatment and Co-morbidity predictors

Co-morbidity of TB with other diseases is major concern when it comes to treatment modalities. It has been shown that co-morbidity with diabetes, HIV/AIDS and mental illnesses raise concerns beyond drug interaction. These co-morbidities have negative effects on adherence to TB medications (Adane, Alene, Koye, & Zeleke, 2013; Gebremariam, Bjune, & Frich, 2010; Mazinyo et al., 2016; Tesfahuneygn et al., 2015). Amplification of drug toxicity in patients on TB/HIV treatment is a factor in determining compliance (Gray & Cohn, 2013). Several studies and a systematic review of qualitative studies from 1966- 2005 established drug side effects as a factor in patient's adherence to anti TBs (Deshmukh et al., 2015; Tesfahuneygn et al., 2015; Tola, Tol, Shojaeizadeh, & Garmaroudi, 2015). Mental illness was elicited as a contributor to non-adherence in a study in Morocco (Kizub et al., 2012) and in a Kenyan study, having previously defaulted treatment was attributed to nonadherence among patients in Nairobi, (Muture et al., 2011). Pill burden was also seen to negatively influence adherence to TB treatment in a survey in Ethiopia (Gebremariam et al., 2010). Some patients stop or altered drug intake patterns because they were feeling better after the few weeks of treatment (Finlay et al., 2012; Tola et al., 2015). However, a study in Brazil revealed that TB/HIV co-morbidity and concomitant treatment of the same led to better adherence (Maruza et al., 2011) All these studies point to the fact that treatment and diseases characteristics can lead to problems with adherence. However, their dynamics in terms of how they affect TB treatment adherence varies dependent on the setting. This thus point to the need to be explore these treatment and co-morbidity predictors of TB in the study area.

#### 2.6.4 Health System Predictors

Gender discrimination and organization of health services were elicited as factors determining adherence (Ali & Prins, 2016; Herrero et al., 2015). Distance from home to treatment centres, unsuitable clinic times, long wait at hospitals before being attended and the necessity of public transport to care centres were some of the health facility related structural factor demonstrated in several studies as a determinant to adherence to TB drugs. Health care workers mistakes or behaviour and lack of structured information giving to the patients on TB care lead to treatment non-adherence(Cherkaoui et al., 2014a; Kizub et al., 2012; Tola et al., 2015). Most of the

non-compliance was experienced during the first and second month of the intensive phase (Muture et al., 2011)

## **2.6.5 Individual predictors**

Patient aspects like inadequate knowledge on the benefits of treatment completion, treatment comprehension difficulties, negative opinion about healthcare workers and inadequate knowledge on TB were shown to lead to poor adherence to TB treatment (Kayigamba et al., 2013; Kulkarni et al., 2013; Wabe & Kebede, 2012). A systematic review revealed patient's perception of health status, attitude, knowledge and social support were significantly associated with adherence (Makanjuola, Taddese, & Booth, 2014). Forgetfulness was elucidated as a factor determining drug adherence (Adane et al., 2013). Disclosure status and beliefs in the severity of TB have also been studied and confirmed to determine the adherence (Gebremariam et al., 2010)

#### **2.6.6 Effect of predictors on adherence**

The above stated studies have explored the factors determining adherence. In most of the studies, the setting has been seen to be a factor in determining effect of the predictors on adherence. In some areas younger age was a predictor of adherence (El-Din, Elhoseeny, & Mohsen, 2013; Marx, Dunbar, Enarson, & Beyers, 2012). In others studies older age was adherence predictor (Ifebunandu & Ukwaja, 2012; Kendall et al., 2013). Some studies also demonstrated lack of food as a positive predictor of adherence (Tadesse, Demissie, Berhane, Kebede, & Abebe, 2013) and others provided evidence to the contrary (Finlay et al., 2012). Rural residence (Musaazi et al., 2017) and urban residence (Méda et al., 2014) were also setting influenced predictors. Several studies have elucidated predictors of adherence to treatment but not on the way and direction of influence on adherence. These truths explicate how important it is to spell out predictors in a specific setting more so one

with adverse treatment outcomes. This can help in focusing adherence interventions to be specific to the target population (Conn, Ruppar, Enriquez, & Cooper, 2016).

Lastly, predictors of treatment adherence interact either to confound or potentiate the each other. Others have shown artefactual relationship upon being adjusted for in logistic regression models (Alobu et al., 2014; El-Din et al., 2013).

# 2.7 Summary

The reviewed studies are not unanimous on the predictors and their net effect on TB treatment adherence. Therefore there is need to explore predictors of TB treatment adherence in this region with high TB prevalence and poor treatment outcomes. The knowledge of the predictors of adherence could lead to exploring of innovative remedy to the problem.

## **CHAPTER THREE**

## METHODOLOGY

## 3.1. Overview

Methodology chapter has the following subtopics: research design, study site, study population, inclusion and exclusion criteria, sampling methods, sample size determination, data collection instruments, data collection, data analysis, ethical consideration, limitation and dissemination of the findings.

# 3.2 Research design

This was a descriptive cross-sectional research based in institutions providing TB treatment in Kisumu East sub-County. This design will adequately address the problem because it is feasible within the time of the study. Earlier longitudinal studies utilizing 24 hour urine Isoniazid (INH), Pill counts and Patient record have demonstrated lower positive predictive values for estimating adherence (Nackers et al., 2012; Ong'ayo, Osanjo, & Oluka, 2014; Yin et al., 2012).

# 3.2. Study site

The study was conducted in Kisumu East sub-County. The Sub-County lies within longitude  $34^{0}10$  E and  $35^{0}20$ E and latitude  $0^{0}20$  S and  $0^{0}50$  S. It has 115,502 households and it covers an area of 559.2 km<sup>2</sup> with a population density of 847 persons per square kilometer (see appendix 3). The Sub-County has a total population of 473,649 as per 2009 census and of this population, 237,973 are female and 235,676 male. The region has a poverty index of 60%, the highest in a Kenyan city. Farming, fishing and trading are the main economic activities of the Sub-County (KNBS, 2009). HIV prevalence is at 18.7%, which is more than thrice the national prevalence (6.04%) (MoH, 2014)

The whole Sub-County has 22 health facilities that provide TB care among other services. A total of 7 out of the 22 health facilities providing TB care in Kisumu East sub-County were considered for the study based on the large number of TB patients attending care in the facilities.

# 3.3 Study population and target population

The study population was TB patients attending TB clinics within Kisumu East sub-County. Kisumu East sub-County has 845 TB patients on treatment with 523 being on treatment for more than one month. The target population were TB patients aged 18 years and above on treatment for more than one month.

# 3.4 Inclusion and exclusion criteria

# 3.4.1 Inclusion Criteria

- Out Patients with TB aged 18 years and above attending TB clinic in Kisumu District Hospital.
- The patient must have been on TB treatment for more than one (1) months
- The patients must have been residents in Kisumu East sub-County for more than 3 months

# 3.4.2 Exclusion Criteria

• Tuberculosis patients that are hospitalised patients, mentally ill and prisoners were excluded from the study.

# 3.5 Sampling method

The area of study, Kisumu East sub-County was purposively sampled. The sample was proportionately allocated per participating facility. A sampling frame was later developed from the TB permanent registers in the facilities. Excel generated random numbers were then used to select the patients from the sampling frame who participated in the study.

# **3.6 Sample size determination**

Taro Yamane formula was used to calculate the sample size. This formula was used because the population of patients with TB in Kisumu East sub-County who have been on treatment for more than a month as of September was known, 523 patients

Taro Yamane's formula: (Yamane, 1967)

 $n = N / [1 + Ne^2]$ 

where:

n = sample size

N = population size (TB patients with TB in Kisumu East sub-County - 523)

e = sampling error (set at 5% or 0.05)

At 95% confidence level,

Therefore:  $n=523/[1+523x0.05^2]$ 

n= 227

Therefore, the sample size with a 10% margin of error and 95% confidence level is

227 TB patients. With addition of 10 percent loss, the final sample size becomes 250

TB patients.

The number of participant interviewed per facility proportionately allocated as per

the table 3.1 below.

 Table 3. 1: Number of Participants interviewed per health facility

Participating Facility	Patients per facility who met criteria	Proportion of the sample	Participants	
Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH)	267	51	128	
Kisumu District Hospital	83	16	40	
Lumumba Health Center	69	13	32	
Migosi Health Center	26	5	12	
Nyalenda Health Center	31	6	14	
Rabuor Health Center	21	4	11	
Railways Health Center	26	5	13	

## **3.7 Data collection instruments**

Data collection was by a self administered structured questionnaire (see appendix 2) which was pretested in Nyahera Subcounty hospital. The data from the pilot study was used to check for appropriateness of the tool and some of the questions were adjusted for clarity purposes. The questionnaire had several sections such as social, demographic and economic information, personal aspects, knowledge, health seeking behaviour, treatment and co-morbidity and adherence. The adherence part of the questionnaire was modified from a TB Medication Adherence Scale (TBMAS) which has positive predictive value of 65.5% and sensitivity of 82.9% in identifying non-adherents (Yin et al., 2012).

## 3.8 Data Collection

Five research assistants were used in data collection. These five were nurses by qualification and were not staffs in the participating facilities. They were trained on data collection using interviewer administered questionnaire, uniformity when asking questions, data recording, finalization of questionnaire, data cleaning before handing over to the researcher and safe storage of data.

Data was collected using an interviewer-administered questionnaire over a period of 4 weeks starting 10<sup>th</sup> November 2016. Two hundred and fifty questionnaires were administered and there was 100% response rate. Data was collected after written consent was obtained.

Adherence within the last 7 days (recent) and adherence during the last one month before the survey was assessed. Patients were asked to report the total number of anti-TB pills they missed 7 days before the survey. These numbers of missed pills was compared to the number of pills prescribed to the patient. Missing 1 (more than 10 percent) dose or drug in the last 7 days was classified as non-adherent. Completely adherent will be considered if no pill was missed in the last 7 days before the survey. Similarly, the last one month non-adherence was calculated as total reported missed pills over the total prescribed pills within that month and classified as adherent if not more than 10% of pills were missed. Patients were also asked to report why they missed the anti-TB drugs. The level of knowledge of the patient about TB and its treatment was determined through a set of questions derived from the set of information routinely provided to patients as part of the national TB program. A patient who scored more than half of questions asked to measure TB knowledge was considered to have good knowledge about TB.

