FACTORS ASSOCIATED WITH TUBERCULOSIS TREATMENT OUTCOMES AMONG PATIENTS NEWLY DIAGNOSED AS MYCOBACTERIUM TUBERCULOSIS SPUTUM SMEAR POSITIVE IN NAIROBI COUNTY

JEPCHUMBA VIOLET ROTICH

MASTER OF SCIENCE

(Public Health)

JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY

2019

Factors associated with tuberculosis treatment outcomes among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear positive in Nairobi County

Jepchumba Violet Rotich

A thesis submitted in partial fulfilment for the degree of Masters of Science in Public Health in the Jomo Kenyatta University of Agriculture and Technology

2019

DECLARATION

This thesis is my original work and has not been presented for a degree in any other university.

Signature: _____ Date: _____

Jepchumba Violet Rotich

This thesis has been submitted for examination with our approval as the university supervisors.

Signature: _____ Date: _____

Prof. Simon Karanja

JKUAT, Kenya

Signature: _____ Date: _____

Dr. Evans Amukoye

KEMRI, Kenya

Signature: _____ Date: _____

Lawrence Muthami

KEMRI, Kenya

DEDICATION

To God and to my loved ones on earth and in heaven.

ACKNOWLEDGEMENT

First and foremost, I thank the almighty God for without him this would not be. My greatest appreciation goes to the TB patients and facility in-charges who were gracious enough to share with us and allow the use of personal and institutional-level data in the study. Special appreciation to the National Tuberculosis, Leprosy and Lung Disease Program and TB treatment facilities for allowing access to data that was used in the study. I express my sincere gratitude to my supervisors: Prof. Simon Karanja, Dr. Evans Amukoye and Lawrence Muthami for your guidance and professional support during the entire learning period. I wish to thank the Ministry of Health and the Nairobi County Health leadership for their support in the research. Last but not least, my family for moral support and encouragement throughout the whole study period.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABBREVIATIONS

C	Cured
CHCW	Community Health Care Workers
CNR	Case notification rate
CRF	Case report forms
D	Death
DLTLD	Division of Leprosy, TB and Lung Disease
DOTS	Directly observed treatment short course
DR	Drug Resistant
DS	Drug Sensitive
EH	ethambutol + isoniazid
EPTB	Extra-pulmonary tuberculosis
ERC	Ethical Review Committee
F	Failure
GDP	Gross Domestic Product
HCW	Health Care Worker
HIV	Human Immuno-deficiency Virus
IUATLD	International Union against TB & Lung Diseases
KEMRI	Kenya Medical Research Institute
KEPH	Kenya Essential Package for Health
MDR-TB	Multi-drug-resistant TB.
NHA	National Health Accounts
NTLD	National Tuberculosis, Leprosy and Lung Disease Program
OOT	Out-Of-Control
PTB	Pulmonary tuberculosis
R	Rifampicin
RHZE	rifampicin + isoniazid + pyrazinamide + ethambutol
SAT	Self-administered treatment
SCC	Short course chemotherapy

SM-	Sputum smear-negative
SM+	Sputum smear-positive
SRS	Simple random sampling
TB	Tuberculosis
TC	Treatment completed
TO	Transferred out (of an administrative area)
TSR	Treatment Success Rate
WHO	World Health Organization
XDR TB	Extremely Drug Resistant TB

OPERATIONAL DEFINITIONS

Continuation phase: This was used in reference to the four months of treatment subsequent to the first two months, using a two drug combination therapy (rifampicin + isoniazid).

Cured: A patient with negative sputum smears on two occasions at the end of treatment.

Death: A patient who died irrespective of cause at any time before envisaged end of treatment.

Intensive phase: This was used in reference to the first two months of treatment for new Sputum Smear Positive Tuberculosis cases using a four drug combination therapy (rifampicin + isoniazid + pyrazinamide + ethambutol).

Transfer Out: A patient referred to another clinician for treatment and whom information on treatment outcome cannot be obtained

Treatment completed: A patient with documented treatment completion but not sputum smear microscopy.

Treatment failure: A patient whose sputum smears remained or became positive again at 5 five months of treatment or later.

Treatment interrupted/Out-Of-Control/Default: A patient who was off treatment for two consecutive months.

Treatment Success Rate: Ppercentage of all new sputum smear positive tuberculosis cases registered under the national tuberculosis control program that successfully completed treatment, with or without bacteriological evidence of success ("cured" and "treatment completed" respectively).

Successful treatment Outcomes: These include the cured and treatment completed

Adverse/unsuccessful Treatment outcomes: These include deaths, failures, defaults and transfer out of cases

ABSTRACT

Tuberculosis (TB) is one of the infectious diseases of public health concern globally. In 2017, it is estimated that 10 million people developed TB globally. More than 1.3 million of the TB cases were notified in the African region. During the same period, Kenya reported 85,188 cases of TB. The research aimed at determining factors associated with TB treatment outcomes among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear-positive within Nairobi County. A prospective cohort study of 291 patients from 25 health facilities in Nairobi county was conducted between December 2014 and July 2015. Purposive sampling was applied to include facilities with the highest caseloads of TB. The facilities included public, private and faith-based offering either TB treatment only or both TB diagnosis and treatment categorized as level II, III and IV according to Kenya Essential Package for Health classification. The allocation of the number of study participants to the facilities was done using probability proportional to size (PPS). All patients who consented to the study were included in the study for the six month treatment period. Questionnaires were administered within the first three weeks of treatment and after twelve weeks of treatment. After six months of treatment, TB registers were reviewed to collect information on treatment outcomes. Questionnaires were administered to the facility in-charges once during the study period. Double entry of all the data collected was done. There was validation to check the concordance of the two data sets. A descriptive analysis of the data was undertaken. Bivariate analysis of patient-level factors, institutional-level factors and treatment outcomes was conducted using Chi-Square and Fisher's exact test. Kaplan-Meier estimator was used in determining the median time to treatment interruption. Survival was analyzed using the Kaplan-Meier probability of failure estimate. The test for the equality of the survivor functions for the level of education, use of alcohol, smoking,perceived availability of sufficient Health Care Workers and nature of facility was done using the log-rank test. Cox regression hazard analysis was undertaken to determine the predictors of treatment interruption. Statistical significance was determined by considering a nominal p-value of less than 5% ($P< 0.05$) with a 95% confidence level. The highest level of education, affliction with another chronic disease, access to information on TB, nature of the facility, and level of the facility according to Kenya Essential Package for Health classification, all exhibited a statistically significant association with TB treatment outcomes ($P<0.05$, Fisher's exact test). Patients who indicated secondary level as the highest level of education posted lower treatment success rates when compared with their counterparts who had achieved primary level education. Cases afflicted by other chronic disease had lower treatment success rates when compared to those who were not affected. Access to TB information showed an association with positive treatment outcomes. Patients treated in private-for-profit and faith-based institutions showed better treatment outcomes compared to those treated in public facilities. Patients treated in Level II facilities (dispensaries) posted positive treatment outcomes when compared to those in Level III facilities (Health Centers). A total of 19 (6.5%) treatment interruptions were observed. The median time to default was 56 [95% CI, 36-105] days. Treatment in a non-public facility [AHR=0.253, 95% CI (0.0585-1.097)] and facilities perceived to have an adequate number of health care

workers to offer Directly Observed Therapy (DOT) [AHR=0.253, 95% CI (0.0919-0.697)] showed a lower hazard for treatment interruption. Attainment of secondary level education [AHR=3.42, 95% CI (0.99-11.815)] exhibited a higher hazard rate of treatment interruption when compared to patients who attained a primary level education. Patient-level and institutional-level characteristics that exhibited a significant association with treatment outcomes in this study, should be factored into the treatment plans for new SM+ TB patients in Nairobi County to achieve higher treatment success rates. These variables should be considered predictors of treatment outcome during TB treatment in Nairobi County. Non-clinical aspects of health care service delivery influence patient adherence to TB treatment. Subsequently, the health-seeking behavior of groups considered to be at high risk for treatment interruption should be incorporated into the design and delivery of TB treatment.

CHAPTER ONE
INTRODUCTION

1.1 Background information

Tuberculosis (TB) is an infectious disease caused by bacillus bacteria. The most common causative organism is *Mycobacterium tuberculosis.* Depending on the affected body organs TB is classified into Pulmonary Tuberculosis (PTB) and Extra-Pulmonary Tuberculosis (EPTB). Pulmonary TB constitutes smear-positive cases ranked as most infectious and in turn accounts for up to 80% of all cases of TB globally (McPhendran & Opie, 1935; Maher, 2009; Shaw & William, 1954; WHO, 2003). Extra-Pulmonary TB affects all body parts except the hair, teeth and nails (WHO, 2013). As per the WHO definitions and reporting framework (2013), TB patients are classified into four categories; patients who have never been treated before and those that have used the anti-TB drugs for less than one month are termed as new cases and they can be either sputum smear-positive (SM+), sputum smear-negative (SM-) or with severe forms of extra-pulmonary TB. The second category includes all patients who are smear-positive and have been previously treated hence have relapsed or are failures or returnees after default. All of these are classified as previously treated smear-positive pulmonary TB cases. The third category encompasses patients diagnosed as sputum smear-negative despite having pulmonary TB or as having extra-pulmonary TB. The patients present less severe infections. The fourth category encompasses chronic TB and multiple drug-resistant cases.

A timely and accurate diagnosis of TB is important for the administration of the correct treatment regimen. Pulmonary Tuberculosis presents with non-specific symptoms with the indicative symptom being the presence of a persistent cough for more than two weeks. Accompanying symptoms include sputum production, fever, night sweats, and loss of weight, chest pain and shortness of breath (Maher, 2009). Diagnosis of PTB is mainly done by microbiological examination of sputum and chest X-ray, on the other hand, diagnosis of EPTB relies heavily on clinical acumen, history and examination for the

correct biopsy to be indicated for suspected patients (David & Masahiro, 2018; WHO, 2014).

Treatment of TB is a key pillar in the fight to reduce TB burden worldwide because it cures the individual and reduces the risk of transmission to the rest of the population (Dowdy *et al*., 2017). With correct management, treatment success rates are very high. Left untreated, TB has a high mortality rate (Tiemersma *et al*., 2011). Among HIV negative patients, the case fatality over 10 years for untreated SM+ TB patients is estimated at a weighted mean of 70% (Range 53-86) and 20 % for culture-positive smear-negative TB (Tiemersma *et al*., 2011). The World Health Organization (WHO, 1994) defined a standardized Short-Course Chemotherapy (SCC) and a strategy; directly observed therapy (DOTS) for treatment of TB. Short-Course Chemotherapy for new SM+ PTB was initiated in Kenya in 1993 and 100% coverage was achieved in 1997. Since the adoption of the TB-DOTS strategy, TB treatment outcomes have improved significantly in Kenya. In 2014, Kenya reported a treatment success rate (TSR) of 86% for all forms of TB (NTLD, 2015) and 81% in 2016 (NTLD, 2017).

In 2013, the Division of Leprosy, Tuberculosis and Lung Disease (DLTLD) published guidelines for the management of TB and leprosy in the country. Tuberculosis treatment involves the use of several drugs taken in combination. The recommended regimen for treatment for new SM+ adults entails two months of intensive phase treatment which is then followed by a continuation phase for four months (DLTLD, 2013). TB treatment outcomes are defined either as treatment successes (cured and completion of treatment) or adverse treatment outcomes (deaths, failures, transfer outs and treatment interrupted/out of control cases) (DTLTD, 2013; WHO/IUATLD, 2013). The WHO has provided standardized criteria to define TB treatment outcomes that are also captured in the WHO TB definitions and reporting framework 2013 (Table 1.1).

Table 1.1: Summary of Tuberculosis treatment outcomes criteria according to WHO/IUATLD recommendations

TB Treatment Outcome	Culture confirmed	Sputum smear microscopy confirmed
Cured	Documented conversion of culture during the Continuations phase.	Sputum smears negative on two occasions at the end of treatment.
Treatment Completed	Documented treatment completion, but no documented culture conversion available at the end of treatment.	Documented treatment completion but no sputum smear microscopy.
Treatment failure	Culture remaining or again becoming positive at 5 months of treatment or later months of treatment.	Sputum smears remaining or again becoming positive at 5 five months or later.
Death	Death of the patient irrespective of cause at any time before envisaged end of treatment.	
Treatment Interrupted	Patient off treatment for 2 consecutive months Or more or failure to complete treatment within 9 for a 6 month or within 12 months for a 9 month regimen or drug intake less than 80%.	
Transfer out	A patient referred to another clinician for treatment In whom information on treatment outcome cannot be obtained.	

The WHO TB reporting framework highlights the use of Treatment Success Rate (TSR) as an indicator to measure success in treatment. Globally, the 2014 TB cohort reported a TSR of 83%. Additionally, a TSR of 52% for MDR/RR-TB (2013 cohort) and 28% for XDR TB (2013 cohort) was realized (WHO, 2016). In Kenya, the 2014 TB patients' cohort realized 87% and 90% TSR for all forms of TB and new bacteriologically confirmed TB cases respectively. Rifampicin resistant cases and MDR-TB cases registered a TSR of 81% (NTLD-P, 2015). In the 2015 cohort, a TSR of 89.4% was realized for all forms of TB and 89.1% for bacteriologically confirmed cases (NTLD-P, 2016). In 2017, a TSR of 82% was reported for all forms of TB in the 2016 cohort (NTLD-P, 2017). The Global Plan (2016-2020) produced by the Stop TB partnership, has set the achievement of a 90% TSR for all people falling ill with TB as a measure of progress towards the goal of ending the TB epidemic by 2030. To achieve this, there is a need for TB patients to access affordable treatment, ensure adherence to correct treatment for the entire treatment duration coupled with social support for the patients.

1.2 Statement of the problem

The World Health Organization indicates that an estimated 10 million people developed TB globally in 2017. Men accounted for 58%, women 32 % and children 10% (WHO, 2018). Tuberculosis is ranked among the top ten causes of death by a single organism (WHO, 2018). In 2017, an estimated 1.3 million deaths (range 1.2-1.4 million) were attributed to TB among HIV-negative patients. An additional estimate of 300,000 deaths was attributed to TB amongst HIV-positive patients in the same year (WHO, 2018). The WHO African region notified 1, 323,450 TB cases in 2017.

Drug-Resistant TB (DR-TB) is increasingly becoming a threat to efforts geared towards ending the TB epidemic. In 2017, an estimated 558 000 people (range, 483 000–639 000) developed rifampicin-resistant TB (RR-TB), out of which 82% had multidrug-resistant TB (MDR-TB) (WHO, 2018). This represented a 14% increase in new cases of drug-resistant TB reported when compared to 2016 in which 490,000 cases were reported

globally (WHO, 2017). With treatment success rates of only 54% reported amongst DR-TB cases globally, it signals higher rates of loss to follow-up, unevaluated treatment outcomes and treatment failure, all of which can sustain transmission of DR-TB in the population (WHO, 2017).

Kenya is one of the fourteen (14) countries classified as having high TB, TB/HIV and MDR-TB burden (WHO, 2017). In 2015/2016, Kenya conducted the National TB population-based prevalence survey which estimated that 169,000 people fall ill with TB every year but only 80,000 are notified. This translates to a gross underestimation of TB Burden in Kenya by almost 40%. There was a 12% increase in case notification of Drug-Sensitive TB (DS-TB) from 75,898 in 2016 to 85,188 (NTLD, 2017), this is still way below the numbers reported in the population-based survey (NTLD, 2017).

Poor adherence to DS-TB drugs can lead to the emergence of Drug-Resistant TB (DR-TB). Resistance to single drugs has been reported in every country and resistance to all of the major anti-tuberculosis drugs has emerged (WHO, 2012). According to the WHO guidelines for the management of DR-TB 2010, drug-resistant bacilli is selected as a consequence of a human error in the prescription of chemotherapy, management of drug supply, case management or process of drug delivery to the patient. These human errors result in adverse treatment outcomes with treatment failure and interruptions providing the selection pressure that results in the development of drug-resistant forms of TB. WHO emphasizes the stringent use of anti-TB drugs to improve adherence resulting in increased chances of cure while reducing relapse, resistance, and deaths among new SM+ patients (WHO, 2010).

Despite the decline in case finding for DS-TB over the years, Kenya has seen a gradual increase in DR-TB case notification from 112 cases in 2010 to 433 in 2015. Notably, there was a 50% increase in 2015, compared to 288 cases in 2014 (NTLD, 2015). The trend has continued with 445 cases notified in 2016 (NTLD, 2016) and 577 cases in 2017 (NTLD

2017). In the Kenyan 2014 cohort, treatment success rate (TSR) for DR- TB patients was 74% with a mortality of 17% (NTLD, 2016). In 2017, a TSR of 73% was reported amongst DR-TB patients (NTLD, 2017).