## **3.9 Data Analysis**

Data was entered, cleaned and analyzed using Statistical Package for Social Sciences (SPSS) version 20. Two hundred and fifty questionnaires were administered and there was 100% response rate. The data for prevalence of adherence among patients on TB treatment was analysed using desriptive statistics, frequencies tables. The prevalence was also desegregated into different grouping characteristics based on demographics of the population and other characteristics.

The data was analyzed using descriptive statistics for socio-demographic variables and bivariate analysis for the selection criteria for inclusion in the binary logistic regression model. Predictors from the bivariate analysis with a  $p \le 0.05$  were included in the final logistic regression model. The binary logistic regression analysis was used for making inference of the predictors of adherence. P values, Odds Ratios and 95% confidence interval (CI) were used to demonstrate significance and the strength of association between selected variables. Significance was assumed at p value  $\le 0.05$ in the final model.

## 3.10 Ethical considerations

The study was approved by Masinde Muliro University of Science and Technology (MMUST) School of Graduate Studies (SGS) (See appendix 7). Ethical clearance was obtained from the MMUST Institutional Ethics Review Committee (IERC) and JOOTRH ethics review committee (See Appendix 4&6). An official data collection permission letter was obtained from the county Director of Medical Services (See appendix 5). A research authorization and permit were acquired from NACOSTI (Appendix 8 and 9). During data collection, written informed consent was obtained from all participants after they are introduced to the purpose of the study and informed about their rights to withdraw from the interview at any time (Appendix 1). To ensure confidentiality and privacy, the names of the participants were not recorded in the questionnaire and data collection in privacy. Principle of justice and impartiality was adhered to by enabling equal opportunity of the target population to participate in the study by use of probability sampling. In addition, the collected information was stored safely; hardcopies will be stored in lockable cabinets and soft copies will be secured by password.

## 3.11 Limitations

The limitation of this study is that it is cross-sectional. Ideally, the adherence patterns of TB patients should be tracked over time in order to better understand how the disease course(s) influences the patient's willingness to co-operate with the prescribed treatment. Despite this limitation, the results of this study provide insight into the predictors of adherence to treatment among TB patients in the study area.

There is a possibility of selection bias because the study site was conveniently sampled. The study relied on respondents self reported adherence thus there is possibility of respondent and recall bias.

# **3.12 Dissemination of findings**

The final copy of research report has been presented in form of thesis to MMUST School of Nursing, Midwifery and Paramedical Sciences. The researcher will publish the final work in a peer reviewed journal. The findings will also be presented in conferences, workshops and in relevant DLTLD forums. Importantly the health authorities in the sub-County of study will also be furnished with a copy of the same report for any deserving action.

### **CHAPTER FOUR**

# RESULTS

## 4.1 Overview

The results chapter has a flow that is congruent with the conceptual framework and flow of analysis because the criteria for inclusion in the final binary logistic regression model had to be met during the initial bivariate analysis. The first section of the results was analysed using descriptive statistics. It has socio-demographic aspects of the respondents and prevalence of TB treatment adherence. The second section has the bivariate analysis results of: demographic predictors, individual predictors, biological predictors and health system predictors of TB treatment adherence. The third section has the output of binary logistic regression analysis which shows the actual predictors of TB treatment adherence and their effect on drug adherence. The summary part shows how each objective of the research has been attained.

#### **4.2 Demographic Characteristics of the Respondents**

Table 4.1 presents the distribution of the demographic characteristics of the respondents and illustration of the level of adherence in the study population. A total of 250 respondents were interviewed in this study. The mean age of the respondents was  $32.5\pm10.9$  with over 90% being below the age of 50. Over 60% of the sampled population was married and those with basic education and above being more than 90%.

Out of the 250 respondents, 226 (90.5%) were categorized as adherent to drugs while 24 (9.6%) were not adherent. There was a significant relationship between age (OR: 0.1; 95% CI 0.0-0.4; p<0.001),residence (OR: 20.6; 95% CI: 7.8-54.1; p<0.001), sex (OR:0.3 ; 95% CI: 0.1-1; p=0.033), marital status (OR:3.3; 95% CI: 1.3-7.9;

p=0.007), number of family members living with the patient (OR:9.9; 95% CI: 4-24.8; p<0.001), and level of education (OR:3.1 ; 95% CI:1.3-7.6; p=0.009), employment status (OR:2.6; 95% CI:1.1-6; p=0.027) and adherence. The other variables did not demonstrate significance in determining adherence.

Variabla	Variable Grouping		Drug Adherence		<b>Bivariate Analysis</b>			
variable	Grouping	Yes n(%)	No n(%)	OR	95%CI	P Value		
Adherence		226(90.4)	24 (9.6)					
Age	≤30 Years	139(97.2)	4 (3.8)	0.1	0.0 - 0.4	<0.001		
	>30 Years	87(81.3)	20(18.7)	0.1	0.0 - 0.4	<0.001		
Sex	Male	128(87.1)	19(12.9)	0.3	0.1 - 1	0.033		
	Female	98 (95.1)	5 (4.9)	0.5	0.1 - 1	0.035		
Residence	Rural	20(55.6)	16(44.4)	20.6	7.8-54.1	<0.001		
	Urban	206(96.3)	8(3.7)	20.0	7.0-34.1	<0.001		
Marital Status	Not Married	86(84.3)	16(15.7)	3.3	1.3 - 7.9	0.007		
	Married	140(94.6)	8(5.4)	5.5	1.5 - 7.9	0.007		
Education	≤Primary	88 (84.6)	16(15.4)	3.1 1.3 - 7.6		0.009		
	>Primary	138(94.5)	8(5.5)	3.1	1.3 - 7.0	0.009		
Employment	Unemployed	80(85.1)	14(14.9)	2.6 1.1 - 6		0.027		
Status	Employed	146(93.6)	10(6.4)	2.0	1.1 - 0	0.027		
Monthly	≤10000	161(88.5)	21(11.5)	2.8	0.8 - 9.8	0.089		
Income (KSh)	>10000	65(95.6)	3(4.4)	2.0	0.0 - 9.0	0.089		
Family	≤3 Members	38(70.4)	16(66.7)	9.9 4 - 24.8		<0.001		
members	>3 Members	188(95.9)	8(4.1)	7.7	4 - 24.0	<b>\U.UU1</b>		
Rooms	$\leq$ 2 Rooms	139(88)	19(12)	2.4	0.9 - 6.6	0.088		
	> 2 Rooms	87(94.6)	5(5.4)	2.4 0.9 - 6.6		0.000		

 Table 4. 1: Demographic Predictors and adherence to TB treatments.

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided.

# 4.3 Individual Predictors of TB treatment adherence

The individual aspects assessed were level of knowledge (figure 3), health seeking behaviour (table 4.2), behavioural skills that modify adherence (table 4.3), sexual and addictive behaviour (table 4.4), individual attitudes (table 4.5).

## 4.3.1. Level of knowledge

The graph below shows the distribution of level of knowledge about TB among the respondents. Level of knowledge was determined by the number of correct responses out of five questions that were derived from the TB client teaching and adherence information. The areas were; TB treatment side effects, length of treatment, reinfection, whether TB is curable and availability of TB drugs. Only three of these areas demonstrated significance in predicting adherence: heard of TB before diagnosis (OR:10.8 ; 95% CI: 4.3–26.7; p<0.001;), knowledge on seriousness of TB (OR:74.3; 95% CI:23.4-236; p<0.001) and overall level of knowledge (OR:7.5; 95% CI:2.2-25.9; p<0.001).

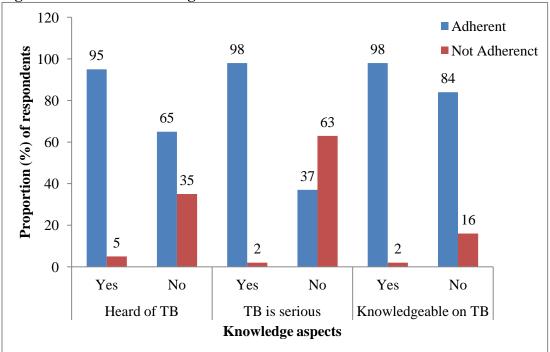


Figure 2: Level of Knowledge and TB treatment Adherence

## 4.3.2 Health Seeking Behaviour

On health seeking behaviour, four aspects demonstrated significance in determining adherence. Time taken between onset of symptoms and seeking health care demonstrated significance (OR: 0.1; 95% CI: 0-0.7; p=0.006) in predicting with adherence. Seeking care regularly (OR: 6.5; 95% CI: 2.2-19.7; p<0.001), satisfaction with care (OR: 54.4; 95% CI: 18.1-164.3; p<0.001) and knowing TB care centers before was diagnosed with the disease (OR:4.1; 95% CI:1.6-10.3; p=0.001) were significant in predicting adherence. About 53% of the respondents sought care regularly, 2.8% saw traditional healer first and 7.6% went to private clinics and 87.6% went to government hospitals.

Health Seeking	8	aviour and 1B treatment AdherenceDrug AdherenceBivariate Analysis			alysis	
Characteristic	Categ.	Yes n (%)	No n (%)	OR	95% CI	P Value
Weeks from onset of TB to	<15	69 (98.6)	1 (1.4)	10	1.3-76.4	0.006
time of Seeking TB Care	≥15	157 (87.2)	23 (12.8)	10		0.000
Knew TB Center Before	Yes	142 (95.3)	7 (4.7)	4.1	1.6-10.3 0	0.001
Knew 1D Center Derore	No	84 (83.2)	17 (16.8)	4.1		0.001
Saaks, Cara Pagularly	Yes	128 (97)	4 (3)	6.5	2.2-19.7	<0.001
Seeks Care Regularly	No	98 (83.1)	20(16.9)	0.5	2.2-19.7	<0.001
Visited Traditional Healer	Yes	5 (71.4)	2 (28.6)	0.2	0-1.4	0.084
First	No	221 (90.9)	22 (9.1)	0.2	0-1.4	0.084
Visited Government	Yes	197 (90)	22 (10)	0.6	0.1-2.8	0.525
Hospital First	No	29 (93.5)	2 (6.5)	0.0		
Dicelogura	Yes	217(90.8)	22 (9.2)	2.2	0.4-10.8	0.323
Disclosure	No	9(81.8)	2 (18.2)	2.2	0.4-10.8	0.325
Satisfied with Care	Yes	218 (96.5)	8 (3.5)	54	10 1 174	-0.001
	No	8(33.3)	16 (66.7)		18.1-164	<0.001

 Table 4. 2: Health Seeking Behaviour and TB treatment Adherence

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided. Categ.-Category

## 4.3.3 Behavioural Skills

In this category, keeping drugs in a bag (OR:5; 95% CI:1.4-17; p=0.005), at workplace (OR:0.1; 95% CI:0-0.09; p=0.02) were significant in predicting adherence. There was a significant relationship between being reminded by a family member to take drugs (OR:5.3; 95% CI:1.9-15: p<0.001), and keeping the drugs visible (OR:0.2; 95% CI:0.1-0.7; p=0.004) and adherence. No significant relationship between the other aspects and adherence was elicited.