The rising cases of DR-TB present a new set of challenges in the management of TB. The economic implications associated with DR-TB are a major challenge to the government and the individual patient. The recommended treatment regimen for drug-sensitive TB lasts six months and the complete course costs US$ 40 per patient. On the other hand, treatment of DR-TB is a major financial constraint costing up to US$ 2000-5000 to treat a single patient. As of 2016, a shorter regimen lasting 9-12 months was introduced which costs US$ 1000 which is still 25 times higher than the cost of treating DS-TB (WHO, 2017). In 2017, Kenya undertook a TB patient cost survey which revealed that the median total cost incurred in a single episode of DS-TB was Ksh. 25,874. The cost is much higher for a single episode of DR-TB reported as Ksh. 145,109.53. The majority of the costs (68.5%) were attributed to nutrition and food supplements (NTLD, 2017). Other than the economic implications, DR-TB treatment lasts much longer, utilizing more toxic drugs all of which can impact on adherence to treatment by the patient. Despite the heavy financial burden incurred in the treatment of DR-TB, the low TSR pose a public health risk due to potential transmission in the general population. This will translate to an increase in the burden of DR-TB which in turn will increase the financial burden of eliminating TB in Kenya. Curbing the rising threat of DR-TB should be prioritized to ensure that the gains made in reducing the burden of DS-TB are not reversed by the emerging risk of DR-TB. The TB management should focus on developing targeted treatment practices to halt the transition of DS-TB to DR-TB by amongst other measures improving adherence to the anti-TB treatment regimen for successful treatment outcomes.

1.3 Justification

Treatment of TB is advantageous to both the individual and the general public. Sputum smear-positive cases of PTB are particularly considered to be highly infectious hence a risk to the society (Dooley *et al*., 1990; McPhendran & Opie, 1935; Riley, 1974; Shaw & William, 1954; Snider *et al*., 1985; Turner *et al*., 2017). The need for discipline and strict adherence to drug regimen over a long period, frequent health facility visits and potential adverse reaction to TB treatment is discouraging to patients on TB treatment (WHO, 2003). Additionally, TB service delivery is associated with non-adherence (Ruru *et al*., 2018). Non-adherence can contribute to the on-going spread of disease and the emergence of DR-TB in the community (Reichman, 1997). Adherence to the TB Treatment over the prescribed duration is affected by multiple factors including amongst other factors willingness to take the medicine (Munro *et al*., 2007). Immense efforts should be focused on correct management of DS-TB to avoid the emergence of resistant bacilli strains that may lead to untreatable TB.

Understanding individual patient attributes e.g age, gender, level of education, economic status, co-infection with other diseases, adverse reaction to TB treatment, ease-off of TB symptoms, lifestyle and knowledge on TB and institutional-level factors e.g capacity and practices that could influence the treatment outcomes of patients is important in informing the interventions for newly diagnosed patients with a focus of achieving successful treatment outcomes for DS-TB. Identifying the factors that are associated with either successful or adverse treatment outcomes could form a basis to guide the development of a systematic way to identify cases that are high risk for adverse treatment outcomes. Targeted interventions can then be implemented to ensure successful treatment outcomes are realized amongst these cases.

1.4 Research Questions

To come up with factors that can guide the identification of TB patients with a higher chance of adverse TB treatment outcomes in Nairobi County, the research focused on identifying patient-level, DOT-system support factors and institutional level factors associated with treatment outcomes.

1) What are the patient-level factors associated with TB treatment outcomes among TB patients in Nairobi County?
2) What are the DOT support system factors associated with TB treatment outcomes among TB patients in Nairobi County?
3) What are the institutional-level factors associated with TB treatment outcomes among TB in Nairobi County?
4) What is the median time to treatment interruption and the associated factors among the patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear-positive in Nairobi County?

1.5 Objectives

1.5.1 General Objective

The overall study objective was to determine factors associated with TB treatment outcomes among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear-positive in facilities within Nairobi County.

1.5.2 Specific Objectives

The general objective was split into four specific objectives to effectively respond to the overall objective. These were;

1. To determine the patient-level factors associated with TB treatment outcomes in Nairobi County.
2. To determine DOT support systems factors associated with TB treatment outcomes in Nairobi County.

3. To determine institutional-level factors associated with TB treatment outcomes in Nairobi County.
4. To determine the median time to default and the associated factors among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear positive in Nairobi County.

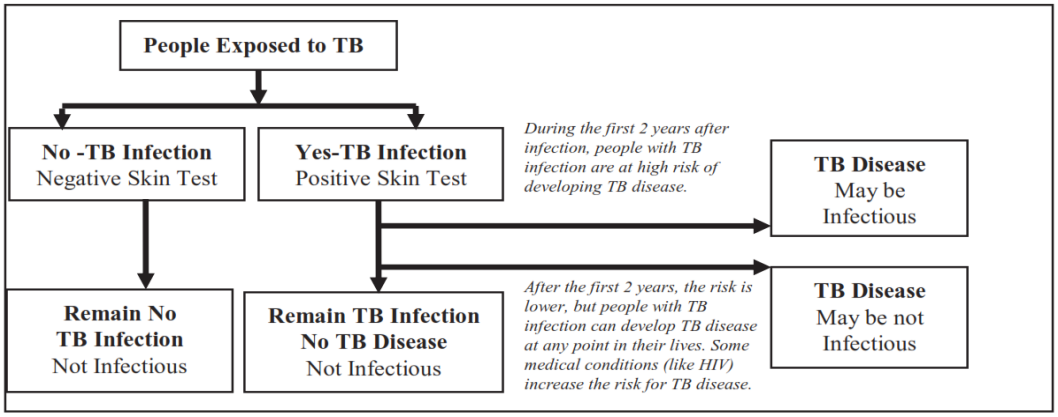
CHAPTER TWO

LITERATURE REVIEW

2.1 Tuberculosis infection and disease

The causative agent of Tuberculosis belongs to a group of bacteria known as *Mycobacterium tuberculosis* complex. While the most common agent is *Mycobacterium tuberculosis*, other agents include *Mycobacterium bovis*, transmitted through contaminated milk and milk products and *Mycobacterium africanum* (Cadmus *et al*., 2010; Glover, 1941; Malone & Gordon, 2017). According to the American Thoracic Society Diagnostic Standards and Classification of Tuberculosis, the transmission of the bacteria is through infectious aerosolized droplet nuclei generated by coughing, laughing, talking, sneezing and singing. The ability to generate infectious aerosolized droplet nuclei is dependent on the infectivity of the patient with SM+ patients considered most infectious (Dooley *et al*., 1990; McPhendran & Opie, 1935; Riley, 1974; Shaw & William, 1954; Snider *et al*., 1985; Turner *et al*., 2017).

Infection with the *Mycobacterium* does not always lead to the development of disease as the immune system can contain the infection and the bacilli remain dormant. Longer durations of exposure to infected persons who are not on treatment increase the chance of infection (Dooley *et al*., 1990). Rapid progression to tuberculosis disease occurs in about 5% of infected cases within the first two years after infection and only about 10-15% of infected persons will develop active disease during their lifetime (Behr *et al*., 2018; Maher, 2009; Sutherland, 1968).



Source: Self-Study Modules on Tuberculosis. Centers for Disease Control and Prevention, 1995

Figure 2.1: Progression of TB infection to disease

Progression from TB infection to TB disease is a result of interactions of multiple factors within the individual and the environment (Lienhardt, 2001). It has been well documented that the most at risk to develop TB include children under five years, the old and those who are immunosuppressed (Corbett *et al*., 2003; Girardi *et al*., 2000). Other than this, Narasimhan *et al*., 2013, has documented the interactions between the internal and external factors that influence the risk of developing TB disease (Figure 2.2).

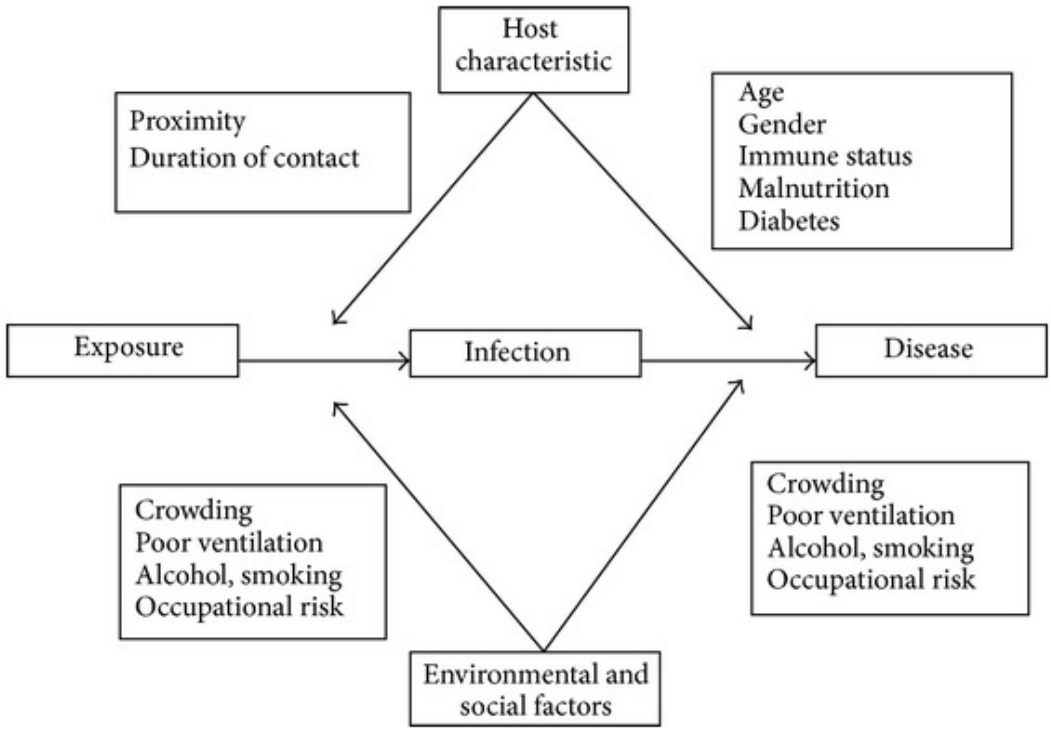


Figure 2.2: Risk factors for Tuberculosis infection and disease

2.2 Tuberculosis epidemiology

Tuberculosis remains a major cause of morbidity and mortality globally. According to the WHO global TB report (2016), there were an estimated 10.4 million new (incident) TB cases worldwide including 480,000 new cases of multidrug-resistant TB (MDR-TB) and an additional 100,000 people with rifampicin-resistant TB (RR-TB). More than half of these cases 5.9 million (56%) were male. People living with HIV accounted for 1.2 million cases (11%) of all new TB (incident) cases. Without stringent interventions, WHO predicts that approximately 1 billion people will become infected, 150 million will become symptomatic and 36 million will die from TB between 2002 and 2020 worldwide (WHO, 2006). Worldwide, 22 countries account for 80 % of the TB disease burden. In 2015, TB remained one of the top 10 causes of death worldwide causing an estimated 1.4 million deaths. In addition to this, 0.4 million deaths among people living with HIV were

attributed to TB (WHO, 2015). It has been estimated that worldwide, TB causes up to 1.7 million deaths each year (WHO, 2008).

Kenya is currently ranked among the 14 countries with high TB, high TB/HIV, and high MDR-TB burden, accounting for 84%, 87% and 84% of the global burden respectively (WHO, 2017). In 2015, Kenya the National Tuberculosis, Leprosy and Lung Disease Program (NTLD) notified a total of 81,518 cases of which 74,742 were new cases while 6,776 were previously treated. Nairobi County notified the highest number of cases at 12,385. Notably, there was a 50% increase in reported cases of DR-TB in 2015, compared to 288 cases in 2014 (NTLD, 2015). The greatest toll has been observed amongst persons of productive age (15-44 years). The large TB burden has been attributed to several factors including HIV co-infection, poverty, social deprivation and limited access to general health services (DLTLD, 2013). In Kenya, 5.9% of patients diagnosed with PTB and 8.5% of those with EPTB died in the 2014 cohort. Deaths amongst TB/HIV co-infected patients increased from 10% in 2013 to 11% in 2014, (NTLD, 2015).

2.3 Tuberculosis economic burden and human resources

The greatest burden of TB falls among adults of reproductive age who are then weakened and often unable to work resulting in an average of 30% decline in productivity. With an infected population of over 8 million, this amounts to $1 billion lost annually. The World Health Organization estimates that the number of deaths due to TB annually stands at approximately 2 million. Each death results in a mean loss of 15 years income and an additional deficit of $11 billion. TB causes up to $12 billion to disappear from the global economy annually (WHO, 2003). In 2009, Kenya's TB expenditure represented 0.1% of the GDP and 1.1 % of health spending (NHA, 2009/2010). In 2012/2013 this figure doubled from Ksh.1.8 billion (US$23.7 million) in 2009/10 to (US$36.1 million) in 2012/13 representing 1.3% of the total health expenditure (NHA, 2011/2012). At the household level, the World Bank has reported that spending on TB can account for as much as 8-20% of annual household income (Laxminaraya *et al*., 2007). In Kenya, 26.5%

of households affected by TB which encompasses 86.4% of those diagnosed with DR-TB experienced catastrophic costs (NTLD-P, 2017).

The availability of resources for TB prevention and care is one of the major components in the implementation plan of the WHO END-TB strategy (WHO, 2015). Kenya has inadequate numbers of Health Care Workers (HCWs) and skills across all cadres of human resources for health compromising on optimal provision of health services to the population. According to Kenya Service Availability and Readiness Assessment Mapping (SARAM, 2013), the doctor-population ratio is less than one (<1) per 10,000 population. The nurse population-ratio was established as 3 per 10,000 people and for registered clinical officers 1 per 10,000. All other cadres of HCWs accounted for less than one (<1) per 10,000. This is very low compared to the WHO recommended standards of 23 doctors, nurses and midwives per 10,000 persons in a population. Significant workforce gaps are complicated by the inequitable distribution of HCWs. The Health Sector-Human Resource Strategy (HS-HRS) 2014-2018, projects that by the year 2030 there will be a challenge in filling general practitioner and nurses' gaps in the country. Kenya has a total of 8,405 health facilities of which 49% are operated by the government (public). Of these 5,840 (69.5%) offer TB management services (SARAM, 2013).

2.4 Tuberculosis diagnosis

Timely diagnosis and effective management of TB is paramount to prevent mortality and morbidity from TB. Early diagnosis of TB including universal drug susceptibility testing (DST) and systematic screening of contacts and high-risk groups is one of the pillars of the WHO END-TB strategy (WHO, 2015).

All persons presenting with a cough of a duration longer than two weeks are screened for TB using sputum smear microscopy unless another source of the cough is well known. As per the current practices within NTLD, a SM+ diagnosis is described as a patient presenting with two weeks of a cough, and at least one of two sputum smear specimens turning out positive for *Mycobacterium tuberculosis* bacilli. Alternatively, a patient

whose two samples turn smear-negative is given antibiotics and on repeat diagnosis, one sample turns positive for *Mycobacterium tuberculosis* bacilli is also classified as SM+.

Diagnosis of EPTB is more challenging and relies heavily on clinical acumen and cumbersome diagnostic techniques that require advanced technology (David & Masahiro, 2018; WHO, 2014). On the other hand, the diagnosis of Paediatric TB remains a major challenge. The inability of the majority of these children to provide lower respiratory tract specimens for microbiological investigations presents the biggest impediment in its diagnosis.

Recently, there has been a scale-up of the use of GeneXpert for TB diagnosis. It is more sensitive and can detect even a small number of bacilli. GeneXpert is a molecular-based technique founded on the principle of hybridization. According to WHO (2011) policy statement on the use of GeneXpert, the technique is accurate and reduces the time needed to diagnose rifampicin resistance for many patients from up-to three months to less than two hours. The use of rapid tests to facilitate early detection of TB is one of the priority indicators for monitoring the END-TB strategy. Globally between 2010 and 2015, a total of 467 GeneXpert instruments were procured by countries eligible for concessional pricing (WHO, 2016). The phased implementation of the roll-out of GeneXpert in Kenya has realized the increase in the number of GeneXpert machines in use from 11 machines in 2012 to 126 machines in 2015 (NTLD, 2015). According to the DLTLD treatment guidelines (2013), GeneXpert diagnosis is indicated majorly for MDR-TB surveillance and general TB diagnosis among HIV+ SM- patients, children and symptomatic patients for and on Isoniazid Preventive Therapy (IPT). Specific diagnostic tests are recommended for different indications of TB (Table 2.1).

Table 2.1: Indication for different TB diagnostics tests

Laboratory Test	Target	Purpose

Smear microscopy (Fluorescent and Light Microscopy)	All pulmonary TB suspects	Detect TB Disease Monitoring Smear positive patients on months 2,3,5 & 8
Culture techniques	TB patients on retreatment, health care workers, symptomatic contacts of drug resistant TB, smear negative PLHIV[1]	Used for recurrent TB (relapses), treatment failure, returnees, Health Care Workers to detect drug resistance
Histology	EPTB[2] patients	Detect lymph node disease Not widely available

For the purposes of this research, the focus will be on new SM+ patients for who follow up on treatment outcomes would be readily possible.

2.5 New Tuberculosis treatment, outcomes and associated factors

The recommended TB treatment is dependent on the type of TB. Six defined possible outcomes are associated with multiple factors.

2.5.1 New Tuberculosis treatment protocol

Treatment of TB is of benefit to both the individual and the public. Prescribing the appropriate regimen and ensuring adherence throughout the treatment period is of utmost importance. According to DLTLD treatment guidelines, without treatment, active pulmonary TB will result in 55-60% deaths, 20-25% spontaneous cure and 20-25% chronic coughing. Proper treatment with anti-TB medicines reduces mortality to less than 5%. The WHO in collaboration with the International Union against Tuberculosis and Lung Disease (IUATLD) has prescribed a standard regimen and dosing for new TB patients (Table 2.2).

[1] People Living With HIV
[2] Extra-Pulmonary TB

Table 2.2: Standard regimen and dosing frequency for new tuberculosis patients according to WHO/IUATLD guidelines

Intensive phase	**Continuation phase**
2 Months of HRZE[1]	4 months of RH
2 months HRZE	4 months of RHE[2] Applies only in countries with high level Isoniazid resistance in new TB patients and where Isoniazid drug susceptibility testing in new patients is not done (or results are Unavailable) before the continuation phase begins

2.5.2 Tuberculosis treatment outcomes

TB treatment outcomes are defined either as treatment successes (cured and completion of treatment) or adverse treatment outcomes (deaths, failures, transfer outs and treatment Interrupted/out-of-control cases/loss to follow up).

2.5.3 Tuberculosis treatment outcome, socio-demographic and socio-economic factors

There is conflicting information as to whether demographic factors have an association with TB treatment outcomes with some studies pointing to an existing relationship and others reporting an absence of a significant association. Sex and level of education are predictors of treatment success (Okanurak *et al*., 2008) and adherence (Xu *et al*., 2009).

[1] Isoniazid (H), Rifampicin (R), Pyrazinamide (Z) and Ethambutol (E)
[2] Rifampicin (R), Isoniazid (H) and Ethambutol (E)

Education is one of the most significant protective factors leading to a significant reduction in the case fatality proportion due to TB (Duarte *et al*., 2009). High mortality has also been shown to occur among TB patients with low levels of education (Belo *et al*., 2011). Age is associated with TB treatment outcomes (Chiang *et al*., 2009; Duarte *et al*., 2009; Vasankari *et al*., 2007). Hospitalized patients aged >65 years have been found to have a higher risk of failing to complete treatment (Cegolon *et al*., 2010) and death (Chiang *et al*., 2009; Nahid *et al*., 2011). Age (> 45 years) has been identified as a factor associated with default (Kapella *et al*., 2009) among TB patients on treatment while advanced age (>65 years) has been inferred as a possible predictor of mortality in patients with PTB (Chiang *et al*., 2009). Increasing age is a predictive factor for mortality in the continuation phase of treatment (Nguyen *et al*., 2011). Patient weight at the initiation of TB treatment is significantly associated with mortality during TB treatment (Burton *et al*., 2011; Getahun *et al*., 2011; Santha *et al*., 2000; Vasantha *et al*., 2008). Underweight has been associated with a tenfold increase in TB mortality (Wen *et al*., 2010). On the contrary, in other studies, no association between age, gender, and TB treatment outcomes were reported (Ahmed *et al*. 2009; Gebrezgabiher *et al*., 2016; Getahun *et al*. 2013).

Studies carried out on factors influencing TB treatment outcomes have identified the economic status of a patient as a factor influencing the adherence to TB treatment which in turn affects outcomes. Indices of wealth have been shown to have an influence on TB treatment outcome with one proxy marker for wealth, not owning a refrigerator accounting for a larger fraction of defaults in Thailand (Kittikraisak *et al*., 2009). Patients with stable sources of income have been shown to have a two-fold better treatment success rate than those unemployed or working for daily wages (Okanurak *et al*., 2008). Unemployment has been associated with increased treatment default by three folds in Estonia (Kliiman & Altraja, 2010). Among poor populations, socio-economic differences and proxy variables such as schooling and distance to health facilities are important risk factors for adverse TB treatment outcomes (Belo *et al*., 2011).

It is the responsibility of the health staff to continuously educate TB patients, their relatives and treatment supporters about the disease. The role of the health worker on patient compliance has been noted with patient counseling and communication reported to improve compliance (Liefooghe *et al*., 1999). Patient knowledge and attitude towards TB and TB treatment have been shown in several studies to have influenced the choices made by TB patients that eventually impact on treatment outcomes. Patients with limited knowledge have been shown to have a higher risk for non-cure outcomes compared to those with sufficient knowledge of TB treatment (Jianzhao *et al*., 2011). In Zambia, Kaona *et al*., 2004, reported that up to 25.7 % of TB patients stopped taking drugs due to a lack of knowledge on the benefits of completing the course of treatment. In Ethiopia, adequate knowledge on TB treatment duration and side effects have been shown to decrease the possibility of default from DOTS which improves adherence and leads to increased chances of a patient getting successful treatment outcomes (Tekle *et.al*., 2002). In Nepal, up to 61% of patients who did not adhere to the treatment course claimed to have insufficient knowledge about the need to take daily treatment especially after the symptoms disappeared (Bam *et al*., 2006). In Gambia defaulting rates are higher among patients who expressed uncertainty over the success of the TB treatment (Hill *et al*., 2005). Attitudes of TB patients in particular patient satisfaction with the services of the health care worker is a factor affecting treatment outcomes (Salles *et al*., 2004).

2.5.4 Tuberculosis treatment outcomes and lifestyle factors

The lifestyle of TB patients has been associated with treatment outcomes. Several studies have shown that smoking does influence TB treatment outcomes with most results indicating that cigarette smoking leads to adverse treatment outcomes including default (Chang *et al*., 2004; Kittikraisak *et al*., 2009) and treatment failure (Santha *et al*., 2000). Smoking marijuana has also been associated with default (Holtz *et al*., 2006). Despite all these pointers towards an association between smoking and TB treatment outcomes, the limited studies conducted so far have failed to produce a sufficient link between the two (Slama *et al*., 2007). More studies, therefore, need to be conducted to support or refute the

potential association between smoking and TB treatment outcomes. Alcohol consumption has been associated with up to a three-fold increase in non-adherence to TB treatment which in turn affects treatment outcomes (Amuha *et al*., 2009). Alcohol abuse defined as registered alcoholism or weekly consumption of at least 14 standard drinks for men and seven standard drinks for women over one year has been associated with up to three-fold increase in TB treatment default (Kliiman & Altraja, 2010). In the study, one standard drink was defined as 10g of absolute alcohol (WHO, 2006). History of excessive alcohol is a significant predictor of death during the intensive phase of TB treatment (Nguyen *et al*., 2011).

2.5.5 Tuberculosis treatment outcomes and Tuberculosis/Human Immunodeficiency Virus infection (TB/HIV)

The emergence of the Human Immunodeficiency Virus (HIV) epidemic triggered a resurgence of TB in most countries. The Human Immunodeficiency Virus has been identified as one of the single most important risk factors for TB infection (Dean *et al*., 2002). Additionally, TB treatment in HIV-infected patients is a major challenge due to possible drug interactions. Common concurrent infections and immuno-pathological reactions can, in turn, affect treatment outcomes. In India, non-initiation of Antiretroviral Therapy (ART) has emerged as a high-risk factor for unfavorable treatment outcomes as well as overall mortality among TB patients (Vijay *et al*., 2011). HIV status has also been associated with increased risk of death and defaults among TB patients under treatment (Burton *et al*., 2011; Duarte *et al*., 2009; Nahid *et al*., 2011). Other chronic illnesses have been inferred as possible predictors of mortality in patients with PTB (Chiang *et al*., 2009; Kim *et al*., 2010). The NTLD program reported a TB/HIV co-infection rate of 31% among the 97% TB cases tested for HIV nationally (NTLD, 2015).

2.5.6 Tuberculosis treatment outcomes, adverse reactions to TB treatment and ease-off of TB clinical symptoms

On its own and when taken with other medications, TB medicine is known to induce adverse effects that usually improve after a few weeks. These adverse reactions to TB treatment tend to lead to cessation of treatment among patients (Kittikraisak *et al*., 2009; Okanurak *et al*., 2008). Medication intolerance or co-morbid illnesses are possible reasons for TB treatment withdrawal amongst these patients. While the continuous presence of symptoms has also been identified as a potential factor leading to default particularly during the continuation phase of TB treatment (Kittikraisak *et al*., 2009), other studies have also shown that some patients stop taking treatment when the symptoms have abated as they believe that they are cured (O'Boyle *et al*., 2002). Several studies have been conducted in an attempt to predict the time to treatment interruption by TB patients and the results have been inconsistent. Kaona *et al*., (2004) reported that more than a third of patients who stopped taking TB treatment did so within the first two months of commencing treatment. In Ethiopia however, the reports indicate that default was highest during the continuation phase (Tekle *et al*., 2004).

2.5.7 Tuberculosis treatment outcomes and Directly Observed Therapy (DOT) system

To achieve successful control of TB, the organization of the system through which the care is provided is essential as this determines the quality of medical care available. There is significant evidence supporting the use of Directly Observed Therapy (DOT) as a strategy to increase the proportion of patients with successful treatment outcomes. More treatment success has been demonstrated in patients, who are treated under DOTs than those who are treated with self-administered therapy (SAT) (Anuwatnonthakate *et al*., 2008; Chung *et al*., 2007; Jasmer *et al*., 2004). Reduced non-adherence has been reported among patients who are under direct observation by village doctors in China (Xu *et al*., 2009). Directly Observed Therapy by a health worker has been associated with reduced risk of default among TB patients (Kapella *et al*., 2009). Not having a DOT supervisor

has shown to be associated with non-cure treatment outcome (Jianzhao *et al*., 2011). Higher TSR have been reported amongst patients treated in facilities specialized to offer TB treatment (Chung *et al*., 2007). This further highlights the importance of quality of healthcare due to specialized training health of workers providing services and capacity of facilities in the overall control of TB.

Treatment outcomes are associated with individual and institutional-related factors. These associations vary between countries and within countries. A clear understanding of the factors that are associated with TB treatment outcomes and timelines in Nairobi County is important in informing National Tuberculosis Programme on the design of interventions to sustain the gains made in the fight against DS-TB. This success includes a high treatment success rate and minimal adverse treatment outcomes among newly-diagnosed SM+ TB patients. Such a scenario will eliminate the pressure required to select DR-TB and stop the surging epidemic from reversing all the gains made in fighting TB in the country.

CHAPTER THREE
MATERIALS AND METHODS

3.1 Study site

The study was undertaken in Nairobi County, one of the 47 counties and the capital city of Kenya. According to the Kenya National Bureau of Statistics 2009 census, 3,138,295 people were living in Nairobi which covers 696km^2. A quick summary of the Nairobi County demographics in comparison to the National average as of 2016 is shown in Table 3.1.

Table 3.1: Nairobi County and National demographic characteristics

	County	**Kenya**
Population	4,232,087	44,200,000
Urban Population	4,232,087	29.9%
Population Density	3009	76
Proportion of males	47.6%	49.5%
Proportion of Children <14	28%	41.6%
Proportion of elderly >65	1%	3.3%
HIV Prevalence	6.1%	5.9%
Poverty Head Count	21%	46%

Adopted from NTLP-P 2016 Annual Report

Nairobi County has consistently registered the highest case notification rates (CNR) of SM+ PTB of 218 per 100,000 in 2009 (DLTLD, 2009) and 220 per 100,000 in 2010 (DLTLD, 2010). In 2016 the CNR was reported at 297 per 100,000 which is higher than the national average of 170 per 100,000 (NTLP-P 2016). This increased to 304 per 100,000 in 2017 (NTLP-P 2017). A total of 25 facilities offering TB treatment within Nairobi County were included in the study. Purposive sampling was applied to include facilities with the highest caseloads of TB based on data from the National TB program in 2012. The facilities included public, private and faith-based offering either TB treatment only or both TB diagnosis and treatment. Public facilities consisted of levels II, III and IV (Table 3.2).

Table 3.2: List and attributes of facilities included in the study in Nairobi County

S.No	Facility Name	Nature of Facility	KEPH
1	Chandaria Health Centre	Public	III
2	Dandora II Health Centre	Public	II
3	Jericho Health Centre	Public	II
4	Kahawa Health Centre	Public	III
5	Kangemi Health Centre	Public	III
6	Kariobangi Health Centre	Public	III
7	Kasarani Health Centre	Public	II
8	Kayole II Sub-District hospital	Public	III
9	Lunga Lunga Health Centre	Public	II
10	Makadara Health centre	Public	III
11	Ngara Health Centre	Public	III
12	Industrial area Remand Health Centre	Public	III
13	Rhodes Chest Clinic	Public	II
14	Riruta Health Centre	Public	III
15	Umoja Health Centre	Public	II
16	Kayole I Health Centre	Public	III
17	Huruma Lions	Public	III
18	Mukuru Kwa Ruben Health Centre	Faith-Based	III
19	Ruaraka Uhai Neema	Faith-Based	IV
20	Soweto Health Centre	Faith-Based	II
21	St. Francis Community	Faith-Based	IV
22	St. Johns	Faith-Based	II
23	St. Marys	Faith-Based	IV
24	Huruma Edarp	Private	II
25	St. Alice Edarp	Private	II

3.2 Study Design

A prospective cohort study of TB patients was undertaken over a period of six months from December 2014 to July 2015. Consenting patients diagnosed as new, SM+ and had not been on treatment for more than three weeks were included in the study. An entry interview was administered to the participants within the first three weeks of treatment. An exit interview was administered to the same participants after twelve weeks of treatment during the continuation phase of treatment. After six months of treatment, the TB registers were reviewed to collect data on treatment outcomes. Structured questionnaires were administered to the facility in-charges once within the study period to collect data on institutional-level characteristics.

3.3 Study Population

The study population was new SM+ PTB patients in Nairobi County. All other TB patients were not included in the study population.

3.3.1 Inclusion criteria

A two-step inclusion criteria was utilized in the study to select first facilities, and secondly the individual patients.

3.3.1.1 Facility inclusion criteria

- Facilities located in Nairobi County
- Facilities offering TB treatment to new SM+ TB patients

3.3.1.2 Patient Inclusion Criteria

- Patients diagnosed as new SM+ and registered in the facility TB register.
- Patients who had been on TB treatment for less than three weeks
- Patients aged 15 years and above
- Patients who gave voluntary informed consent to participate in the study

3.3.2 Exclusion criteria

- Patients who did not give informed consent
- Paediatric patients were excluded from the study (<15 years).
- Patients who had been on treatment for more than three weeks.

3.4 Study Variables

Independent variables: -Individual and institutional characteristics.

- Patient-level factors

  Age

  Gender

  Level of Education

  Source of income, frequency of payment and average monthly income

  Lifestyle practices (Alcohol and Smoking)

  Other chronic illnesses afflicting the TB patient

  Presence and type of adverse reaction to TB treatment

  Presence and type of observed ease-off of TB clinical symptoms upon treatment

  Time spent to access health services

- DOT support system characteristics

  Type of DOT support

  Reason for choosing DOT support system

- Institutional-level factors

  Nature of the facility: Private vs. public institutions

  Level of the facility as per the Kenya Essential Package for Health (KEPH) classification

  TB services: Diagnostic & treatment centres, treatment centres, resources available (specific nurse, room for TB services), personnel training on TB diagnosis, treatment and counselling sessions

Dependent variable: New SM+ TB treatment outcomes

Cured

Completed treatment

Transferred out

Treatment interrupted/Default/Loss to follow-up

Failure

Death

The interactions between the independent and independent variables for the four objectives is summarized in Figure 3.