Category		Drug Adherence		<b>Bivariate Analysis</b>		
		Yes n(%)	No n(%)	OR	95% CI	P Value
Cuphoard	Yes	77 (88.5)	10 (11.5)	0.7	03 17	0.458
Cupboard	No	149 (91.4)	14 (8.6)	0.7	0.3 - 1.7	0.438
Pag	Yes	94 (96.9)	3 (3.1)	5	1 / 17	0.005
Dag	No	132 (86.3)	21 (13.7)	3	1.4 - 1/	0.003
Dockat	Yes	6 (75)	2 (25)	0.3	0.1 – 1.6	0.133
FUCKEI	No	220 (90.9)	22 (9.1)	0.5		0.155
Work	Yes	3 (60)	2 (40)	0.1	0-0.9	0.02
place	No	223 (91)	22 (9)	0.1		0.02
Takes	Evening	64 (91.4)	6 (8.6)	0.8	0.3 – 2.2	0.731
Meds	Morning	162 (90)	18 (10)	0.0		0.751
Alarm	Yes	8 (80)	2 (20)	0.4	0.1.2	0.255
Alaliii	No	218 (90.8)	22 (9.2)	0.4	0.1 - 2	0.233
Family	Yes	132 (96.4)	5 (3.6)	53	10 15	<0.001
Reminds	No	94 (83.2)	19 (16.8)	3.3	1.9 – 13	<0.001
Incorporate	Yes	76 (87.4)	11 (12.6)	0.6	03 14	0.233
in Routine	No	150 (92)	13 (8)	0.0	0.5 – 1.4	0.233
Keeps	Yes	8 (66.7)	4 (33.3)	0.2	01 07	0.004
Visible	No	218 (91.6)	20 (8.4)	0.4	0.1 – 0.7	0.004
	Cupboard Bag Pocket Work place Takes Meds Alarm Family Reminds Incorporate in Routine Keeps	Yes           No           Bag         Yes           Bag         Yes           Pocket         Yes           Pocket         Yes           No         Yes           Pocket         No           Steinily         Yes           Reminds         No           Incorporate         Yes           in Routine         No           Keeps         Yes           Visible         No	Category         Yes $n(%)$ Cupboard         Yes $77 (88.5)$ No         149 (91.4)           Bag         Yes $94 (96.9)$ No         132 (86.3)           Pocket         Yes $6 (75)$ No         220 (90.9)           Work         Yes $3 (60)$ place         No         223 (91)           Takes         Evening $64 (91.4)$ Meds         Morning $162 (90)$ Alarm         Yes $8 (80)$ No         218 (90.8)           Family         Yes $132 (96.4)$ Reminds         No         94 (83.2)           Incorporate         Yes $76 (87.4)$ in Routine         No         150 (92)           Keeps         Yes $8 (66.7)$ Visible         No         218 (91.6)	CategoryYes n(%)No n(%)CupboardYes $77 (88.5)$ $10 (11.5)$ No $149 (91.4)$ $14 (8.6)$ BagYes $94 (96.9)$ $3 (3.1)$ No $132 (86.3)$ $21 (13.7)$ PocketYes $6 (75)$ $2 (25)$ No $220 (90.9)$ $22 (9.1)$ WorkYes $3 (60)$ $2 (40)$ placeNo $223 (91)$ $22 (9)$ TakesEvening $64 (91.4)$ $6 (8.6)$ MedsMorning $162 (90)$ $18 (10)$ AlarmYes $8 (80)$ $2 (20)$ No $218 (90.8)$ $22 (9.2)$ FamilyYes $132 (96.4)$ $5 (3.6)$ RemindsNo $94 (83.2)$ $19 (16.8)$ IncorporateYes $76 (87.4)$ $11 (12.6)$ in RoutineNo $150 (92)$ $13 (8)$ KeepsYes $8 (66.7)$ $4 (33.3)$ VisibleNo $218 (91.6)$ $20 (8.4)$	CategoryYes n(%)No n(%)ORCupboardYes $77 (88.5)$ $10 (11.5)$ $0.7$ No $149 (91.4)$ $14 (8.6)$ $0.7$ BagYes $94 (96.9)$ $3 (3.1)$ $5$ PocketYes $6 (75)$ $2 (25)$ $0.3$ PocketYes $3 (60)$ $2 (40)$ $0.1$ placeNo $223 (91)$ $22 (9)$ $0.1$ TakesEvening $64 (91.4)$ $6 (8.6)$ $0.8$ MedsMorning $162 (90)$ $18 (10)$ $0.8$ AlarmYes $8 (80)$ $2 (20)$ $0.4$ FamilyYes $132 (96.4)$ $5 (3.6)$ $5.3$ RemindsNo $94 (83.2)$ $19 (16.8)$ $5.3$ IncorporateYes $76 (87.4)$ $11 (12.6)$ $0.6$ KeepsYes $8 (66.7)$ $4 (33.3)$ $0.2$ VisibleNo $218 (91.6)$ $20 (8.4)$ $0.2$	$\begin{array}{ c c c c c c } \hline \mbox{Ves n(\%)} & \mbox{No n(\%)} & \mbox{OR} & \mbox{95\% CI} \\ \hline \mbox{Cupboard} & \mbox{Yes} & \mbox{77 (88.5)} & \mbox{10 (11.5)} \\ \hline \mbox{No} & \mbox{149 (91.4)} & \mbox{14 (8.6)} & \mbox{0.7} & \mbox{0.3 - 1.7} \\ \hline \mbox{Mo} & \mbox{132 (86.3)} & \mbox{21 (13.7)} & \mbox{5} & \mbox{1.4 - 17} \\ \hline \mbox{Pocket} & \mbox{Yes} & \mbox{6 (75)} & \mbox{2 (25)} & \\ \hline \mbox{No} & \mbox{220 (90.9)} & \mbox{22 (9.1)} & \mbox{0.1} & 0.1$

Table 4. 3:Behavioural Skills that Modify Adherence

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided.

# 4.3.4 Sexual and other Addictive Behaviour

Thirty nine percent of the client interviewed demonstrated the key characteristics under sexual and addictive behaviour group. Of these 5.2% (OR:0.02; 95% CI:0-0.1; p < 0.001) smoked cigarette, 10% (OR:0.01; 95% CI:0.0.03; p < 0.001) took alcohol, 1.2% (OR:0.21; 95% CI:0.0-2.4; p=0.16) smoked bhang 0.8% (OR:0.1; 95% CI:0.01-1.7; *p*=0.052) chewed miraa and 22% (OR:0.07; 95% CI:0.02-0.2; *p*<0.001) had more than 1 sexual partner. Thus a significant relationship demonstrated between more than one sexual partner, smoking cigarette, alcohol drinking and adherence. All addictive aspects collapsed together into one variable "addictive behaviour" without the aspect of having more than one sexual partner demonstrated significance (OR:0.004; 95% CI:0.02; p<0.001) in predicting adherence.

		Drug Ad	herence	Biva	riate Analys	sis
Characteristic	Categ.	Yes n (%)	No n (%)	OR	95% CI	P Value
Smokes	Yes	3 (23.1)	10 (76.9)	0.0	0-0.1	<0.001
Cigarettes	No	223 (94.1)	14 (5.9)	2	0-0.1	<0.001
Takes Alcohol	Yes	6 (24)	19 (76)	0.0	0- 0.03	<0.001
Takes Alconor	No	220 (97.8)	5 (2.2)	1	0- 0.03	<0.001
Chews Miraa	Yes	1 (50)	1 (50)	0.1	0.01 – 1.7	0.052
Chews Millaa	No	225 (90.7)	23 (9.3)	0.1	0.01 - 1.7	0.052
>1 cay partners	Yes	37 (67.3)	18 (32.7)	0.0	0.02 - 0.2	<0.001
>1 sex partners	No	189 (96.9)	6 (3.1)	7	0.02 - 0.2	<0.001
Addictive	Yes	6 (22.2)	21 (77.8)	0.0	0 - 0.02	<0.001
Behaviour	No	220 (98.7)	3 (1.3)	04	0 - 0.02	<0.001

 Table 4. 4: Sexual and other Addictive Behaviour and TB Treatment Adherence

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the P values are 2 sided. Categ.-Category

## 4.3.5. Individual's attitudes towards TB and its Treatment

Table 4.5 below shows the distribution of individual attitudes and their significance in determining adherence. There only existed a statistically significant (OR: 0.91; 95% CI:0 .95-1.34; p=0.040;) relationship between the attitude that TB and its treatment affects family responsibilities and adherence.