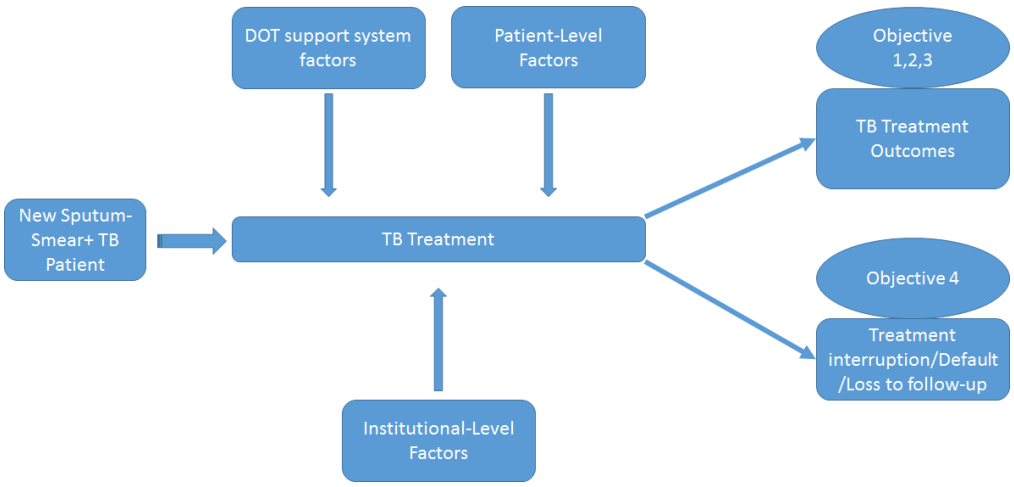


Figure 3.1: An illustration of the interaction between independent and dependent variables for objective 1-4

3.5 Sample Size Determination

The sample size was calculated based on the total number of SM+ cases notified in 2010 in Nairobi County. The hypothesis for the sample size calculation was based on an expected adverse (failure, deaths and Transfer-out) treatment outcomes in new SM+ TB cases of 12%. The following formula was used to calculate the sample size with finite population correction:

$$n\,(SRS) = \frac{N * z^2 * p * (1 - p)}{d^2 * (N - 1) + z^2 * p * (1 - p)}$$

(Daniel W, 1999)

Where:

N = total number of new smear positive cases registered during one year in the Nairobi County (N=6013)

z = z-value (from the standard normal distribution) that corresponds to the desired confidence level (if confidence interval = 95%, z = 1.96);

d = absolute precision (0.03);

p = expected proportion of adverse outcomes (0.12)

n (SRS) = 317

3.6 Sampling techniques

The allocation of participants in the facilities was done using probability proportional to size (PPS) based on the new SM+ caseloads reported to the national program in 2012. New SM+ TB patients within the target facilities who had been on treatment for not more than three weeks were recruited for the study. From the start of the recruitment, all patients in selected facilities that met the inclusion criteria and consented to participate in the study were included in the study.

3.7 Procedures of data collection, instruments and techniques

3.7.1 Preliminary procedures

Approval for the research was sought and received from the KEMRI-Centre for Respiratory Disease (Annex 1) and the KEMRI-ethics review committee (Annex 2). Additionally, permission to access facilities was sought and received from the National TB program (Annex 3) and the Nairobi County Health Department (Annex 4). Using data from the National TB program, 25 facilities that met the inclusion criteria were selected.

3.7.2 Training of enumerators

In collaboration with the Nairobi County, 25 enumerators well versed with TB disease were identified and a one-day training conducted at the Nairobi County Health Department board room. The enumerators were briefed on the project, trained on the content and use of individual patient and facility-in-charge questionnaire, patient inclusion criteria and the process of seeking consent. A practice session was conducted during the training. The questionnaire was edited to eliminate questions that were deemed too technical and would pose a challenge to some patients.

3.7.3 Data collection

Data was collected from individual patients and facility-in-charge. A record review was done at the end of the study.

3.7.3.1 Individual patient data collection

An individual patient questionnaire was used to interview the patients at the entry (Annex 5) and exit (Annex 6). The enumerators were stationed at the TB treatment facilities. The TB patients were approached after receiving TB services in the facility. Patients were briefed at the interview stations about the project after which a written informed consent (Annex 7) was sought. Written assent was sought from patients less than 18 years old (Annex 8). Fully informed, explicit and active voluntary consent was sought from each participant. Each potential study subject was given the full extent of the implications of

participating in the study. The consent forms were prepared in both English and Kiswahili. All the study subjects were given the autonomous choice to withdraw at any point during the study unconditionally. Patients who met the inclusion criteria and consented were included in the study. The date of the start of TB treatment was recorded in order to inform the point of the second interview.

3.7.3.2 Facility in-charge data collection

Tuberculosis treatment facility in-charge was interviewed once during the study period on a day convenient to them. The enumerators briefed them on the project before seeking informed consent (Annex 7) to undertake the interview. A facility in-charge tool (Annex 9) was used to collect the data by administering individual interviews in their offices.

3.7.3.3 Record review

Treatment outcomes were extracted from the National TB electronic data database (TIBU) using a treatment outcome tool (Annex 10). The unique patient registration numbers were used to track the individual patients from the 25 facilities and their outcomes recorded.

3.7.3.4 Biases and control of bias

Possible non-response bias was taken into consideration in the design of the study. Seasoned community HCWs with a vast knowledge of TB were used as enumerators. Confidentiality was emphasized to the TB patients before conducting the interviews.

3. 7. 5 Data Management and analysis

On receipt of questionnaires, internal and external consistency of data was verified. Double entry of all the data collected was done. There was validation to check the concordance of the two data sets. Once this had been done, a second manual validation was conducted to ensure that what was entered into the database exists in the questionnaires.

The access based database system (MS. Access 2013 version 15) was designed to allow entry of all the data from the questionnaires. The data was verified and keyed in after arrival from the site. Received data was cross-checked against the national TB electronic database (TIBU) for concordance. Registration numbers that were not captured in TIBU were not included in the analysis. The access database was password-secured accessible to only the investigator.

3.8 Statistical analysis

A descriptive analysis of the data was undertaken. The independent variables were described in terms of percentiles, medians, and means. Continuous data was categorized during analysis. Multiple answer questions answers were analyzed either individually or categorized. Pooled stratified estimates were calculated for the six standard treatment outcomes. Bivariate analysis was conducted using Fisher's exact test to investigate the association between the independent and dependent variables for objective 1-3 and Chi-Square to determine association with treatment interruption in objective 4. Kaplan-Meier estimator was used to determine median-time to treatment interruption among the study subjects in objective 4. Patients lost to follow-up for reasons other than factor under analysis were censored in the Kaplan-Meier survival analysis. Survival was analyzed using the Kaplan-Meier probability of failure estimate to assess the probability of loss to follow up in the different categories of patients. The test for the equality of the survivor functions was done using the log-rank test to establish if the observed difference in survival was significant. The cumulative risk of incidence within groups was calculated to determine the risk between the groups. Cox regression hazard analysis was undertaken to determine the predictors of treatment interruption. Statistical significance was determined by considering a nominal p-value of less than 5% ($P< 0.05$) with a 95% confidence level. The analysis was done using STATA version 13 (StataCorp. 2013. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

3.9 Confidentiality

The data collected during the study were handled in confidentiality and were not and shall not be released for other uses other than that which the research study sought to. All study subjects were assigned a numerical key to be utilized during the study period. The interviews were conducted in a designated location in the facility. The questionnaires were only identified by a number and the TB treatment registration number. No names were recorded in the questionnaires. The filled questionnaires were collected from the facility in-charge twice a week. No enumerator was allowed to leave the facility with the questionnaires. The paper copies of the questionnaires were stored in a locked cabinet. All electronic data was stored in password-protected computer files accessible only to the researcher.

CHAPTER FOUR

RESULTS

4.1 Introduction and response rate

This chapter will provide the results from the analysis of the data collected to determine if there are any associations between patient-level, institutional-level associated factors and, TB treatment outcomes in Nairobi County. Additionally, the results will highlight the median time to default and factors associated with this outcome. A total of 291 new smear-positive (SM+) TB patients diagnosed between December 2014 and July 2015 from twenty-five facilities within Nairobi County were included in the study. This represented a 92% response rate.

4.2 Patient-level factors

4.2.1. Socio-demographic and Socio-economic characteristics

Of the 291 respondents, 215 (74%) were male. The TB patients had a mean age of 32.3 (22.3-42.3) years. More than half of the patients were aged between 51-70 years (168; 57.3%). About half of the patients 147 (50.2%) had attained a secondary level of education. A large proportion of the study participants 212 (72.2 %) had a source of income of which 117 (55 %) were self-employed. Employed persons were further grouped based on the frequency of payment, 65 (65%) received payment monthly. Monthly income among the 200 respondents averaged Ksh. 11,626±11,723 (Table 4.1).

Table 4.1: Frequency distribution of socio-demographic and socio-economic characteristics of TB patients in Nairobi County.

Variable	Variable Category	Frequency (%)	95% CI of proportions
Gender	Male	215 (74.00)	69-79
	Female	76 (26.00)	21-31
	Total	291 (100)	
Age	15-24 years	53 (18.21)	14-.23
	25-34 years	136 (46.74)	42-.53
	35-44 years	63 (21.65)	17-26
	45 years and above	34 (11.68)	8-15
	Non –response	5 (1.72)	0-4
	Total	291 (100)	
Weight[1] (at entry in Kgs)	≤32 years	5 (1.74)	0.7-4
	33-50	103 (31.16)	29-41
	51-70	168 (57.34)	52-63
	≥71	13 (4.48)	3-8
	Non-response	2 (2.22)	0.5-4
	Total	291 (100)	
Weight (at exit in Kgs)	≤32 years	6 (2.05)	0.9-4.5
	33-50	64 (21.84)	17-26
	51-70	159 (54.17)	48-59
	≥71	17 (5.8)	3-9
	Non-response	45 (16.04)	12-20
	Total	291 (100)	
Highest level of education	Primary	98 (33.68)	28-39
	Secondary	146 (50.17)	44-55
	Post-secondary	38 (13.06)	10-18
	Non-response	9 (3.09)	2-6
	Total	291 (100)	
Have source of income?	Yes	210 (72.16)	67-77
	No	75 (25.77)	21-31
	Non-response	6 (2.06)	0-4
	Total	291 (100)	
Source of income	Self-employed	117 (55.71)	48-62

[1] Weight groups based on dosing guidelines

	Employed	93 (44.29)	38-52
	Total	210 (100)	
Frequency of payment	Daily	20 (15)	9-24
	Weekly	15 (15)	9-24
	Monthly	65 (85)	55-74
	Total	100	
Monthly Income	≤10,000	124 (59.25)	52-65
	10,001-20,000	53 (25.24)	20-32
	10,001-30,000	14 (6.67)	4-10
	30,001 and above	7 (3.33)	2-7
	Non-response	12 (5.71)	3-10
	Total	210	

4.2.2 Lifestyle –Smoking and alcohol consumption

History of smoking was investigated among the study participants. At recruitment, 135 (46.39%) of the patients had a history of smoking. Majority of the patients with a history of smoking 73 (54.48%) had smoked within 8 weeks or less to the day of recruitment into the study. During the continuation phase of treatment, majority of the respondents 64 (80%), were not smoking (Table 4.2).

Table 4.2: Smoking characteristics among TB patients in Nairobi County

Variable	**Variable Category**	**Frequency (%)**	**95% CI of proportions (%)**
History of smoking			
(Entry Interview)	Yes	135 (46.39)	40-51
	No	154 (52.92)	47-59
	Non-response	2 (0.69)	0-3
	Total	291	
Last time Smoked			
(Entry Interview)	1-8 weeks	73 (54.48)	46-63
	9-24 weeks	16 (11.94)	7-19
	>24 weeks	35 (26.12)	19-34

	Non-response	11 (07.46)	4-13
	Total	135	
History of smoking			
(Exit interview)	Yes	80 (27.49)	23-33
	No	179 (61.51)	55-66
	Non response	32 (11.00)	8-15
	Total	291	
Last time smoked			
(Exit interview)	1-8 weeks	8 (10.00)	5-19
	9-24 weeks	41 (51.25)	40-62
	>24 weeks	23 (28.75)	20-40
	Non response	8 (10.00)	5-19
	Total	80	
Smoking during treatment	Yes	8 (10.96)	5-20
	No	64 (80)	79-93
	Non response	8 (10.00)	5-19
	Total	82	

A history of alcohol consumption was investigated among the study participants. At recruitment, 166 (57.04%) of the patients reported a history of alcohol use. More than half of the patients with a history of alcohol use 93 (56.63%) had consumed alcohol within 8 weeks or less to the day of recruitment into the study. (Table 4.3).

Table 4.3: Alcohol consumption characteristics among TB patients in Nairobi County

Variable	Variable Category	Frequency (%)	95% CI of proportions (%)
History of alcohol consumption (Entry Interview)	Yes	166 (57.04)	51-63
	No	120 (41.24)	36-47
	Non-response	5 (1.72)	0-4
	Total	291	
Last time consumed alcohol (Entry Interview)	1-8 weeks	93 (56.63)	49-64
	9-24 weeks	37 (21.69)	16-29
	>24 weeks	24 (14.46)	10-21
	Non-response	12 (07.22)	4-12
	Total	166	
History of alcohol consumption (Exit interview)	Yes	100 (34.71)	29-40
	No	155 (52.92)	47-58
	Non response	36 (12.37)	9-17
	Total	291	
Last time consumed alcohol (Exit interview)	1-8 weeks	11 (11)	6-19
	9-24 weeks	57 (57)	46-66
	>24 weeks	26 (26)	18-35
	Non response	6 (6)	3-14
	Total	100	
Alcohol consumption during treatment	Yes	11 (11.83)	06-20
	No	83 (88.17)	80-93
	Total	94	

4.2.3 Time travelled to access health services

Most of the participants 251 (86.25%) spent one hour or less traveling to access a health facility. The mean travel time to the facility reported by the participants was 1.07 ± 0.3 hrs.

4.2.4 Adverse reaction to TB treatment

From the findings, 87 (29.9%) of the participants reported an adverse reaction to TB treatment within the first three weeks of treatment, most of whom, 49 (55.68%) reported at least one adverse reaction to TB treatment. Amongst all the study participants, skin irritation 33 (11.3%) was the most commonly reported adverse reaction to TB treatment. General body pains, vomiting, and fatigue were also experienced by some of the study participants (Table 4.4).

Table 4.4: Frequency of adverse reaction to TB treatment during the intensive phase of treatment among patients in Nairobi County

Adverse reaction to TB treatment	Frequency (%)
Skin irritation	33 (11.3)
General body pains	16 (5.5)
Vomiting	12 (4.1)
Fatigue	7 (2.4)

During the continuation phase of treatment, the participants who reported the continued experience of adverse reaction to TB treatment dropped to 49 (16.84%), with most 19 (6.5%) reporting skin irritation. Body pains, vomiting/ nausea was also reported at this stage of treatment (Table 4.5).

Table 4.5: Frequency of adverse reactions to TB treatment during the continuation phase of treatment among patients in Nairobi County

Adverse reaction to TB treatment	Frequency (%)
Skin irritation	19 (6.5)
General body pains	10 (3.4)
Vomiting/nausea	11 (3.7)

4.2.5 Ease-off of TB symptoms upon treatment

Within the first three weeks of treatment, relief on at least one TB symptom was reported by 156(53.61%) of the patients of whom 96 (61.53%) reported an ease-off of one TB symptom. Only 3(1.94%) reported relief from 3 or more TB. Reduced coughing was reported by the majority of the study participants 76 (26.1%). Other symptoms that eased-off at the same period amongst the participants included body pains, night sweating, and appetite loss and, fatigue (Table 4.6).

Table 4.6: TB clinical symptoms that eased-off upon TB treatment among patients in Nairobi County

Eased-off TB symptom	Frequency (%)
Coughing	76 (26.1)
General body pains	20 (6.8)
Night sweat	39 (13.4)
Appetite loss	18 (6.2)
Fatigue	10 (3.4)

4.2.6 Other chronic disease afflicting the study participants

The diagnosis of another chronic disease was reported by 43 (14.78%) of the patients. HIV/AIDS was the most encountered other chronic disease in 36 (83. 7%) (Table 4.7).