Characteristic	Categ.	Adherence			<b>Bivariate Analysis</b>			
Characteristic	Categ.	Yes n (%)	No n (%)	OR	95% CI	P Value		
Prefers to be Isolated	Yes	26(81.2)	6(18.8)	2.5	0.9-7	0.098		
Because of TB	No	200(91.7)	18(8.3)	2.3	0.9-7	0.098		
Affects Family	Yes	154(93.3)	11(6.7)	2.5	1.1-5.9	0.04		
Responsibilities	No	72(84.7)	13(15.3)	2.3	1.1-3.9	0.04		
Females Have Difficulty	/ Yes	54(84.4)	10(15.6)	0.4	0.2-1.0	0.082		
Seeking Treatment	No	172(92.5)	14(7.5)	0.4	0.2-1.0	0.082		
Affects Relationships	Yes	68(85)	12(15)	0.4	0.2-1	0.064		
Affects Relationships	No	158(92.9)	12(7.1)	0.4	0.2-1	0.064		

Table 4. 5: Individual's attitudes towards TB and its Treatment

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the P values are 2 sided. Categ. – Category

#### 4.4 Biological predictors of TB treatment adherence

This section portrays the results of the biological predictors of TB treatment adherence. The biological predictors include; co-morbidity (table 4.6), treatment characteristics (table 4.7 and 4.8), reasons for missing drug (figure 4) and reasons for missing clinic appointments (figure 5)

#### 4.4.1 Co-morbidity

This table portrays other diseases that the patient had apart from TB, whether they were on treatment for the same or not and their perceived effects of TB treatment on the other treatments. Only the attribute of thinking that TB treatment affects the other

concomitant treatments for co-morbidity was significant (OR:0.03; 95% CI:0-0.1;

*p*<0.001).

	e 4. 6: Distribution of Co-i		Drug Adherence		<b>Bivariate Analysis</b>		
Char	acteristic	Categ.	Yes n(%)	No n(%)	OR	95% CI	P Value
	Other Disease	Yes	132 (88)	18 (12)	0.5	0.2 - 1.2	0.115
Concurrent	Other Disease	No	94 (94)	6 (6)	0.5	0.2 - 1.2	0.115
morbidities		Yes	109 (87.2)	16 (12.8)	0.5	0.2 1.1	0.096
and their	HIV Positive	No	117 (93.6)	8 (6.4)	0.5	0.2 - 1.1	0.086
Treatment	TB Rx Affects the	Yes	13 (44.8)	16 (55.2)	0.03	0 - 0.1	<0.001
	other Treatments	No	118 (95.9)	5 (4.1)	0.03	0 - 0.1	<0.001
Here TD	Makes other Drugs	Yes	2 (33.3)	4 (66.3)	0.4	0.1 - 2.2	0.258
How TB Treatment	Less Effective	No	17 (58.6)	12 (41.4)	0.4	0.1 - 2.2	0.258
Affects	Lead to Many Pills	Yes	10 (52.6)	9 (47.4)	0.9	0.2 - 3.3	0.83
	Lead to Marry 1 ms	No	9 (56.3)	7 (43.7)	0.7	0.2 - 5.5	0.05
other		Yes	7 (63.6)	4 (36.4)	1.0	0.4.7.6	0.452
Treatment	More Side Effects	No	12 (50)	12 (50)	1.8	.8 0.4 - 7.6	0.452

Table 4. 6: Distribution of Co-morbidity Aspects

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided. Categ.- Category

## 4.4.2 Treatment characteristics

Table 9 shows the distribution of previous treatment aspects such as having had previous treatments(OR:11.1; 95% CI:4.2-29.6; p<0.001), completion of previous treatments(OR:18.5 ; 95% CI:4.6-73.6; p<0.001) and self discontinuation from previous treatments (OR:0.13 ; 95% CI:0.01-1.2; p<0.049). These aspect demonstrated significance in determining adherence. Other previous treatment characteristics did not display significance in predicting adherence.

# **Table 4. 7: Previous treatment characteristics**

Characteristic		tagan	Drug Adherence		<b>Bivariate Analysis</b>		
Charac	teristic Ca	ategory	Yes n(%)	No n(%)	OR	95% CI	P Value
	Previous	Yes	48 (72.7)	18 (27.3)	0.1	0.02.0.2	-0.001
Previous	Treatment	No	178 (96.7)	6 (3.3)	0.1	0.03-0.2	<0.001
Treatment	Complete Prev	v. Yes	48 (94.1)	3 (5.9)	10	1 ( 72 (	.0.001
	Treatment	No	13 (46.4)	15 (53.6)	19	4.6 - 73.6	<0.001
	Cida Effecto	Yes	0 (0)	3 (100)	0.5	0.3 - 0.7	0.000
	Side Effects	No	13 (52)	12 (48)	0.5		0.088
Reason	Self	Yes	1 (14.3)	6 (85.7)	0.1	0.01 - 1.2	0.049
Patient	Discontinue	No	12 (57.1)	9 (42.9)	0.1	0.01 - 1.2	0.049
Didn't	Felt Better	Yes	2 (66.7)	1 (33.3)	2.6	0.2 21.0	0.457
Complete	Fell Beller	No	11 (44)	14 (56)	2.0	0.2 - 31.9	0.457
Previous	Too Many	Yes	3 (50)	3 (50)	1.2	0.2.7.2	0.042
Treatment	Drugs	No	10 (45.5)	12 (54.5)	1.2	0.2 - 7.3	0.843
		Yes	5 (83.3)	1 (16.7)	0.6	0.1 - 7 0.68	0 (01
	Big Drugs	No	25 (89.3)	3 (10.7)	0.6		0.681

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided.

Figure 3 below shows current treatment aspects that were studied. There was no significant relationship between treatment period (months on treatment) and adherence (OR: 0.7; 95% CI: 0.3-1.8; p=0.509). Seventy two percent of those who did not comply with clinic appointments were adherent compared to 98% who were compliant and were adherent.

## **Figure 3: Current Treatment Aspects and adherence**

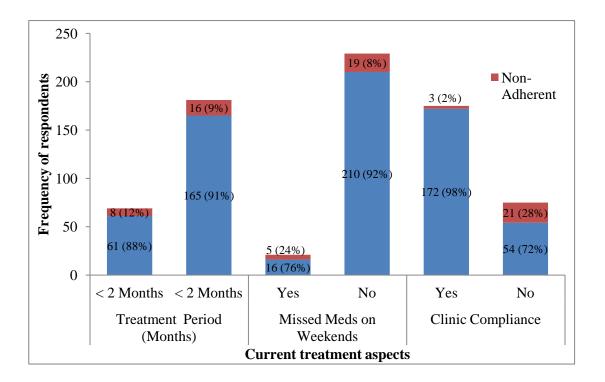


Figure 4 below alludes to the reasons given by the respondents for missing their drugs. The main reason for missing was forgetting (29.2%). The other reasons were; medication time not fitting in the schedule of the patient and being hospitalized

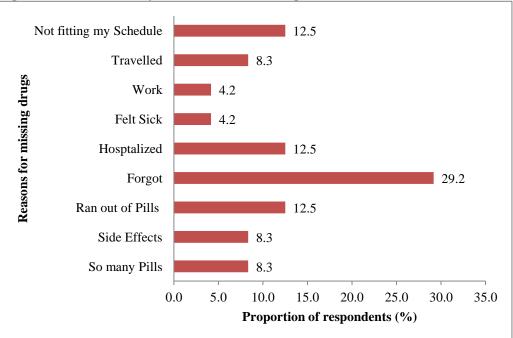


Figure 4: Reasons Why Patient Missed Drugs

Figure 5 shows the reasons why patients missed clinic dates. The most predominant reason for missing medication was travelling (25%) followed by work (23%) and forgetting (19%) respectively

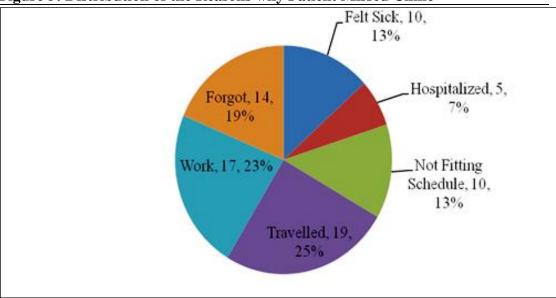


Figure 5: Distribution of the Reasons why Patient Missed Clinic

#### 4.5 Health System predictors of TB treatment adherence

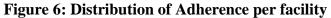
This show the aspects related to the health facility, service providers, services provided and quality of the services. Ninety two percent (p=0.128) thought the conditions of the health facility they were receiving care from were in good. However 6.4% (OR:3.6; 95% CI1.1-12.1; p=0.031) thought the behaviour of health workers within the facilities was not good. Waiting time (OR:7.7; 95% CI:3.1-18.9; p<0.001) also was a significant predictor of adherence. Other aspects of the health care system were not significant in determining adherence; treatment facility well equipped (79.4%, p=0.633), Drugs Available at the treatment Facility (p=0.419), educated on taking the drugs (p=0.419) and time to Facility (p=0.120)

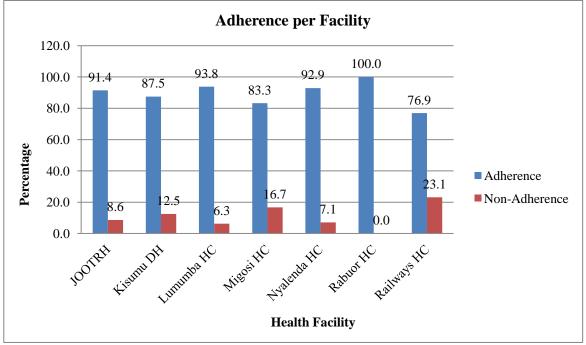
Chanastaristic		Drug Ad	Drug Adherence			nalysis	
Characteristic		Yes	No	OR	95% CI	P Value	
Behaviour of	Good	214 (91.5)	20 (8.5)	3.6	1.1 – 12.1	0.031	
HCW	Bad	12 (75)	4 (25)	5.0	1.1 - 12.1	0.031	
Facility is well	Yes	179 (89.9)	20 (10.1)	0.8	0.2 - 2.3	0.633	
equipped	No	47 (90.2)	4 (9.8)	0.8	0.2 - 2.3	0.055	
Waiting Time	<30	200 (94.3)	12 (5.7)	7.7	3.1 – 18.9	<0.001	
(Min)	>30	26 (68.4)	12 (31.6)	1.1	5.1 - 16.9	<0.001	
Time to Facility	< 1	196 (91.6)	18 (8.4)	2.2	0.8 - 5.9	0.12	
(Hours)	>1	30 (83.3)	6 (16.7)	2.2	0.0 - 3.9	0.12	

 Table 4. 8: Health Care System

Numbers in brackets are proportions. Significance was determined by Pearson Chisquare analysis. Values in bold are statistically significant at  $P \le 0.05$ . All the *P* values are 2 sided.

Figure 5 below show the level of adherence of patients per facility. There was no significant relationship between health facility where the respondents were taking their TB treatment and adherence. There was significance difference in adherence between hospitals and health centers (OR:1; 95% CI: 0.4-2.5; p=0.953)





#### 4.6. Predictors of Adherence and their effect on Adherence

The regression analysis table below (table 4.10) has all the aspects of adherence which were significant from the preliminary bivariate analysis. Overall, there were 27 variable portrayed by the initial bivariate analysis as being significant. These were the variable included in the binary regression analysis.