Table 4.7: Frequency distribution of other chronic diseases afflicting TB patients in Nairobi County

Other chronic diseases	Frequency (%)	95% CI of proportions (%)
HIV/AIDS	36 (70.51)	56-81
Diabetes	3 (5.88)	1.8-17
GIT disorders/Ulcers	2 (3.92)	.9-15
Hypertension	1 (1.96)	.2-13
Kidney ailments	1 (1.96)	.2-13
Non response	8 (15.69)	9-29

4.2.7 Knowledge on TB transmission

From the findings, 273 (93.81%) of the patients had heard of TB. Most of the study participants, 284 (97.59%) were aware that TB is communicable. Some respondents 111, (38.10%), mentioned bacteria as one of the causes of TB. A large proportion of the participants 216 (74.23%) listed TB as an airborne disease. Contact and sharing items were mentioned by some of the participants (84; 28.87%) as one factor that increased the likelihood of TB transmission. Of importance to note is the fact that 60 (20.62%) of the study participants were not aware of a single factor that increased the likelihood of TB transmission. Covering mouth when coughing was the most reported measure implemented by the participants to protect family members from infection. It was reported by 123 (42.27%) (Table 4.8).

Table 4.8: Knowledge on TB transmission among TB patients in Nairobi County

TB Knowledge Variable	Variable Category	Frequency (%)
Cause of TB	Bacteria	111 (38.10)
	Other (Environmental, lifestyle viruses)	175 (60.18)
	Non-response	5 (01.72)
	Total	291
TB spread	Yes	286 (98.28)

	No	4	(1.37)
	Non-response	1	(0.35)
	Total	291	
Medium of TB transmission			
	Airborne	216	(74.23)
	Sharing items/Contact	66	(22.68)
	Non-response	9	(03.09)
	Total	291	
Increase likelihood of TB transmission	Environmental/Hygiene conditions	39	(22.45)
	Lifestyle	37	(12.71)
	Contact	84	(28.87)
	Low Immunity	34	(11.68)
	Poor nutrition	18	(6.19%)
	Don't Know	60	(20.62)
	Non response	23	(07.90)
How to protect family from infection	Improving ventilation	102	(35.05)
	Adherence to treatment	51	(17.53)
	Confirmed diagnosis	55	(18.90)
	Don't know	8	(2.75)
	Non response	7	(2.41)

4.2.8 Knowledge on TB symptoms

The majority of the patients 230 (79.04%) indicated coughing as one of the symptoms of TB out of which 143 (49.14%) were aware of the two-week threshold for it to be considered suspicious for TB disease. The TB patient's knowledge of TB symptoms was good with only 7 (2.41%) not knowing a single symptom of TB. Nearly half of the participants (48.08%) were aware of the two weeks persistent- cough threshold used to justify the need for TB testing in most health facilities (Table 4.9).

Table 4.9: Knowledge on TB symptoms among TB patients in Nairobi County

TB Knowledge Variable	Variable Category	Frequency (%)
Symptoms of TB	Coughing	230 (70.04)
	Weight loss	129 (44.33)
	Night Sweat	123 (42.27)
	Loss of appetite	59 (20.27)
	Chest pain	60 (20.62)
	Don't know	7 (2.41)
	Non-response	11 (3.78)
Duration of Suspicious cough		
	2 weeks	143 (49.14)
	Other	106 (36.43)
	Don't know	30 (10.31)
	Non response	12 (4.12)

4.2.9 Knowledge on TB diagnosis and Treatment

On diagnosis techniques, 277 (95.19%) mentioned sputum smear as one of the methods used to diagnose TB. The majority of the respondents 272 (93.47%) knew that diagnosis with TB did not translate to an HIV positive status. The availability of free TB treatment was known to most patients 284(98%). Most also knew where to access the services and 283 (97.25%) and 263 (90%) were aware that TB is curable. Knowledge of the duration of TB treatment for new SM+ TB patients was correctly indicated by 282 (96.91%) of the participants as six months of which 273 (93.81%) mentioned getting well and stopping transmission as the most important reasons for seeking TB treatment (Table 4.10). TB diagnosis and treatment knowledge amongst TB patients who participated in the study was very good.

Table 4.10: Knowledge on TB diagnosis and treatment among TB patients in Nairobi County

TB Knowledge Variable	Variable Category	Frequency (%)
TB diagnostic methods	Sputum Smear	275 (95.19)
	Chest-X-ray	129 (44.33)
	Non-response	5 (01.72)
Does TB diagnosis Signal HIV infection	Yes	13 (4.47)
	No	272 (93.47)
	Don't know	4 (1.37)
	Non-response	2 (0.69)
Is TB treatment free	Yes	284 (98)
	No	3 (1.03)
	Non response	4 (1.37)
Know where to access TB services	Yes	283 (97.25)
	Non response	8 (2.75)
Is TB curable	Yes	263 (90.00)
	No	3 (1.03)
	Don't know	19 (6.53)
	Non response	6 (2.06)
Duration of treatment for new SM+ TB	6 months	282 (96.91)
	Other	6 (2.06)
	Non response	3 (1.03)
Importance of TB treatment	Get well and Stop transmission	273 (93.81)
	Don't Know	14 (4.81)
	Non response	4 (1.37)

4.2.10 Access to TB information and TB services

Less than half of the study participants 107 (36.76), had heard about multiple drug-resistant TB (MDR-TB). About two-thirds of the participants 180 (61.86%) mentioned health facilities and healthcare works (HCWs) as the main source of TB information. Information on TB disease and treatment was availed to 275 (94.50%) of the participants upon diagnosis. The information influenced decision making for 252 (89.59%) of the study participants on TB treatment. Counselling and information provision on subsequent visits was accorded to 252 (86.59%) of the study participants. Less than half of the participants 118 (40.55%) rated TB treatment services offered to them as excellent (Table 4.11). The results showed that there was a concerted effort to inform TB patients about the disease. The only aspect that displayed a worrying trend was knowledge of MDR-TB, with less than half of the study participants being aware of drug-resistant TB.

Table 4.11: Information accessibility and perception of TB service among TB patients in Nairobi County.

TB Knowledge Variable	Variable Category	Frequency (%)
Heard about MDR	Yes	107 (36.76)
	No	176 (60.48)
	Non-response	8 (2.76)
Main sources of TB information	Health facility/HCWs	180 (61.86)
	Friends/family/general community	92 (31.62)
	IEC/Media	88 (30.24)
	Non response	12 (4.12)
Counselling upon diagnosis	Yes	275 (94.50)
	No	12 (4.12)
	Non response	4 (1.37)
Did counselling influence decision making	Yes	252 (89.59)
	No	4 (1.37)
	Non response	27 (9.28)
Continuous counselling	Yes	252 (86.59)
	No	32 (11.00)
	Non response	7 (2.41)
Perception of TB services		
	Excellent	118 (40.55)
	Good	146 (50.17)
	Average	19 (6.53)
	Bad	2 (0.69)
	Non response	6 (2.06)

4.3. Aggregate Summary of TB treatment outcomes

A treatment success rate of 86.94% was recorded among the study participants. About two-thirds of the patients were cured 200 (68.73%) (Table 4.12).

Table 4.12: Aggregate summary of TB treatment outcomes among TB patients in Nairobi County

Treatment Outcomes	**Frequency (%)**	**95% CI of Proportions**
Cured	200 (68.73)	63-73
Treatment Completed	53 (18.21)	14-23
Transfer Out	8 (2.75)	1.3-5.4
Interrupted/Default	19 (6.53)	4.1-10
Failure	2 (0.69)	0.17-2.72
Death	9 (3.09)	1.6-5.8
Total (n)	291(100)	

4.4 Analysis of association between patient-level factors and TB treatment outcomes

Findings from the study indicated a statistically significant association between the highest level of education and treatment outcomes (P= 0.003, Fisher's Exact Test). The highest treatment success rates (TSR) (92%) were observed amongst patients with a post-secondary level of education. Gender, age, having a source of income or not and the type of employment reported by the study participants did not reveal any significant association to treatment outcomes (Table 4.13).

Table 4.13: Association between socio-demographic & socio-economic characteristics and TB treatment outcomes among TB patients in Nairobi County**.**

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Level of Education	Primacy	65 (67)	20 (21)	4 (4)	3 (3)	1 (1)	4 (4)	0.003
	Secondary	96 (66)	30 (21)	4 (3)	15 (10)	0 (0)	1 (1)	
	Post-Secondary	33 (87)	2 (5)	0 (0)	0 (0)	0 (0)	3 (9)	
Gender	Male	143(55)	42(18.8)	6(2.8)	15(7.0)	2(0.9)	7(3.9)	0.927
	Female	55(74.3)	13(16.1)	2(2.7)	3(4.1)	0(0)	2(2.7)	
Age in years	15-24	36(69.2)	8(15.4)	191.9)	6(11.5)	0(0)	1(1.9)	0.117
	25-34	99(72.8)	11(16.1)	2(1.2)	9(6.6)	1(0.7)	3(2.2)	
	35-44	44(69.8)	1(15.9)	3(4.8)	4(6.4)	0(0)	2(3.2)	
	45+	18(51.4)	11(3.4)	2(5.8)	0(0)	1(2.9)	3(8.6)	
Weight[7]	≤32 years	3(60)	1(20)	0(0)	0(0)	0(0)	1(20)	0.172
	33-50	66(64.7)	21(20.6)	5(4.9)	4(3.90	2(1.9)	4(2.9)	

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death
[7] Weight groups based on dosing guidelines

(at entry in Kg)	31-70	121(72.5)	25(14.9)	3(1.8)	14(8.38)	0(0)	4(2.40)	
	≥71	8(61.54)	5(38.46)	0(0)	0(0)	0(0)	0(0)	
Weight (at exit in Kg)	≤32 years	3(50)	3(50)	0(0)	0(0)	0(0)	0(0)	
	33-50	41(65.1)	13(20.6)	2(3.8)	5(7.94)	1(1.6)	1(1.6)	0.534
	31-70	121(76.6)	21(13.3)	4(2.5)	10(6.3)	1(1.63)	1(1.63)	
	≥71	13(76.5)	4(23.5)	0(0)	0(0)	0(0)	0(0)	
Have source of income	Yes	144(68.6)	35(16.7)	7(3.3)	15(7.1)	1(0.5)	8(3.8)	0.359
	No	52(69.3)	17(22.7)	0(0.0)	4(5.3)	1(1.3)	1(1.3)	
Source of Income	Self-Employed	81(69.2)	20(17.1)	4(3.4)	7(6)	1(0.85)	4(3.4)	0.952
	Employed	64(68.8)	15(16.1)	2(2.2)	8(8.6)	0(0)	4(4.3)	
Wage Payment								0.063
	Daily	9 (64)	0 (0)	1 (7)	2 (14)	0 (0)	2 (14)	
	Weekly	8 (53)	3 (20)	1 (7)	3 (20)	0 (0)	0 (0)	
	Monthly	45 (71)	12 (19)	1 (2)	3 (5)	0 (0)	2 (3)	
Monthly Income	≤10,000	89(71.8)	17(13.7)	4.(3.2)	8(6.5)	1(0.8)	5(4.0)	0.718
	10,001-20,000	32(60.4)	11(20.8)	2(3.8)	7(13.2)	0(0)	1(1.89)	
	20,001-30,000	11(78.6)	3(21.4)	0(0)	0(0)	0(0)	0(0)	
	30,001& above	5(71.4)	1(14.3)	0(0)	0(0)	0(0)	1(14.3)	

The investigation into smoking variables did not reveal significant associations with TB treatment outcomes (Table 4.14).

Table 4.14: Association between smoking and TB treatment outcomes among TB patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
History of Smoking (Entry)	Yes	92(68.20	24(17.8)	4(3)	12(8.9)	1(0.7)	2(1.5)	0.488
	No	107(69.5)	28(18.9	4(2.6)	7(4.6)	1(0.6)	7(4.6)	
Last time Smoked	1-8 Wks	50(68.5)	13(17.9)	2(2.7)	7(9.6)	0(0)	1(1.4)	0.900
	9-24 Wks	12(75)	3(18.8)	0(0)	1(6.3)	0(0)	0(0)	
	>24 Wks	21(58.3)	8(22.2)	2(5.6)	3(8.3)	1(2.9)	1(2.9)	
History of Smoking (Exit)	Yes	54(68.4)	14(17.7)	4(5.1)	4(5.1)	1(1.3)	2(2.5)	0.314
	No	130(73)	30(16.9)	2(1.1)	13(7.3)	1(0.6)	2(1.1)	
Last time Smoked	1-8 Wks	5(62.5)	0(0)	1(12.5)	2(25)	0(0)	0(0)	0.327
	9-24 Wks	28(66.9)	8(19.1)	1(2.4)	3(7.1)	1(2.4)	1(2.4)	
	>24 Wks	15(68.2)	4(18.2)	2(9.1)	0(0)	0(0)	1(4.55)	
Smoking during Treatment	Yes	5(62.5)	0(0)	1(12.5)	2(25)	0(0)	0(0)	0.164
	No	43(67.2)	12(18.8)	3(4.7)	3(4.7)	1(1.6)	2(3.1)	

An investigation into alcohol consumption variables did not reveal significant associations with TB treatment outcomes (Table 4.15).

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Table 4.15: Association between alcohol consumption and TB treatment outcomes among TB Patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
History of alcohol use (Entry)	Yes	88(73.3)	20(16.7)	2(1.2)	4(3.3)	1(0.8)	5(4.2)	0.240
	No	107(64.5)	33(19.9)	6(3.6)	15(9.0)	1(0.6)	4(2.4)	
Last time consumed	1-8 Wks	64(68.8)	16(17.2)	1(1.1)	10(10.8)	0(0)	2(2.2)	0.121
	9-24 Wks	25(67.6)	6(16.2)	3(8.1)	1(2.7)	1(2.7)	1(2.7)	
	>24 Wks	13(54.2)	7(29.2)	2(8.3)	1(4.2)	0(0)	1(4.2)	
History of alcohol use (Exit)	Yes	73(73)	13(13)	4(4)	7(7)	1(1)	2(2)	0.582
	No	109(70.3)	30(19.4)	2(1.3)	10(6.5)	1(0.7)	3(1.9)	
Last time consumed	1-8 Wks	7(63.6)	0(0)	1(9.10	3(27.3)	0(0)	0(0)	0.275
	9-24 Wks	44(75.9)	7(12.1)	1(1.72)	4(6.9)	1(1.7)	1(1.7)	
	>24 Wks	18(69.2)	4(15.4)	2(7.7)	1(3.9)	0(0)	1(3.9)	
Alcohol use during Treatment	Yes	7(63.4)	0(0)	1(9.1);	3(27.3)	0(0)	0(0)	0.141
	No	61(73.5)	11(13.3)	3(3.6)	5(6.0)	1(1.2)	2(2.4)	

Distance to the medical facility did not show a statistically significant association with TB treatment outcomes among TB patients in Nairobi County (Table 4.16).

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Table 4.16: Association between times travelled to health facility and TB treatment outcomes among TB patients in Nairobi County**.**

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%**)**	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Time travelled to treatment facility	≤1hr	172(68.5)	44(17.5)	7(2.8)	19(7.6)	2(0.8)	7(2.8)	0.882
	>1	12(85.7)	2(14.3)	0(0)	0(0)	0(0)	0(0)	

Adverse reaction to TB treatment during both the intensive and continuation phase, ease-off of TB symptoms upon treatment during both the intensive or continuation phase did not reveal a statistically significant association with TB treatment (Table 4.17).

Table 4.17: Association between adverse reactions to TB treatment, ease-off of TB symptoms and TB treatment outcomes among TB patients in Nairobi County**.**

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%**)**	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Adverse reaction to TB treatment (Intensive phase)	Yes	61(70.1)	15(17.2)	4(4.6)	4(4.6)	0(0.0)	3(3.5)	0.699
	No	128(66.7)	37(19.3)	4(2.1)	15(7.8)	2(1.0)	6(3.1)	
Adverse reaction to TB	Yes	39(79.6)	6(12.2)	2(4.1)	2(4.1)	0(0)	0(0)	0.485
	No	140(69.7)	39(19.4)	3(1.5)	14(7.0)	1(0.5)	4(2.0)	

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

treatment (Extensive)								
Ease-off of TB symptoms (Intensive Phase)	Yes No	109(69.9) 33(55.9)	31(19.9) 13(22.0)	4(2.6) 3(5.1)	8(5.1) 5(8.5)	0(0.0) 1(1.7)	4(2.6) 4(6.8)	0.133
Ease-off of TB Symptoms (Extensive)	Yes No	81(77.1) 32(68.1)	15(14.3) 10(21.3)	3(2.9) 1(2.1)	5(4.8) 1(2.1)	0(0) 1(2.1)	1(1.0) 2(4.3)	0.280

Analysis into the association between the presence of another chronic disease and TB treatment outcomes revealed a statistically significant association (Table 4.18)

Table 4.18: Association between co-infection with other chronic disease and TB treatment outcomes among TB patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Other chronic disease	Yes	23(53.50	8(18.6)	3(7.0)	5(11.6)	0(0)	4(9.3)	0.023
	No	166(70.3)	45(19.1)	5(2.1)	12(5.5)	2(0.9)	5(2.1)	

Findings from the study showed that aspects related to the cause of TB and transmission had no statistically significant association with TB treatment outcome (Table 4.19).