There were 15 out of the 27 variables that were included in the regression model demonstrating a significant association with adherence. Some of them had negative influence on adherence (Negative B value) or positive influence (Positive B value).

Those that were positively associated with adherence were urban residence; (OR:21.8; 95% CI:5.4-87.5; p<0.001), more than 3 family members(OR:5.7; 95% CI:1.7-19.1; p=0.005), having heard about TB before diagnosis (OR:12.3; 95% CI:2.9-53.4; p<0.001), knowing that TB is serious (OR:81.1; 95% CI:19.1-344; p<0.001), being knowledgeable on TB and its treatment (OR:7.5; 95% CI:1.4-39.4; p=0.017), generally seeking care more often even when not sick (OR:7.2; 95% CI:1.4-37.5; p=0.019), being satisfied with TB care (OR:157; 95% CI:25.6-961; p<0.001), keeping the medication in a bag (OR:5.3; 95% CI:1.5-19.1; p=0.011), being reminded by family member to take the drugs (OR:4.4; 95% CI:1.5-13; p=0.007), waiting time of less than 30 minutes (OR:7.1; 95% CI:2.8-18.3; p<0.001), feeling that TB affects family responsibility (OR:11.2; 95% CI:3-51.6; p<0.001) and clinic compliance (OR:3.6; 95% CI:1-13.5; p<0.001),

Being male (OR:0.2; 95% CI:0-0.9; p=0.036), taking more than 15 weeks before seeking care even after onset of signs and symptoms of TB (OR:0; 95% CI:0-0.5; p=0.013), and perceiving that TB treatment affected other concomitant treatments

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(OR:0; 95% CI:0-0.1; p<0.001) were negatively associated with adherence. This is to mean they would positively enhance non adherence.

Other aspect lost their significance after inclusion in the regression model. These were: age (Bivariate p<0.001 and Regression p=0.066); marital status (Bivariate p=0.007 and Regression p=0.756); education (Bivariate p=0.009 and Regression p=0.116); employment status (Bivariate p= 0.027and Regression p=0.694); storing medication at workplace (Bivariate p=0.02 and Regression p=0.304); keeping drugs visible where they can be seen to enhance remembrance of dosing time (Bivariate p= 0.004 and Regression p=0.077); cigarette smoking (Bivariate p=0.001 and Regression p=0.713); more than one sex partner (Bivariate p=0.001 and Regression p=0.999); behaviour of health care workers (Bivariate p=0.031 and Regression p=0.576); and missing drugs over the weekend (Bivariate p=0.021 and Regression p=0.057).

Variable	Grouping Characteristic	В	OR	95%C.I.	Sig.
	Age	-1.2	0.3	0.1-1.1	0.066
	Sex	-1.6	0.2	0.0-0.9	0.036
Demographic	Residence	3.1	21.8	5.4-87.5	<0.001
Characteristics	Marital status	0.2	1.2	0.3-4.4	0.756
Characteristics	Education	1	2.6	0.8-8.9	0.116
	Employment status	0.2	1.3	0.4-4.4	0.694
	Number of family members	1.7	5.7	1.7-19.1	0.005
	Heard TB before diagnosis	2.5	12.3	2.9–53	0.001
Knowledge	TB is serious	4.4	81.1	19.1–344	<0.001
	Knowledgeable on TB	2	7.5	1.4–39.4	0.017
Attitudes to TB	Tb drugs affects the other drug	-3.3	0	0.0-0.1	<0.001
and its Care	Tb affects family responsibilities	2.4	11.2	3–41.6	<0.001
Treatment	First treatment	2.3	9.7	3.3-28	<0.001
Characteristics	Thist treatment	2.3	).1	5.5-20	<0.001
	Time before seeking care (weeks)	3.6	3.7	2.2-6.7	0.013
Health Seeking	Knew TB care center before diagnosis	1.3	3.7	0.9-14.9	0.071
Behaviour	Satisfied with TB care services	5.1	157.9	25-970	<0.001
	Seek health care	2	7.3	1.4-38	0.018
Sexual /Addictive	More than one Sexual Partners	-0.9	0.4	0.1-2.0	0.277
behaviour	Addictive behaviour	-5.1	0.006	10-3-0.03	<0.001
Daharriangal	Keeps drugs in a bag	1.7	5.3	1.5-19.1	0.011
Behavioural	Family member reminds dose time	1.5	4.4	1.5-13.0	0.007
Modifiers	Keeps drugs visible	-1.3	0.3	0.1-1.1	0.077
Health Care	Behaviour of HCW	0.4	1.5	0.4-5.8	0.576
System	Waiting time	2	7.1	2.8-18.3	<0.001

Table 4. 9: Regression Analysis of the Predictors	S
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Odds Ratios (OR) and 95% Confidence Intervals (95% CI). The first category (0=No) was set as the reference group in the logistic regression analyses. Values in bold are statistically significant at  $P \le 0.05$ . B is the regression coefficient and R the exponent of B.

#### 4.7. Chapter Summary

The chapter dealt with the analysis of the data that was collected. The chapter organization was informed by the operational framework of the IBM theory.

The first research question that was on prevalence of adherence in the study area has been fully answered. The prevalence of adherence is 90.4%.

The second research question that was on establishing the predictors of adherence in the study area has been answered fully. The significant predictors of adherence that have been identified after the regression analysis (see table 4.10 above) are: urban residence;, more than 3 family members, having heard about TB before diagnosis, knowing that TB is serious, being knowledgeable on TB and its treatment, generally seeking care more often even when not sick, being satisfied with TB care, keeping the medication in a bag, being reminded by family member to take the drugs, waiting time of less than 30 minutes, feeling that TB affects family responsibility and clinic compliance. Being male (OR:0.2; 95% CI:0-0.9; p=0.036), taking more than 15 weeks before seeking care even after onset of signs and symptoms of TB (OR:0; 95% CI:0-0.5; p=0.013), and perceiving that TB treatment affected other concomitant treatments (OR:0; 95% CI:0-0.1;p<0.001) were negatively associated with adherence. This is to mean they would positively enhance non adherence.

The third research question that was on the effect of the predictors on prevalence has been answered. There are those predictors that have a positive effect (positive B values) on adherence thus enhancing it and there are those that have a negative effect (negative B values) on adherence thus leading to non adherence.

#### **CHAPTER FIVE**

## DISCUSSION

#### 5.1 Overview

The discussion contains a critical review of this study in light of other studies done earlier. The flow assumes that of the results, that is: sociodemographic predictors, Individual predictors, treatment and co-morbidity predictors and health system related predictors.

#### 5.2 Sociodemographic Characteristics and TB treatment adherence

Adherence to TB treatment in this population was at 90.5% from self reported adherence. This could be lower considering Nackers et al., (2012) estimated overall adherence of 95.2 among adult TB patients in Homabay County, Kenya. This study was by INH urine test, pill count and VAS. A study in South Africa estimated adherence to be 89% (Mazinyo et al., 2016). This study utilized convenient sampling thus likelihood of selection bias. Likewise, the study was conducted only in TB/HIV co-infected people and co-morbidity is one of the confounders of adherence thus speculation that that could have been the reason for low adherence (Tola et al., 2015). Other studies in China and Argentina estimated adherence as 84 and 88% respectively (Herrero et al., 2015; Zhou et al., 2012). Whereas China study was in a migrant population, the Argentina one was in a general TB patients' population. The current study used probability sampling while the aforementioned one used convenient sampling. However, TBMAS has a sensitivity of 82.9% thus the study area prevalence of adherence could be lower (Yin et al., 2012).

Prevalence of adherence among female patients was 95.1%. This was higher than that of males' 87.1% (p=0.036). These results were consistent with the findings in other studies (Alobu et al., 2014; Tola et al., 2015). Female patients have better

social support than male patients. This helps them have better health seeking and health maintenance behaviour than males (Kigozi, Heunis, Chikobvu, Botha, & van Rensburg, 2017; Thompson et al., 2016)

This study was in concurred with other findings that periurban and urban residence offers better physical access to care which promotes adherence (Eticha & Kassa, 2014; Tesfahuneygn et al., 2015).

There was no significant relationship between employment status or family's average monthly income and adherence. This is supported by other results (Anyaike et al., 2013) where income (p=0.76) and employment (p=0.66) were not significant in determining adherence. This was in consensus with another study in Uganda (Sendagire, Van der Loeff, Kambugu, Konde-Lule, & Cobelens, 2012). This could be attributed to the fact that TB treatment in Kenya is largely free therefore the earning of the patient cannot be a determining factor of adherence. Studies whose findings were contrary to this findings were (Cherkaoui et al., 2014b; Naidoo, Peltzer, Louw, Matseke, Mchunu, et al., 2013). These studies found either of the two predictors was significant in determining adherence. In another study it was however established that a steady employment was significant in determining adherence (Kendall et al., 2013).

In the current study, the number of family members of more than 3 showed significant association (OR: 5.7; 95% CI: 1.7-19.1; p=0.005) with adherence. This could be due better family structural and functional social support from family members thus enhancing adherence. In accidence to this were findings from a study in Ethiopia where there was significant relationship between family size of more than 5 members and adherence (Belén & Alende, 2012; Berhe, Enquselassie, & Aseffa, 2012). Converse findings were in study conducted in Ethiopia that showed no

significance between family size and adherence (Tesfahuneygn et al., 2015).

#### **5.3 Individual predictors**

Under this aspect, the following were surveyed: health care seeking behaviour; behavioural skills; sexual and addictive behaviour; individual attitudes towards TB and its treatment and level of knowledge on TB.

## 5.3.1 Level of Knowledge

Inadequate knowledge about TB adversely impacts adherence (Anaam et al., 2013; Wabe & Kebede, 2012). The current study established a significant association (p=0.017) between overall knowledge on TB with adherence to TB treatment. This finding was also demonstrated in other knowledge aspects in the current survey such as: had heard of TB before diagnosis (p<0.001) and knowing that TB is a serious disease (p<0.001). Knowledge is a strong determinant of adherence. However, a study in Northern Ethiopia established that knowing that TB was preventable led to increased non adherence among the respondents (Kiros et al., 2014)

#### 5.3.2 Health care seeking behaviour

A number of researches acknowledge the role of delays in treatment initiation and outcome. These delays can be either patient or provider occasioned, or both. Patient delays are mostly due to less severe symptoms or search for alternative medicine (Evans et al., 2017; Harris et al., 2016). The current study established significant relationship between the time taken before diagnosis and care and adherence (p=0.013), for those who had taken more than 15 weeks before care. Some have purported that those who seek health care late often have poor health care seeking behaviour; they wait for the worst of symptoms for them to seek care. This could imply that those individuals are less likely to continue with treatment especially

when the symptoms of the disease abate (Ayisi et al., 2011).

Disclosure has been established in several surveys as key determinant of adherence to TB treatment. It forms part of social functional support where family and friends can act as pill companions constantly encouraging the patient to comply with care (Anyaike et al., 2013; Tadesse et al., 2013). Social support received by patients play important role in improving treatment adherence. Lack of family and social support predicts poor treatment adherence (Kulkarni et al., 2013). This study however, did not establish any significant relationship between disclosure (p=0.323) and adherence.

#### 5.3.3 Behavioural skills

Behavioural skills are a strong predictor of adherence. Some of the established behaviour that could aid in adherence are; use of alarm, integrating the time of taking the drugs with daily routine like brushing of teeth or supper time or asking a family member or friend to remind one every time one has to take the drug (Kendall et al., 2013; Theron et al., 2015). The current study did establish a significant association between keeping the drugs in a bag (OR:5.3; 95% CI 1.5-19.1; p=0.011) and being reminded by family members to take drugs and adherence (OR:4.4; 95% CI:1.5-13; p=0.007). During analysis, all kinds of bags i.e. purse, pouches, and handbags were collapsed under one variable "bag". It was, therefore, speculated that these bags are mostly portable thus the patient can carry the drugs on their safaris. This can aid in adherence in case the patient hadn't taken the drug at home before leaving for safari.

#### 5.3.4 Sexual and other addictive behaviour

The present study demonstrates a significant association between addictive behaviour and TB treatment adherence. In carried out in South Africa, there was a significant relationship (p<0.001) between smoking and non-adherence (Tachfouti et al., 2013). Several other studies (Anaam et al., 2013; Bagchi, Ambe, & Sathiakumar, 2010) are in agreement with Tachfouti et al., (2013).

Alcohol consumption is a risk factor for non-adherence (Naidoo, Peltzer, Louw, Matseke, McHunu, et al., 2013; Sendagire et al., 2012). A study in South Africa, Naidoo et al., (2013) showed a significant (p<0.001) difference in adherence between alcohol users and non-alcohol users. The current study however did not demonstrate significant difference in adherence for the two groups.

### 5.3.5 Individual attitudes towards TB and TB treatment

In this study, perception that TB affects family responsibilities was associated with adherence (p<0.001). This could be explained by the fact that this perception enhances perceived severity of TB thus modifying adherence positively (W.H.O, 2003).

#### **5.4 Co-morbidity and Treatment aspects**

Co-morbidity, treatment characteristics and period on treatment were the aspects studied under this category of predictors.

### 5.4.1 Co-morbidity

Under this category only one stratifying factor was significantly associated adherence albeit a negative association. Those who were on treatment and thought that TB drugs affected the other concomitant treatments were less likely to be adherent to TB treatment. Many previous studies suggested that co-morbidity significantly reduced adherence (Adane et al., 2013; Ogundele, Moodley, Pillay, & Seebregts, 2016). These studies were among patients with TB/HIV co-infected patients. Kiros et al., (2014) established that treatment side effects were augmented by TB/HIV simultaneous treatment which predicted non-adherence. Concomitant treatment could lead increased pill burden; enhanced drug side effects and different clinic days. However, some studies established a unique enhancement of TB adherence in TB/HIV co-infection. This was attributed to adherence counseling that HIV positive patients got and the support groups that have been established to enhance adherence (Gray & Cohn, 2013; Naidoo, Peltzer, Louw, Matseke, McHunu, et al., 2013). The current study did not elicit a significant relationship between TB/HIV co-morbidity

### **5.4.2 Treatment characteristics**

The current study established taht first treatment, completion of previous treatment and self discontinuation from previous treatment were significantly associated with adherence. This was in consensus with a study in Nigeria that established that previous treatments were a predictor of treatment non-adherence. Patients who did not adhere to treatment previously were shown to be at high risk of not adhering to the current regimen (Tesfahuneygn et al., 2015; Theron et al., 2015). In some studies more number of previous treatments affected adherence negatively (Karl Peltzer & Pengpid, 2015). In Kenya, 10% of newly reported cases were recurrent cases and it is likely that most of these recurrences were due to the failure of patients to adhere to their regimen (WHO, 2016).

#### **5.4.3 Period of treatment**

There was no demonstrable association between period on treatment (p=0.509) and adherence in this study.. This is contrary with previous findings in studies elsewhere (Adane et al., 2013; Anyaike et al., 2013). It is hypothesized that most of the patients in continuation phase have abated signs and symptoms thus slowly losing their perceived severity of the disease leading to poor adherence to medication. Length of period of treatment is also a determinant adherence thus by the virtue that they have been on treatment for a longer period could explain the trend (WHO, 2015a).

#### **5.5 Health System Predictors**

The present study showed no significant difference in adherence between those who thought the behaviour of health workers towards them was good and those thought it was bad. In a study in India, the authors proposed that distrust of health workers in regard to their patients' self-efficacy in their behavioural abilities might serve as a barrier in the relationship between health care providers and patients (Dolma et al., 2013). It was speculated that the same mechanism might play a role in the relationship between health care workers and non-adherent patients. Health care workers' role in adherence cannot be overemphasized. The person handling TB patients could aid them in exploring the difficulties experienced and thus better solution that could enhance adherence (Anaam et al., 2013; Wabe & Kebede, 2012).

The current study showed that waiting time was associated with adherence. Other studies showed that waiting time and time taken to the facility (Kiros et al., 2014; Sendagire et al., 2012), drugs availability (Elbireer et al., 2011) were health system related predictors of adherence. The current study, however, did not explicate any significant relationship between adherence and time taken to the health facility (p=0.12) and drugs (p=0.419) and equipment availability (p=0.633).

#### **CHAPTER SIX**

# CONCLUSION AND RECOMMENDATIONS

#### 6.1 CONCLUSION

#### **6.1.1 Prevalence**

Prevalence of adherence in the study area was comparable (90.5%) with the basic minimum recommended by WHO (90%). Desegregation of adherence among different demographic characteristics showed lower level of adherence among the males and those from rural areas.

#### **6.1.2 Predictors of TB treatment adherence**

The factors predicting adherence in Kisumu East sub-County were identified. These were: urban residence; more than 3 family members; having heard about TB before diagnosis; knowing that TB is serious; being knowledgeable on TB and its treatment; generally seeking care more often even when not sick; being satisfied with TB care; being reminded by family member to take the drugs; waiting time of less than 30 minutes; feeling that TB affects family responsibility; and clinic compliance; male gender; taking more than 15 weeks before seeking care even after onset of signs and symptoms of TB and perceiving that TB treatment affected other concomitant treatments.

#### 6.1.3 Effect of predictors on TB adherence

Some of the predictors demonstrated negative effect on TB treatment adherence. These were; being male, taking more time from onset of signs and symptoms to seeking care, having addictive behaviour and waiting time at the facility more than 30 minutes before care.

# 6.2 RECOMMENDATIONS

# **6.2.1 Prevalence of Adherence**

• TB programs should enhance adherence counseling and psychosocial support to the groups that that presented with lower prevalence.

# **6.2.1 Predictors of Adherence**

- Sociodemographic characteristics identified as predictors of adherence, in this case: area of residence, number of family members and sex should provide a guideline for groups to be flagged for timely interventions to enhance adherence.
- Health education should be enhanced at individual and community level on the signs and symptoms, treatment and the importance of seeking care early.
- The patients classified as retreatments should be actively followed for adherence because they had a higher preponderance of not adhering to treatment than the first time patients and intensive phase respectively.

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# **APPENDIX 1: INFORMATION SHEET AND CONSENT FORM**

#### **INFORMATION SHEET**

The following information is to enable you to give voluntary, informed consent to participate in this study. Please read the information carefully before signing the consent form (part B). To be verbally read for those who are not able to read.

**Study title**: Predictors of TB treatment adherence of patients aged above 18 years attending TB clinics in Kisumu East sub-County.

Investigators Names: Morris Senghor Shisanya

Address	Ministry of Medical Services
	Kisumu East District Hospital,
	Po Box 1818 - 40100
	Kisumu.
	Tel: 0720 640 142

#### Aim and Significance of the study

This study aims at describing and analyzing the predictors of TB treatment adherence among patients aged above 18 years attending TB clinics in Kisumu East sub-County This therefore will be a tool for TB policy makers and program planners to enhance adherence to TB care and better treatment outcomes.

## What participation will involve

Participation in the research is dependent upon signing the informed consent form. Upon signing the consent form, you will be asked detailed questions on social, economic and demographic information and concerning treatment and the tuberculosis. This information will be recorded onto forms. The participant in this study will be required to give honest information to their level best.

# **Data Security**

All information you provide will remain confidential. Only the study team will have access to this information and will be treated with confidentiality unless your express permission is obtained. You may withdraw from participating in this study at any time without giving reasons. This will not affect services you are receiving.

# **CONSENT FORM**

Please read the previous information sheet (or have the information read to you) carefully before completing and signing this consent form. Should you have any questions about the study please feel free to ask the investigator prior to signing your consent

# **Consent Form for the Study**

Predictors of TB treatment adherence of patients aged above 18 years attending TB clinics in Kisumu East sub-County.

Investigators Names: Morris Senghor Shisanya

Address	Ministry of Medical Services
	Kisumu East sub-County Hospital,
	Po Box 1818 - 40100
	Kisumu.
	Tel: 0720 640 142

# FOR COMPLETION BY PARTICIPANTS

I have read (or the enumerator has read to me) the following sheet concerning this study and I understand what will be required of me if I take part in the study.

I understand that at any time I may withdraw from the study without giving a reason and this will not affect the care am receiving.