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Table 4.19: Association between TB cause, Transmission and TB treatment outcomes in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Cause of TB	Bacteria	70(63.1)	23(20.7)	3(2.7)	10(9.0)	2(1.8)	3(2.7)	0.331
	Other	125(71.4)	30(17.1)	5(2.9)	9(5.1)	0(0)	6(3.4)	
Medium of transmission	Air	148(68.5)	40(18.5)	5(2.3)	14(6.5)	2(0.9)	7(3.2)	0.871
	Other	46(69.7)	11(16.7)	3(4.6)	5(7.6)	0(0)	1(1.52)	
Increase likelihood of transmission	1 factor	101(63.5)	30(187)	7(4.4)	12(7.6)	2(1.3)	7(4.4)	0.247
	2 factors	38(77.6)	5(10.2)	1(2.0)	5(10.2)	0(0)	0(0)	
	None	42(70)	15(25)	0(0)	2(3.3)	0(0)	1(6.7)	
How to Protect family	1 factor	125(70.6)	28(15.8)	4(2.3)	13(7.3)	1(0.7)	6(3.4)	0.892
	2 factors	64(65.3)	20(20.4)	4(4.1)	6(6.10	1(1.0)	3(3.1)	
	3 factors	1(100)	0(0)	0(0)	0(0)	0(0)	0(0)	
	None	5(65.2)	3(37.5)	0(0)	0(0)	0(0)	0(0)	

Variables related to TB diagnosis and treatment did not reveal a statistically significant association with TB treatment outcomes (Table 4.20).

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Table 4.20: Association between knowledge on TB diagnosis &treatment and TB treatment outcomes among TB patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Diagnosis of TB	1 method	119(72.6)	26(15.9)	4(2.4)	12(7.3)	0(0)	3(1.8)	0.202
	2 methods	77(63.1)	26(21.3)	4(3.3)	7(5.7)	2(1.6)	6(4.9)	
TB Diagnosis signals HIV infection	Yes	12(70.6)	2(11.8)	0(0)	1(5.9)	0(0)	2(11.8)	0.389
	No	186(68.4)	51(18.8)	8(2.9)	18(6.6)	2(0.7)	7(2.6)	
Is TB Treatment free	Yes	197(69.4)	52(18.3)	6(2.1)	18(6.3)	2(0.7	9(3.2)	0.103
	No	1(33.3)	2(66.7)	0(0)	0(0)	0(0)	0(0)	
Is TB curable	Yes	184(70)	44(16.7)	8(3.0)	16916.0)	2(0.8)	9(3.4)	0.442
	No	2(66.7)	1(33.3)	0(0)	0(0)	0(0)	0(0)	
	Don't know	10(52.6)	7(36.8)	0(0)	2(10.5)	0(0)	0(0)	
Duration of treatment for new SM+ TB	6 months	195(69.2)	51(18.1)	7(2.5)	19(6.7)	2(0.7)	8(2.8)	0.115
	Other	3(50)	1(16.7)	1(16.7)	0(0)	0(0)	1(16.7)	
Importance of TB treatment	Get well &Stop spread	189(69.2)	48(17.6)	8(2.9)	17(6.2)	2(0.7)	9(3.3)	0.327
	Don't know	7(50)	5(35.7)	0(0)	2(16.3)	0(0)	0(0)	

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Knowledge of TB symptoms and its association with TB treatment outcome was investigated. There was no statistically significant association between the two variables in this study (Table 4.21).

Table 4.21: Association between knowledge on TB symptoms and TB treatment outcomes among TB patients in Nairobi County

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Symptoms of TB	1	55(67.9)	18(22.2)	3(3.7)	4(4.9)	0(0)	1(1.2)	0.246
	2	123(69.6)	31(16.2)	5(2.6)	13(6.8)	2(1.1)	7(3.7)	
	3	0(0)	0(0)	0(0)	1(100)	0(0)	0(0)	
	Don't know	3(42.9)	3(42.9)	0(0)	1(14.3)	0(0)	0(0)	
Duration of suspicious cough	2 weeks	92(64.3)	30(21)	2(1.4)	13(9.1)	2(1.4)	4(2.8)	0.440
	Other	77(72.6)	17(6.0)	4(3.8)	4(3.8)	0(0)	4(3.8)	
	Don't know	21(70)	0(0)	0(0)	2(6.7)	5(16.8)	2(6.7)	

Findings from the study showed that the number of sources of information accessed by the patients had a significant association with treatment outcome (P=0.001, Fisher's Exact Test). Lower Treatment Success rates (68%) were observed amongst patients who indicated having had no access information on TB (Table 4.22).

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Table 4.22: Association between numbers of source of TB information accessed by the patients and TB treatment outcomes among TB patients in Nairobi

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Sources of Information	None	6 (30)	6 (38)	0 (0)	3 (19)	0 (0)	1 (6)	0.001
	1 source	124 (67)	41 (22)	6 (3)	12 (6)	1 (1)	2 (1)	
	≥2 sources	59 (78)	6 (8)	2 (3)	3 (4)	0 (0)	6 (8)	

Analysis of all other aspects of TB general knowledge, diagnosis and treatment revealed no statistically significant associations with treatment outcomes (Table 4.23).

Table 4.23: Association between information accessibility and perceived quality of services by the patient TB and TB treatment outcomes among TB patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1]** Freq. (%)	**TC[2]** Freq. (%)	**TO[3]** Freq. (%)	**OOC[4]** Freq. (%)	**F[5]** Freq. (%)	**D[6]** Freq. (%)	**Fishers Exact Test (P)**
Symptoms of TB	1	77(72)	15(14)	4(3.7)	6(5.6)	2(1.9	3(2.8)	0.285
	2	116(65.9)	38(21.6)	4(2.3)	12(6.8	0(0)	6(3.4)	
	Yes	188(68.4)	52(18.9)	7(2.6)	17(6.2)	2(0.7)	9(3.3)	0.485
	No	9(75)	1(8.3)	1(8.3)	1(8.3)	0(0)	0(0)	

[1] Cured
[2] Treatment completed
[3] Transfer out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Received counselling on diagnosis								
Did it influence decision making	Yes No	185(71.2) 2(50)	44(16.9) 1(25)	7(2.7) 0(0)	14(5.4) 1(25)	2(0.8) 0(0)	8(3.1) 0(0)	0.338
Continuous counselling offered	Yes No	168(66.7) 26(81.3)	49(19.4) 4(12.5)	8(3.2) 0(0)	17(6.8) 1(3.1)	2(0.8) 0(0)	8(3.2) 1(3.1)	0.749
Rate TB Service	Excellent& Good Average &Bad	181(68.6) 14(66.7)	49(18.6) 4(19.1)	8(3) 0(0)	15(5.7) 3(14.3)	2(0.8) 0(0)	9(3.4) 0(0)	0.590

4.5 Directly Observed Therapy (DOT) support

4.5.1 DOT support systems utilized by TB patients

About two-thirds of the participants 187 (64.26%) were conversant with DOT. The family was the preferred choice of DOT support during the intensive phase (201; 69.07) of TB treatment. Thirty-six percent (36%) of the participants were practicing Self-administration of TB drugs (SAT). This was the second most popular mode of TB treatment among the participants despite it not being recognized nor encouraged by the TB treatment guidelines globally. Additional support systems (friends and employers) were mentioned by the participants (Table 4.24).

Table 4.24: Frequency of DOT support systems and Self-administration of TB drugs during intensive phase of treatment among TB patients in Nairobi County.

Type of DOT support System	Frequency (%)	95% CI of proportions
Family	201 (69.07)	63-74
SAT	36 (13.37)	9-17
HCW	18 (6.19)	4-10
Friend	5 (1.72)	0-4
CHCW	3 (1.03)	0-3
Employer	1(0.34)	0-2
Non-Response	27(9.27)	6-13

During the continuation phase of treatment, the family remained the preferred choice of DOT support system utilized by the study participants. There were no reports of the use of employer or friends during the continuation phase as a DOT support system.

4.5.2 Choice of DOT support system

Convenience was one of the reasons indicated by about half of the study participants, (167; 57.39%) to have guided their decision in choosing a specific DOT support system. Table

4.25 shows the frequency distribution of the other factors that influenced the choice of the DOT support system utilized by the study participants.

Table 4.25: Frequency distribution of factors that influenced choice of DOT support systems by TB patients in Nairobi County.

Reason for choosing support system	Frequency (%)
Convenience	167 (57.39)
No alternative	20 (6.87)
Personal responsibility	9 (3.09)
Trust	10 (3.44
Good support	12 (4.12)
Non-response	23 (21.65)

4.5.3 Association between DOT support and TB treatment outcomes

Conversance with DOT, the system of DOT support utilized and the reasons for choosing particular DOT support systems did not exhibit a statistically significant association with TB treatment outcomes (Table 4.26).

Table 4.26: Association between DOT support system variables and TB treatment outcomes among TB patients in Nairobi County

		TB Treatment Outcome						
Independent Variable	Variable Category	**C**[1] Freq. (%)	**TC**[2] Freq. (%)	**TO**[3] Freq. (%)	**OOC**[4] Freq. (%)	**F**[5] Freq. (%)	**D**[6] Freq. (%)	**Fishers Exact Test (P)**
Heard of DOT	Yes	133(71.1)	30(16)	4(2.1)	13(7)	2(1.1)	5(2.7)	0.665
	No	44(66.7)	13(19.7)	3(4.6)	3(4.6)	0(0)	3(4.6)	

[1] Cured
[2] Treatment completed
[3] Transferred out
[4] Out of control/Default/Loss to follow up
[5] Failure
[6] Death

Support system utilized	Family	141(70.2)	36(17.9)	3(1.5)	13(6.5)	2(1)	6(3)	0.458
	SAT	23(63.9)	6(16.7)	3(8.3)	3(8.3)	0(0)	1(2.8)	
	HCW	12(66.7)	4(22.2)	1(5.6)	1(5.6)	0(0)	0(0)	
	Friend	3(60)	0(0)	1(20)	0(0)	0(0)	1(20)	
	CHCW	2(66.7)	1(33.3)	0(0)	0(0)	0(0)	0(0)	
	Employer	1(100)	0(0)	0(0)	0(0)	0(0)	0(0)	

4.6 Institutional level characteristics of facilities

A total of 25 facilities were included in the study. Public facilities accounted for 68% of the facilities. Almost half of the facilities, 12 (48%) were level III (health centres). Diagnostic and treatment services were offered in 21 (84%) of the facilities. Among the institutions offering diagnosis, 20 (80%) indicated that their lab staff had been trained specifically on TB diagnosis protocols. The availability of a specific TB clinic room was reported in 21 (84 %) of the facilities with 20 (84%) indicating that specific HCWs had been allocated to offer TB services. A further 20 (80%) facilities indicated that HCWs had been trained on TB management. Continuous counselling was offered to patients in 23 (92%) of these institutions throughout the treatment period while 19 (76%) reporting that they had enough HCWs to offer DOT support to patients (Table 4.27).

Table 4.27: Summary of Institutional level characteristics of facilities

Institutional Characteristics	**Variable categories**	**Frequency (%)**	**95% CI of proportions (%)**
Nature of facility	Public	17 (68)	46-84
	Private	2 (8)	2-19
	Faith based	6 (24)	11-46
Level per KEPH	II	10 (40)	22-61
	III	12 (48)	28-68
	IV	3 (12)	4-33
Diagnostic and treatment capacity	Treatment only	4 (16)	7-38
	Diagnostic and treatment	21 (84)	62-94
Lab staff trained on TB diagnosis	Yes	20 (80)	58-92
	No	2 (8)	2-29
	Non response	3 (12)	4-33

Availability of specific TB room	Yes	21 (84)	62-93
	No	4 (16)	7-38
Allocation of specific HCW	Yes	21 (84)	62-93
	No	4 (16)	7-38
HCW trained in TB management	Yes	20 (80)	58-92
	No	5 (20)	8-42
Continuous counselling offered to TB patients	Yes	23 (92)	71-98
	No	1 (4)	0-26
	Non Response	1 (4)	0-26
Sufficient staff to offer DOT	Yes	19(76)	54-89
	No	5 (20)	8-42
	Non Response	1 (4)	0-26

4.7 Association between institutional characteristics and TB treatment outcomes

The nature of the facility (Private, faith-based or public) showed a statistically significant association with TB treatment outcome, (P<0.000, Fisher's Exact Test). The highest TSR (94%) was observed in faith-based facilities. The level of the facility as per the KEPH classification similarly showed a statistically significant association with TB treatment outcomes, (P<0.000, Fisher's Exact Test). Diagnostic and treatment capacity, availability of adequate HCWs to offer DOT, availability of a specific TB clinic or TB nurse, training on TB management or diagnosis and offer of continuous counselling or not did not reveal statistically significant relationships (Table 4.28).

Table 4.28: Association between institutional characteristics and TB treatment outcomes among TB patients in Nairobi County.

		TB Treatment Outcome						
Independent Variable	Variable Category	**C[1] Freq. (%)**	**TC[2] Freq. (%)**	**TO[3] Freq. (%)**	**OOC[4] Freq. (%)**	**F[5] Freq. (%)**	**D[6] Freq. (%)**	**Fishers Exact Test (P)**
Nature of facility								<0.000
	Public	148 (74)	24 (12)	6 (3)	17 (9)	0 (0)	5 (3)	
	Private	13 (34)	18 (47)	1 (3)	1 (3)	2 (5)	3 (8)	
	Faith based	39 (73)	11 (21)	1 (2)	1 (2)	0 (0)	1 (2)	
KEPH level	II	76 (55)	43 (31)	6 (4)	6 (4)	2 (1)	6 (4)	<0.000
	III	107 (82)	6 (5)	2 (2)	13 (10)	0 (0)	2 (2)	
	IV	33(71.7)	8(17.4)	1(2.2)	2(4.4)	0(0)	2(4.4)	
Diagnostic and Treatment Capacity	Treatment only	18(60)	6(20)	0(0)	4(13.3)	0(0)	2(6.7)	0.329
	Diagnosis& Treatment	182(69.7)	47(18)	8(3.1)	15(5.8)	2(0.8)	7(2.7)	

[1] Cured
[2] Treatment Completed
[3] Transferred Out
[4] Out of Control/Default/loss to follow up
[5] Failure
[6] Death

Lab staffed trained on diagnosis	Yes No	168(69.4) 16(88.9)	40(16.5) 29(11.1)	8(3.3) 0(0)	16(6.6) 0(0)	2(0.8) 0(0)	8(3.3) 0(0)	0.804
TB-specific room available	Yes No	178(71.2) 22(53.7)	42(16.8) 11(26.8)	7(2.8) 1(2.4)	14(5.6) 5(12.2)	2(0.8) 0(0)	7(2.8) 2(4.9)	0.162
Specific HCW for TB	Yes No	172(68.5) 28(70)	44(17.5) 9(22.5)	8(3.2) 0(0)	17(6.8) 2(5.0)	2(0.8) 0(0)	1(3.2) 192.5)	0.917
HCWs trained on TB	Yes No	167(68.2) 33(71.7)	45(13.4) 8(17.4)	7(2.9) 1(2.2)	17(7.0) 2(4.4)	2(0.8) 0(0)	7(2.9) 2(4.4)	0.960
Continuous counselling	Yes No	188(69.9) 5(83.3)	45(16.7) 1(16.7)	8(3) 0(0)	17(6.3) 0(0)	2(0.7) 0(0)	9(3.4) 0(0)	1.000
Sufficient staff to offer DOT	Yes No	168(70.9) 25(65.8)	41(17.3) 5(13.2)	8(3.4) 0(0)	11(4.6) 6(15.8)	2(0.8) 0(0)	7(3) 2(5.3)	0.131

4.8 Median time to treatment interruption and survival analysis

4.8.1. Median time to default

Out of the 291 patients, 19 (6.5%) interrupted their treatment. The median time to treatment interruption was 56 [95% CI, 36-105] days. Ten (10; 52.6%) of the treatment interruptions occurred within the first two months of treatment.

4.8.2 Association between Socio-demographic characteristics with treatment interruption

The highest level of education reported by the participants showed a statistically significant association with treatment interruption, $\chi 2$ (4.523, 1) $p<0.05$. All other socio-demographic attributes did not reveal a statistically significant association (Table 4.29).

Table 3.29: Association between Socio-demographic characteristics and TB treatment interruption among TB patients in Nairobi County

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	**Treatment interruption**	**χ^2 ,df (P-value)**
Gender	Female	72 (95.95)	4 (4.05)	0.82,1 (0.365)
	Male	200 (92.99)	15(7.01)	
Age	15-24yrs	47(88.68)	6(11.32)	4.38,3 (0.223)
	25-34yrs	127(93.38)	9(6.62)	
	33-44yrs	59(93.65)	4(6.35)	
	45yrs &above	35(100)	0(0)	
Weight[1] (at entry in Kgs)	≤32	5(100)	0(0)	3.48,3 (0.323)
	33-50	99(96.12)	4(3.88)	
	51-70	153(91.62)	4(8.38)	
	≥71	13(100)	0(0)	
Weight (at exit in Kgs)	≤32	6(100)	0(0)	1.83,3 (0.608)
	33-50	59(92.19)	5(7.81)	
	51-70	148(93.67)	10(6.33)	
	≥71	17(100)	0(0)	

[1] Weight groups based on dosing guidelines

Education level	Primary	95 (96.14)	3 (3.06)	8.37,2 (0.015)
	Secondary	130 (89.66)	14 (10.34)	
	Post-Secondary	40 (100)	0(0)	
Have source of income	Yes	196(92.89)	15(7.11)	0.28,1 (0.596)
	No	71(94.67)	4(5.3)	
What source	Employed	86(91.49)	8(8.51)	0.50,1 (0.478)
	Self-Employed	110(94.02)	7(5.98)	
Frequency of payment	Daily	16(84.21)	1(15.79)	4.77, 2(0.092)
	Week	62(95.38)	3(4.62)	
	Monthly	12(80.0)	3(20.0)	
Monthly Income	≤10,000	117(93.60)	8(6.4)	4.39,3 (0.22)
	10,001-20,000	46(86.79)	7(13.21)	
	20,001-30,000	14(100)	0(0)	
	30,0001 & above	7(100)	0(0)	

Smoking during treatment was associated with TB treatment interruption. However, having a history of smoking and was not associated with treatment interruption (Table 4.30).

Table 4.30: Association between smoking and treatment interruption among TB patients in Nairobi County

Characteristics		**TB Treatment Outcome**		
		No. censored Freq. (%)	**Treatment interruption**	**χ^2,df (P-value)**
History of Smoking (Entry)	Yes	123(91.11)	12(8.89)	1.2535,1(0.133)
	No	148(95.48)	7(4.52)	
Last time Smoked (Entry)	1-8 Wks	66(90.41)	7(9.59)	0.1960,2(0.907)
	9-24 Wks	15(93.75)	1(6.25)	
	≥24 Wks	33(91.67)	3(8.33)	
History of Smoking (Exit)	Yes	76(95)	4(5)	0.4476,1(0.503)
	No	167(92.7)	13(7.22)	
Last time Smoked (Exit)	1-8 Wks	6(75)	(25)	5.7496,2(0.056)
	9-24 Wks	40(93.02)	3(6.98)	
	≥24 Wks	22(100)	0(0)	
	Yes	6(75)	2(25)	4.6393,1(0.031)

Smoking on Treatment	No	62(95.38)	3(4.62)	

Continued use of alcohol during treatment displayed a statistically significant association, χ^2 (5.732, 1) $p<0.05$ with treatment interruption (Table 4.31).

Table 4.31: Association between alcohol consumption and treatment interruption among TB patients in Nairobi County

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	**Treatment interruption**	**χ^2,df (P-value)**
History of alcohol use (Entry)	Yes	152(91.02)	15(8.98)	3.6040,1(0.058)
	No	116(96.67)	4(3.3)	
Last time indulged (Entry)	1-8 Wks	84(89.36)	10(10.64)	2.8490,2(0.241)
	9-24 Wks	36(97.3)	1(2.7)	
	≥24 Wks	23(95.83)	1(4.17)	
History of alcohol use (Exit)	Yes	94(93.07)	7(6.93)	0.0226,1(0.880)
	No	145(93.55)	10(6.45)	
Last time indulged (Exit)	1-8 Wks	8(72.73)	3(27.27)	6.0370,2 (0.050)
	9-24 Wks	55(93.22)	4(6.78)	
	≥24 Wks	25(96.15)	1(3.83)	
Alcohol on Treatment	Yes	8(72.73)	3(27.27)	5.7329,1(0.017)
	No	79(94.05)	5(5.95)	

The time utilized by patients to access treatment was not associated with TB treatment outcomes (Table 4.32).

Table 4.32: Association between time taken to access TB treatment and treatment interruption among TB patients in Nairobi County.

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Time to Treatment facility	≤1 hour	233(92.46)	19(7.54)	1.2984,1,(0.255)
	1 hour	16(100)	0(0)	

Adverse reactions to TB treatment and ease-off of TB symptoms during the intensive and extensive phase of treatment did not exhibit a statistically significant association with TB treatment interruption (Table 4.33).

Table 4.33: Association between adverse reaction to TB treatment and ease-off of TB symptoms and Treatment interruption among TB patients in Nairobi County.

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Adverse reaction to TB Treatment (Entry)	Yes	83(95.4)	4(4.60)	0.9553,1(0.328)
	No	178(92.23)	15(7.77)	
Adverse reaction to TB treatment (Exit)	Yes	47(95.92)	2(4.08)	0.5363,1(0.464)
	No	188(93.07)	14(4.08)	
Ease-off of TB symptoms (Entry)	Yes	147(94.84)	8(5.16)	0.0544,1,(0.816)
	No	1(100)	0(0)	
Ease-off of TB symptoms (Exit)	Yes	100(95.24)	5(4.76)	0.5942,1,(0.441)
	No	46(97.87)	1(2.13)	

Co-infection with other chronic diseases among the TB patients was not associated with treatment interruption (Table 4.34).

Table 4.34: Association between co-infection with other chronic illness and treatment interruption among TB patients in Nairobi County

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Co-infection with other chronic disease	Yes	38(88.37)	5(11.63	2.2831,1(0.131)
	No	224(94.51)	13(5.49)	

As assessment of the knowledge on TB transmission did not reveal a statistically significant association with TB treatment interruption (Table 4.35).

Table 4.35: Association between knowledge on TB transmission and treatment interruption among TB patients in Nairobi County.

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
TB diagnostic Method	1 diagnostic method	115(94.26)	7(5.74)	1.2673,1(0.605)
	2 diagnostic method	153(92.73)	12(7.27)	
Does TB signal HIV infection	Yes	13(100)	0(0)	3.1358,2(0.208)
	No	255(93.41)	18(6.59)	
	Don't know	3(75.0)	1(25.0)	
TB treatment free	Yes	267(93.68)	18(6.32)	0.2021,1(0.065)
	No	3(100)	(0)	
Is TB curable	Yes	248(93.94)	16(6.06)	0.8030,2(0.669)
	No	3(100)	0(0)	
	Don't know	17(89.47)	2(10.53)	
Duration of TB treatment (New SM+)	6 months	264(93.29)	19(6.71)	0.4312,1(0.511)
	Other	6(100)	0(0)	

An analysis of knowledge on TB symptoms did not reveal a statistically significant association with TB treatment interruption (Table 4.36).

Table 4.36: Association between knowledge on TB symptoms and treatment interruption among TB patients in Nairobi County.

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Symptoms of TB	1 Symptom	86(93.48)	6(6.52)	0.1254,3(0.986)
	2 Symptoms	31(93.94)	2(6.06)	
	3 Symptoms	1(100)	0(0)	
Duration of suspicious cough	2 weeks	130(90.910	12(0.09)	2.773,2(0.250)
	Other	103(96.26)	4(3.74)	
	Don't know	28(93.33)	2(6.67)	

A look into the association between information accessibility, TB services, and treatment interruption did not reveal a significant association (Table 4.37).

Table 4.37: Association between information accessibility, TB services and treatment interruption among TB patients in Nairobi County

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Hear about MDR TB	Yes	101(94.39)	6(5.61)	0.1544,1(0.694)
	No	165(93.22)	12(6.78)	
Sources of Information	1 source	105(92.92)	8(7.08)	1.8756,2(0.39)
	2 sources	24(96)	1(4)	
	3 sources	49(98)	1(2)	
Counselling upon diagnosis	Yes	259(93.84)	17(6.16)	0.0928,1,(0.761)
	No	11(91.67)	1(8.33)	
	Yes	247(94.64)	14(5.36)	2.8446,1(0.092)

Did counselling influence decision making	No	3(75)	1(25)	
Continuous counselling offered	Yes No	236(93.28) 31(96.88)	17(6.72) 1(3.13)	0.6203,1(0.431)
Rate TB Services	Excellent/good Average/bad	250(94.34) 18(85.71)	15(5.66) 3(14.29)	2.4546,1,(0.117)

Analysis of conversance with DOT support system did not reveal a statistically significant relationship with TB treatment interruptions (Table 4.38).

Table 48: Association between conversance with DOT and treatment interruption among TB patients in Nairobi County.

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2 ,df (P-value)
Conversant with DOT	Yes	175(93.09)	13(6.91)	0.4647,1,(0.495)
	No	63(95.45)	3(4.55)	

Amongst the institutional variables, statistically significant associations were observed between perceived availability of adequate HCWs to offer DOT support, $\chi 2$ (8.001, 1) $p<0.05$ and whether the facility offering the treatment was public, private or faith-based, $\chi 2$ (4.0350, 1) $p<0.05$. The other patient-level and institutional level factors investigated did not exhibit statistically significant associations with treatment interruption (Table 4.39).

Table 4.39: Association between institutional-level characteristics and treatment interruption among TB patients in Nairobi County

Characteristics		TB Treatment Outcome		
		No. censored Freq. (%)	Treatment interruption	χ^2,df (P-value)
Nature of facility	Public	184(91.54)	17(8.46)	4.0350,1 (0.045)
	Non-Public	89(97.80)	2(2.20)	
Level in KEPH	II	134(95.71)	6(4.29)	5.2740,2,(0.072)
	III	117(90)	13(10)	
	IV	21(100)	0(0)	
Diagnostic & Treatment capacity	Diagnostic &Treatment	247(94.27)	15(13.33)	2.5612,1,(0.110)
	Treatment only	25(86.67)	4(13.33)	
Lab staffed trained on TB	Yes	227(93.42)	16(6.58)	1.2626,1,(0.261)
	No	18(100)	0(0)	
Specific TB room available	Yes	236(94.42)	14(5.58)	2.5369,1,(0.111)
	No	36(87.80)	5(12.20)	
Specific HCW for TB	Yes	234(93.25)	17(6.75)	0.1730,1,(0.677)
	No	38(950	2(5.0)	
HCWs trained in TB management	Yes	228(93.09)	17(6.91)	0.4184,1,(0.518)
	No	44(95.65)	2(4.35)	
Continuous counselling offered	Yes	253(93.70)	17(6.30)	0.4026,1(0.526)
	No	6(100)	0(0)	
Sufficient staff for DOT	Yes	227 (95.8)	10 (4.2)	8.005,1 (0.005)
	No	32 (84.2)	6 (14.8)	

4.8.3 Kaplan-Meier failure estimates within patient-level categories

The probability of default during the follow-up grouped according to the highest level of education showed a significant difference in failure curves (log-rank test; $\chi 2=8.07$, 2, $P<0.0177$) shown in Figure 4.1.

Similarly, the probability of failure curves for use/non-use of alcohol during treatment showed a significant difference (log-rank test; $\chi 2=5.69$, 1, $P<0.0170$) displayed a significant difference (Figure 4.2). Lastly, the probability of failure curve for smoking/not smoking during treatment showed a significant difference (log-rank test; $\chi 2=4.71$, 1, $P<0.03$). The probability of failures curves (Figure 4.3).

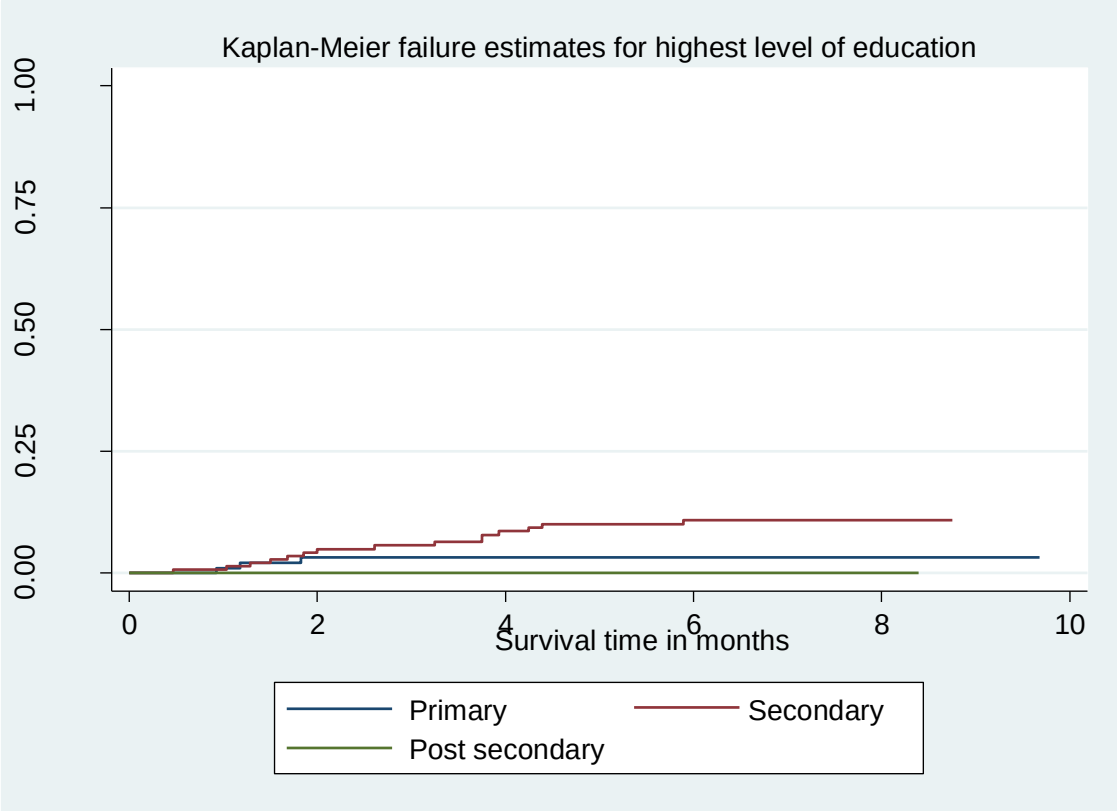


Figure 4.1: Kaplan-Meier failure estimates for highest level of education among TB patients in Nairobi County.