# I AGREE TO TAKE PART IN THE STUDY:

# **APPENDIX 2: QUESTIONNAIRE**

# Questionnaire

sampli	<b>ion criteria:</b> (Male and ng criteria)	l female indiv	viduals age 18 ar	nd above	years as per
RESPO	ONDENT ID				
Health	facility name	]	Initials of respon	ndent:	
	#:		_		
Name	of Interviewer:		Signature:		
Δ	CLINIC ATTENDA	CF (checked	hy interviewer	•)	
	Has the patient missed				
1.	This the patient missee		[1]	51y.	
		No			
2	If yes how many times				
	DEMOGRAPHIC A				
	What is your age please				
	Indicate gender of the	-			
۷.		Male	[1]		
2		Female		44 - 3	19 (D )
3.	What is the highest let options)		-	e attaine	
		Did not go to			1
		Primary educ	cation		3
		Secondary			4
		Tertiary			
		Any other (S	pecify:		)
4.	Where do you stay (N	ame of the pl	ace)		
5.	Which type of area do	you come fr	om?		
		Urban	[1]		
		Rural	[2]		
		Don't know	[98]		
6.	What is your current r	narital status:	?		
	•			[1]	
		Married		[2]	
				[3]	
		Widowed		[4]	
7.	What is your job statu	s?			
	5 5	Employed	1		
		Unemployed	2		
		Housewife	3		
		Farmer	4		
			lease specify)		
8.	What is your personal				_
0.			().		
	<5000	1			

8.

5000 - 9999

Don't know

10000 to 14999

More than 15000

1	
2	Please tell me the number of your
3	5
4	family members you are currently
98	living with? (just enter the

number in the box provided) \_\_\_\_\_

10. Please tell me the number of rooms in your house? (just enter the number in the box provided)

# C. KNOWLEDGE ON TB

1. Had you ever heard of TB before you were diagnosed?

Yes [1] No [2]

2. In your opinion is TB a serious disease?

Yes [1] No [2]

3. I would read some statements about TB treatment. Please tell me YES if you agree or NO if you disagree with them?

STATEMENT	YES	N O	DON'T KNO W
TB treatment has side effects that far outweigh the benefits	1	2	98
TB treatment is for a long duration	1	2	98
Even after TB treatment and cure one cannot be re-infected with TB	1	2	98
TB is not a curable disease even with adherence to treatment	1	2	98
There are good TB drugs available for the TB patients	1	2	98

# D. TREATMENT AND COMOBIDITY

1. How long have you been on treatment for TB

Less than 1 months [1]

2 months [3]

More than 2 months [4]

Don't Know [98]

2. Is this the first time you are being treated for TB

Yes	[1]
No	[2]

- [2]
- 3. If **NO**. a) How many previous treatments have you had \_\_\_\_\_
  - b) Did you complete the previous treatment(s) Yes

Yes	[1]
No	[2]

- c) If No, Give the reasons that you feel made you **NOT** to complete)
- 4. Do you have any other disease(s)/ health condition(s)

Yes	[1]
No	[2]

5. If **YES**;

a) Which disease(s) /condition(s)

LIST)

b) Are you on treatment for the same

Yes [1]

- c) If on other treatment, do you think TB treatment affects the other treatment(s)
  - Yes [1]
  - No [2]
- d) If **YES**, In what way does TB treatment affects other treatments

# E. <u>HEALTH SEEKING BEHAVIOUR</u>

1. How often do you generally seek health care at a clinic or hospital? (Check one.)

	one.)		
	Twice a year	[1]	
	Once a year	[2]	
	Less than a year but t	twice in the past [3]	
	Once in the past 5 ye	ars [4]	
	Not in the past year	[0]	
2.	Where do you usually seek c	care when sick?	
	Governemnt Hospita	1 [1]	
	Private clinic	[2]	
	Traditional healer	[3]	
	Pharmacy	[4]	
	Don't know	[98]	
3.	Where did you first seek care	e when felt sick with the current illness?	
	Governemnt Hospita	1 [1]	
	Private clinic	[2]	
	Traditional healer	[3]	
	Pharmacy	[4]	
	Don't know	[98]	
4.	Have you told anyone about	your current illness (TB)?	
	Yes	[1]	
	No	[2]	
5.	If YES Who?	,,,,,,	
6.	Are you satisfied with servic	es you are receiving currently?	
	Yes	[1]	
	No	[2]	

7. After how long did you seek health care since the onset of the signs of your current illness.

### F. <u>HEALTH CARE</u>

1. **<u>DID</u>** you know of facilities offering TB care in your area <u>BEFORE</u> you were diagnosed with your current problem?

2	1
Yes	[1]
No	[2]
Don't know	[98]

2. What do you think about the facilities offering Treatment for TB in your area?

Good	[1]
Poor	[2]

- Poor [2] Don't know [98]
- 3. What do you think about the behaviour of doctor at the facilities offering Treatment for TB in your area?

Good	[1]
Poor	[2]
Don't know	[98]
4. Do you think facilities o	ffering Treatment for TB in your area are well equipped?
Yes	[1]
No	[2]
Don't know	[98]
5. Are the medicines relial	bly available at facilities offering you treatment?
Yes	[1]
No	[2]
Don't know	[98]
6. Were you educated a	t the TB treatment facility on how to take your TB
	e initiation of treatment?
Yes	[1]
No	[2]
Don't know	[98]
7. Were you educated on	the importance of taking your TB medications as per the
schedule?	
Yes	[1]
No	[2]
Don't know	[98]
6. In your experience HOW	<i>V</i> is the waiting time at facility offering treatment for TB?
Short (Less than 30	minutes)
Long (More than 30	) Minutes)
Don't Know	
7 How long does it take to	reach the facility offering you treatment for TB?
<1 hour	1

<1 hour	1
>1 hour	2
Don't Know	98

# G. PERSONAL ASPECTS

I would read some statements. Please tell me YES if you agree or NO if you disagree with them?

NO	STATEMENT	YES	NO
1	You are ashamed for having TB		
2	You would hide that you have TB		
3	TB treatment has severe side effects that far outweigh the		
	benefits		
4	TB treatment very costly		
5	You would prefer to be isolated because of having TB		
6	TB affects family responsibilities		
7	There are less chances of getting married due to TB diagnosis		
8	Females get difficulty in deciding to be treated for TB?		
9	TB affects relationship with other community members.		
10	Do you smoke cigarette		
11	Do you take alcohol		
12	Do you Smoke bhang		
13	Do you chew miraa		
14	Do you use any injectable drug of abuse		

15	You have more than one sexual partner	
16	You know your HIV status	

# **H. ADHERENCE**

I'd like to ask you some questions to help us understand your experience with the TB medications you are taking.

Most people with TB infection have medications to take every day for many months.

We need to understand how people with TB infection take their medications. So please tell us what you are really doing. Do not worry about telling us that you do not take all your medications. We need to know what is really happening, not what you think we "want to hear."

- 1. Where do you keep your medications?\_\_\_\_
- 2. When do you take your medications?
  - a. morning
  - b. afternoon
  - c. evening
  - d. at bed time
- 3. How do you take your medications?
  - a. with food
  - b. without food
  - c. what else?
- 4. How do you remember to take your medications?
  - a. family member reminds you
  - b. keep medications visible
  - c. incorporate to a specific daily routine (e.g., dinner, brushing teeth, etc.)
  - d. other
- 5. In the last 7 days, did you miss any of your TB medications?
- Yes [1] No [2]

6a. If yes, how many doses did you miss?\_\_\_\_

7. Why did you miss taking your medications?

# INTERVIEWER: DO NOT READ THIS LIST, JUST USE IT TO CODE ANSWERS TO QUESTIONS

# Check ✓ column R for patient responses

	R		R
1. didn't fit in your daily routine		2. didn't feel like taking them/coming in	
3. simply forgot		4. busy with school work	
5. were too busy/had other priorities		6. were away from home	
7. felt sick or ill		8. were hospitalized	
9. felt depressed or overwhelmed		10. had legal issues such as court cases	
11. were experiencing			
abuse/domestic violence		12. were working	
13. were caring for relatives		14. fell asleep/slept through dose time	
15. ran out of pills		16. didn't understand regimen	
17. too hard to take so many pills		18. didn't think the medicine was helping	
19. wanted to avoid side effects		20. felt like the drug was toxic/harmful	

21. had other appointments	22. fear of interactions with other meds	
23. were drunk or high	99. other	

8. Some people find that they forget to take their pills on the weekend days. Did you miss any of your anti-TB medications last weekend – last Saturday and Sunday?

Yes	[1]
No	[2]

Ask **9** only if NO missed doses were reported in questions 5-8. Otherwise skip to question 10.

- 9. When was the last time you missed any of your TB medications?
  - a. Within the past week
  - b. 1-2 weeks ago
  - c. 2-4 weeks ago
  - d. More than one month ago
  - e. Never missed medication
- 10. Do you keep monthly appointment?

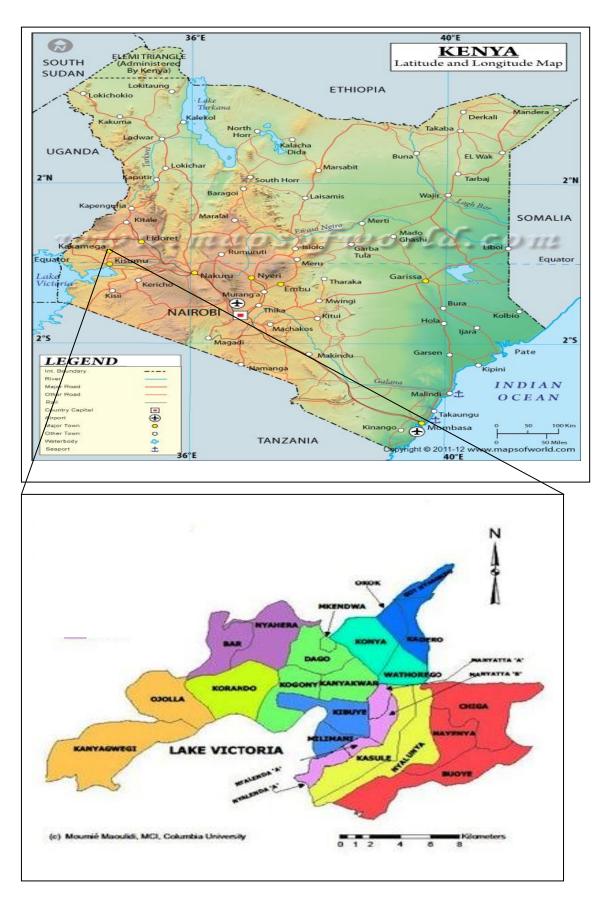
•	-	•
Yes		[1]
No		[2]

11. If **NO**, Why did you miss your monthly clinic appointment?

# INTERVIEWER: DO NOT READ THIS LIST, JUST USE IT TO CODE ANSWERS TO QUESTIONS

# Check $\checkmark$ column R for patient responses

	R		R
		2. didn't feel like taking them/coming	
1. didn't fit in your daily routine		in	
3. simply forgot		4. busy with school work	
5. were too busy/had other priorities		6. were away from home	
7. felt sick or ill		8. were hospitalized	
		10. had legal issues such as court	
9. felt depressed or overwhelmed		cases	
11. were experiencing abuse/domestic			
violence		12. were working	
13. were caring for relatives		14. fell asleep/slept through dose time	
15. ran out of pills		16. didn't understand regimen	
		18. didn't think the medicine was	
17. too hard to take so many pills		helping	
		20. felt like the drug was	
19. wanted to avoid side effects		toxic/harmful	
		22. fear of interactions with other	
21. had other appointments		meds	
23. were drunk or high		99. other	



# **APPENDIX 3: MAP OF RESEARCH AREA**

# **APPENDIX 4: MMUST IERC ETHICAL APPROVAL**



 MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY

 Tel: 056-31375
 P. O. Box 190

 Fax: 056-30153
 Kakamega

 E-mail: rel@mmust.ac.ke
 50100

 Website: www.mmust.ac.ke
 Kenya

Institutional Ethics Review Committee (IERC)

MMU/COR: 403009(48)

13th June, 2016

Morris Senghor Shisanya Registration No. HNR/G/49/14 Masinde Muliro University of Science and Technology P. O. Box 190-50100 KAKAMEGA

Dear Shisanya,

# RE: ETHICAL APPROVAL TO CONDUCT RESEARCH

The IERC received your proposal titled "Predictors of TB Treatment Adherence of Patients Aged above 18 Years Attending TB Clinic in Kisumu East District" for review. Having reviewed your work, the committee has given ethical clearance for you to conduct research as proposed.

On behalf of IERC and the University Senate, my congratulations. We wish you success in your research endeavour.

Yours faithfully,

Dr. Nguka Gordon Ag. Chairman, Institutional Ethics Review Committee

Copy to:

- The Secretary, National Bio-Ethics Committee
- Vice Chancellor
- DVC (PR&I)
   DVC (A & F)
- DVC (A&SA)

# **APPENDIX 5: DATA COLLECTION APPROVAL BY THE COUNTY**

# **COUNTY GOVERNMENT OF KISUMU** Telegrams: "PRO.(MED)" Tel: 254-057-2020105 Fax: 254-057-2023176 County Director of Health, Kisumu. P. O. Box 721-40100, KISUMU. E-mail: kisumucdh@gmail.com **MINISTRY OF HEALTH** REF: GN/62/VOLIII/(84) Date: 25th February, 2015 TO WHOM IT MAY CONCERN Dear Sir/ Madam, **RE: DATA COLLECTION BY MORRIS SENGHOR** This is to introduce to you the above named who is a nurse the Kisumu District Hospital pursuing his masters in Nursing at Masinde Muliro University of science and technology. Kindly accord him assistance as he seeks to collect data from your facility. He has ethical approval from JOOTRH ethics committee for your perusal and detail. Thanks for your assistance COUNTY DIRECTOR OF HEALTH KISUMU Dr. Onyango D. O County Director of Health KISUMU COUNTY From the Office of Director of Health

# **APPENDIX 6: JOOTRH IREC APPROVAL**



# **MINISTRY OF HEAL/TH**

Telegrams: "MEDICAL", Kisumu Telephone: 057-2020801/2020803/2020321 Fax: 057-2024337 E-mail: ercjootrh@gmail.com When replying please quote

ERC.1B/VOL.1/262

Ref: .....

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL P.O. BOX 849 <u>KISUMU</u> 15<sup>th</sup> June, 2016 Date

MORRIS SENGOR, MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY.

Dear Morris,

#### RE: FORMAL APPROVAL TO CONDUCT RESEARCH ENTITLED: "PREDICTORS OF TB TREATMENT ADHERENCE AMONG PATIENTS ABOVE 18 YEARS ATTENDING TB CLINICIN KISUMU EAST DISTRICT".

The JOOTRH ERC (ACCREDITATION NO. 01713) has reviewed your protocol and found it ethically satisfactory. You are therefore, permitted to commence your study immediately. Note that this approval is granted for a period of one year (15<sup>th</sup> June, 2016 to 15<sup>th</sup> June, 2017). If it is necessary to proceed with this research beyond the approved period, you will be required to apply for further extension to the committee.

Also note that you will be required to notify the committee of any protocol amendment(s), serious or unexpected outcomes related to the conduct of the study or termination for any reason.

Finally, note that you will also be required to share the findings of the study in both hard and soft copies upon completion.

The JOOTRH ERC takes this opportunity to thank you for choosing the institution and wishes you the best in your endeavours.

Yours sincerely,

WILBRODA'N. MAKUNDA For: SECRETARY - ERC, JOOTRH - KISUMU.

JOOTRH ETHICS & REVIEW COMMITTEE P. O. Box 849 - 40100 KISUMU

#### **APPENDIX 7: SGS APPROVAL OF THE STUDY**



#### MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

Tel: 056-30870 Fax: 056-30153 E-mail: dean<u>sgs@mmust.ac.ke</u> Website: <u>www.mmust.ac.ke</u>

P.O Box 190 Kakamega – 50100 Kenya

Date: 12th October, 2016

Office of the Dean (School of Graduate Studies)

Ref: MMU/COR: 509079

Morris Senghor Shisanya HNR/G/49/2014 P.O. Box 190-50100 KAKAMEGA

Dear Mr, Shisanya

#### RE: APPROVAL OF PROPOSAL

Following communication from the Departmental Graduate Studies Committee and the Faculty Graduate Studies Committee, I am pleased to inform you that the Board of the School of Graduate Studiesmeeting held on 4<sup>th</sup> August, 2016considered and approved yourMasters proposal entitled: '*Predictors of Tuberculosis Treatment Adherence of Patients Aged above 18 Years Attending Tuberculosis Clinic in Kisumu East Sub- County.* "andappointed the following as supervisors:

Mr. John Arudo
 Prof. Aggrey Oloo

Department of Clinical Nursing& Health Informatics - MMUST
 School of Public health - UON

You are required to submit through your supervisor(s) progress reports every three months to the Dean SGS. Such reports should be copied to the following: Chairman, School of Nursing and Midwifery Graduate Studies Committee and Chairman, Clinical Nursing and Health Management. Kindly adhere to research ethics consideration in conducting research.

It is the policy and regulations of the University that you observe a deadline of two years from the date of registration to complete your Masters thesis. Do not hesitate to consult this office in case of any problem encountered in the course of your work.

We wish you the best in your research and hope the study will make original contribution to knowledge.

Yours & incerely, 

PROF. HENRY KEMONI EXECUTIVE DEAN, SCHOOL OF GRADUATE STUDIES

### **APPENDIX 8: NACOSTI RESEARCH AUTHORIZATION**



#### NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

Telephone:+254-20-2213471, 2241349,3310571,2219420 Fax:+254-20-318245,318249 Email:dg@naccesti.go.ke Website: www.naccesti.go.ke when replying please quote

Ref. No.

9<sup>4</sup> Floor, Utalii House Uhuru Highway P.O. Box 30623-00100 NAIROBI-KENYA

Date: 8<sup>th</sup> November, 2016

Morris Senghor Shisanya Masinde Muliro University of Science and Technology P.O. Box 190-50100 KAKAMEGA.

#### RE: RESEARCH AUTHORIZATION

NACOSTI/P/16/95877/14032

Following your application for authority to carry out research on "*Predictors of Tuberculosis treatment adherence of patients aged above 18 years attending Tuberculosis Clinic in Kisumu East Sub-County*," I am pleased to inform you that you have been authorized to undertake research in Kisumu County for the period ending 8<sup>th</sup> November, 2017.

You are advised to report to the County Commissioner, the County Director of Education and the County Director of Health Services, Kisumu County before embarking on the research project.

On completion of the research, you are expected to submit two hard copies and one soft copy in pdf of the research report/thesis to our office.

mm BONIFACE WANYAM FOR: DIRECTOR-GENERAL/CEO

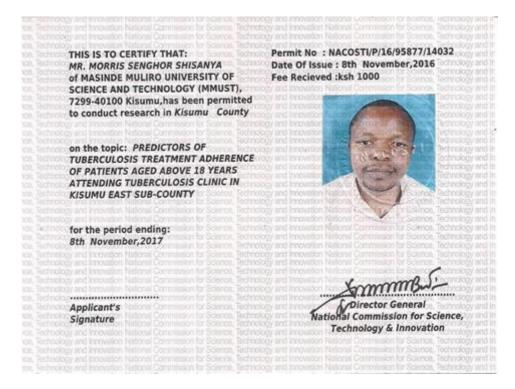
Copy to:

The County Commissioner Kisumu County.

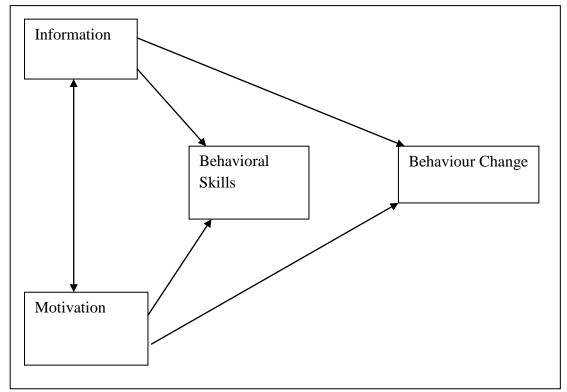
The County Director of Education Kisumu County.

National Commission for Science, Technology and Innovation is ISO 9001-2008 Cartilled

# **APPENDIX 9: NACOSTI PERMIT**



# APPENDIX 10 INFORMATION MOTIVATION BEHAVIOUR MODEL



(Iribarren et al., 2014; W.H.O, 2003)