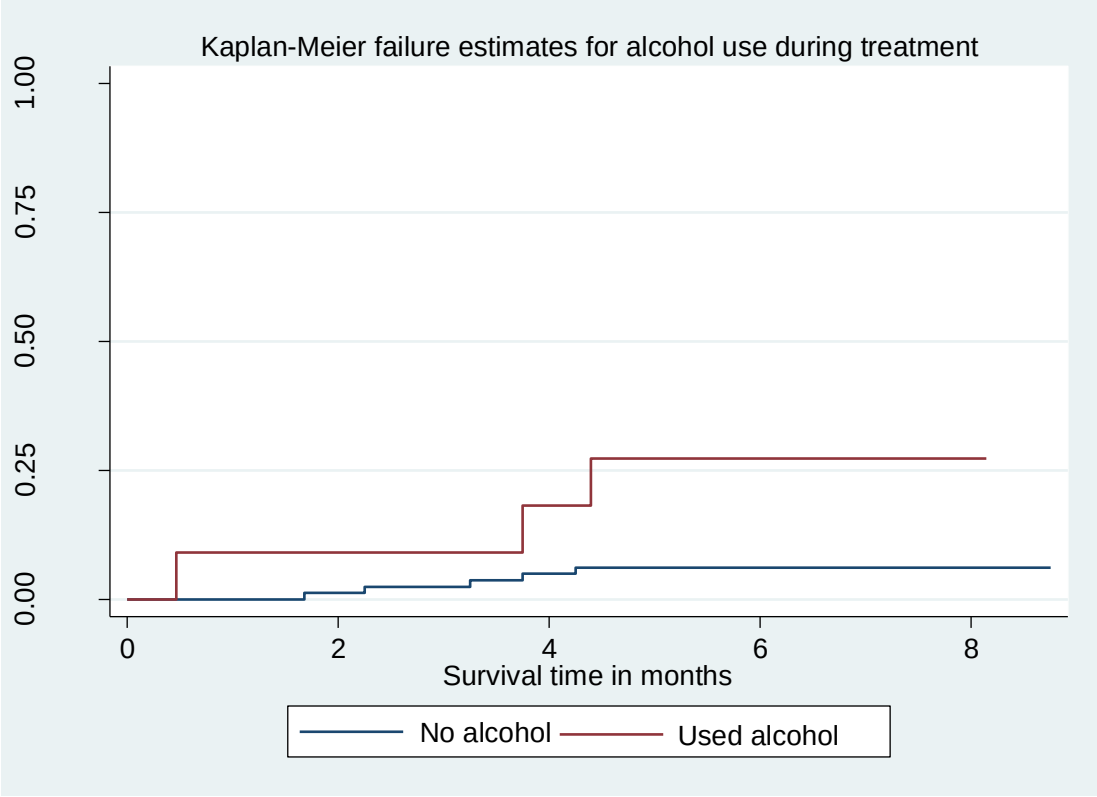


Figure 4.2: Kaplan-Meier failure estimates for alcohol use during treatment among TB patients in Nairobi County.

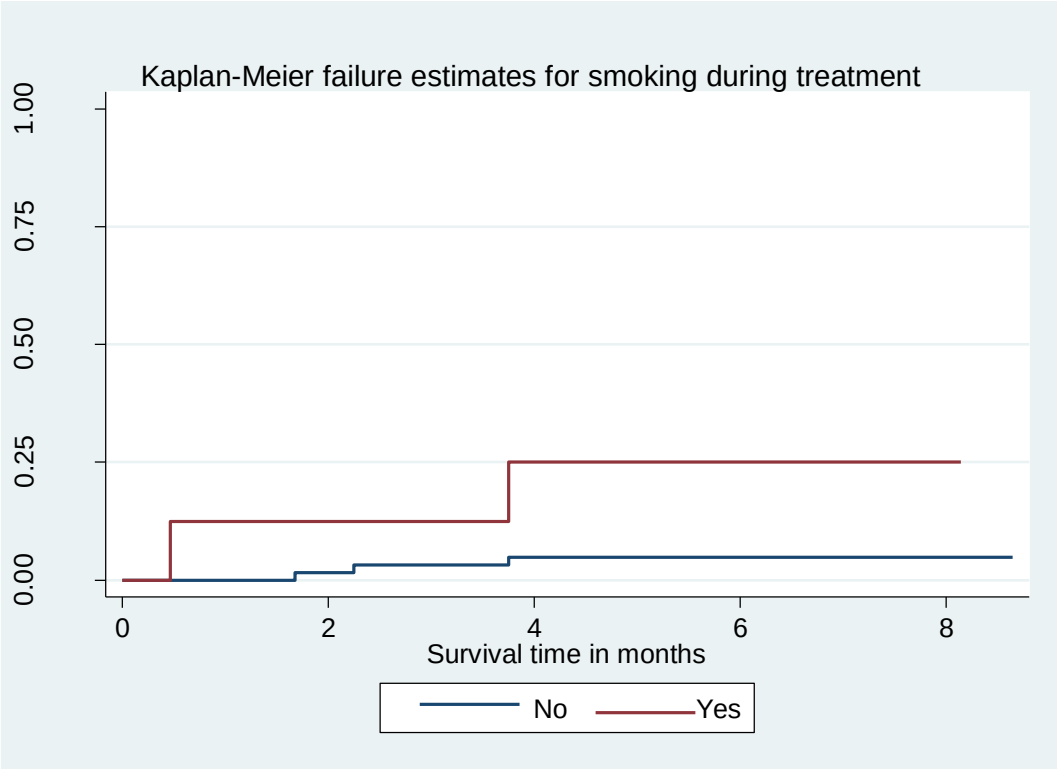


Figure 4.3: Kaplan-Meier failure estimates for smoking during treatment among TB patients in Nairobi County.

Of the institutional factors, failure curves for perceived availability/lack of adequate HCWs to offer DOT showed a significant difference (log-rank test; $\chi 2=8.26$, 1 P=0.0041) shown in Figure 4.4. Additionally, failure curves on receiving treatment in a public/non-public facility displayed a statistically significant difference (log-rank test; $\chi 2=3.94$, 1, P=0.0472) (Figure 4.5).

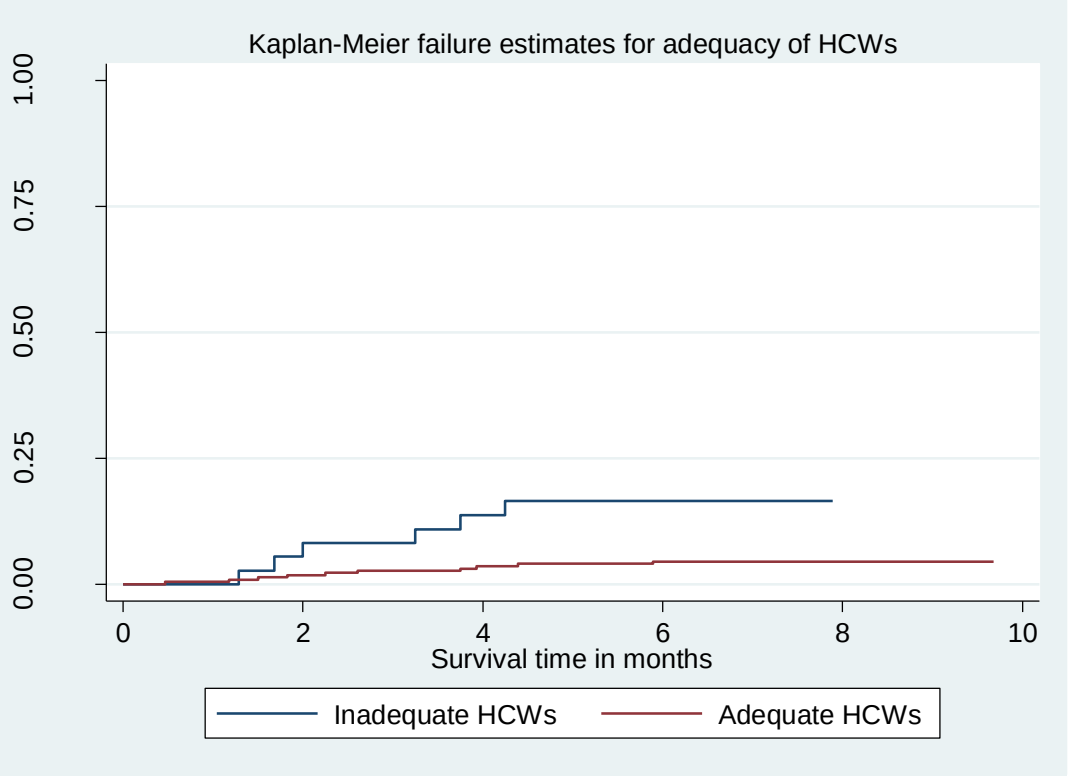


Figure 4.4: Kaplan-Meier failure estimates for perceived adequacy of HCWs in TB treatment facilities in Nairobi County.

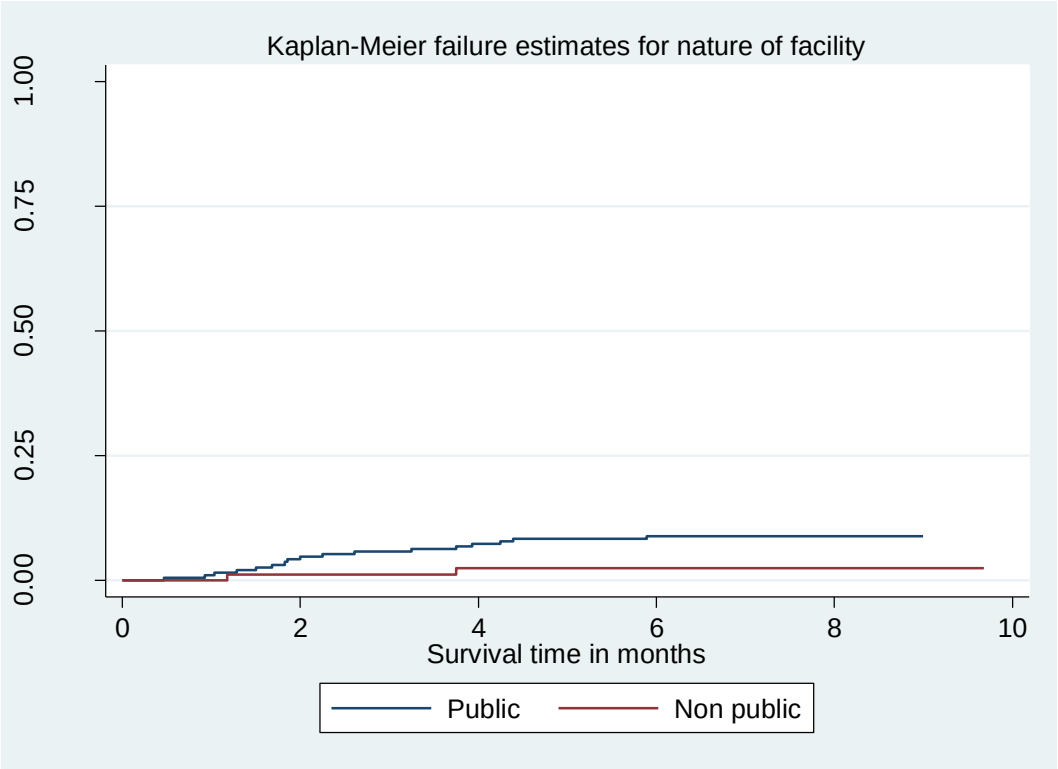


Figure 4.5: Kaplan-Meier failure estimates for nature of TB treatment facilities in Nairobi County

During the entire treatment period, the cumulative probability of failure amongst patients with secondary level education was 0.1075 (95% CI 0.0662-0.1720) while those with primary level education had 0.0315 (95% CI 0.0103-0.0945). This translates into a 3-fold increase in cumulative risk for treatment interruption amongst patients with secondary level education when compared to those with primary level education. Similarly, continued use of alcohol during treatment showed a higher cumulative probability of failure 0.2727 (95% CI 0.0972-0.6292) when compared to patients who did not use alcohol during treatment 0.0266 (95% CI 0.0260-0.1413). This represented a 4-fold increase in risk for treatment interruption among patients who continue to use alcohol during TB treatment.

Patients who continued smoking during treatment had a higher cumulative probability of failure 0.255 (95% CI 0.061-0.6852) when compared to patients who were not smoking during treatment and who had a cumulative probability of failure of 0.048 (95% CI 0.0157-0.1415). This translates to a 5-fold increase in cumulative risk for treatment interruption among patients who continue smoking during TB treatment.

4.8.5 Institution-level factors and risk for treatment interruption

Facilities perceived to have an inadequate staff to offer DOT support had a higher cumulative probability of failure 0.1646 (95% CI 0.0775-0.3304) compared to facilities perceived to have adequate staff 0.0443 (95% CI 0.0241-0.0807). This translates to a 3.7-fold increase in risk for treatment interruption in facilities perceived to have fewer HCWs. Public facilities had a higher cumulative probability of treatment interruption 0.0879 (95% CI 0.0555-0.1375) compared to private-for-profit and Faith-based 0.0231 (95% CI 0.0058-0.0893). This shows a 3.8-fold increase in risk for treatment interruption among patients treated in public facilities when compared to their counterparts in non-Public facilities.

4.8.6 Predictors of treatment interruption

Univariable Cox-Proportional Hazard analysis showed patients that continued alcohol consumption during treatment had a much higher hazard compared to those who did not engage in alcohol consumption. Similarly, patients who reported a secondary level as the highest level of education had an increased hazard when compared to their primary level counterparts. Additionally, patients treated in facilities with perceived availability of adequate HCWs to offer DOT support had a lower hazard for treatment interruption. Similarly, patients treated in private-for-profit and faith-based facilities had a lower hazard when compared to their counterparts in public facilities. (Table 4.40).

Table 4.40: Univariable cox proportional hazard analysis of factors associated with TB treatment interruption among TB patients in Nairobi County

Univariable				
Variable	**Hazard Ratio (95% CI)**	**Z-Stat**	**p>|z| Value**	**LR[1] χ^2,df, p-value**
Public vs. non-public	. 253 (0.0585-1.097)	-1.84	0.066	4.77,1,(0.0289)
Adequate vs Inadequate HCWs	. 253 (0.0919-0.697)	-2.66	0.008	5.97,1,(0.0146)
Primary vs Secondary	3.42 (0.99-11.815)	1.94	0.052	4.82,1,(0.0281)
Alcohol use during treatment	4.82 (1.152-20.178)	2.15	0.031	3.79,1,(0.050)
Smoking during treatment	5.73 (0.957-34.291)	1.91	0.056	2.97,1,(0.0846)

Nature of facility, adequacy of HCWs and the highest level of education were included in the multivariable analysis. Alcohol use during treatment and smoking during treatment were excluded from the model due to low patients consuming alcohol and smoking during treatment. Patients treated in private for-profit and faith-based facilities had lower hazard. This was similar for patients treated in facilities perceived to have adequate HCWs to offer DOT support. On the contrary, patients with secondary level education had a higher hazard (Table 4.41).

[1] Likelihood Ratio

Table 4.41: Multivariable cox proportional hazard analysis of factors associated with TB treatment interruption among TB patients in Nairobi County

	Multivariable			
Variable	**Adjusted Hazard Ratio (95% CI)**	**Z-Stat**	**p>|z| Value**	**χ^2 ,df, p-value**
Public vs. non-public	.210 (0.046-0.952)	-2.02	0.043	17.37,2,(0.0006)
Adequate vs Inadequate HCWs	.195 (0.068-.0.561)	-3.03	0.002	
Primary vs Secondary	5.28 (1.183-23.585)	2.18	0.029	

CHAPTER FIVE

DISCUSSION,CONCLUSION & RECCOMENDATIONS

5.1 Discussion

5.1.1 Aggregate treatment outcome

In this study, a treatment success rate of 86% was observed. This was lower than the treatment success rate reported countrywide by the NTLD program for new TB cases reported at 89 % for the 2014 cohort (NTLD, 2015). The national TB program has, however, highlighted an increase in deaths among cases of pulmonary TB. This authenticates the low treatment success rate observed in the study that only involved SM+ TB cases (NTLD, 2015).

5.1.2 Factors associated with TB treatment outcome

5.1.2.1 Highest level of education

The highest level of education attained by the study participants showed a statistically significant association with TB treatment outcomes. Patients with post-graduate qualifications posted the best treatment success rates at 92% which is higher than the national average. The level of education has been associated with successful treatment outcomes among bacteriologically confirmed TB cases in Turkey where young people with higher levels of education posted higher treatment success rates (Sengul *et al*., 2015). Illiteracy and lower levels of education have been identified as a risk factor for unsuccessful treatment outcomes in Malaysia among new sputum smear-positive TB patients (Atif *et al*., 2014; Liew *et al*., 2015). Lower treatment success rates have been reported in Somalia amongst patients who were considered illiterate having received religious education only (Marian *et al*., 2017). This study supports observed trends with regards to the level of education and its association with tuberculosis treatment outcomes. This could be attributed to improved understanding of consequences resulting from non-adherence to TB treatment hence improved health-seeking behaviors. Of interest in this

study though is the fact that patients who had moderate education having attained secondary level education performed worst with the lowest treatment success rates and accounted for more than 50% of all the treatment interruption observed. Inappropriate health-seeking behaviors have been reported amongst patients with secondary level education in Nigeria as they preferred self-treatment and seeking medical care from medicine vendors (Latunji & Akinyemi, 2018). This has also been reported in Ghana where a patient with secondary education was less likely to seek care in a health facility (Kuuire *et al*., 2016).It is advisable to further investigate this phenomenon as the results point towards the existence of a higher risk group previously overlooked.

5.1.2.2 Infection with other chronic disease

Co-infection with a different chronic disease presents major challenges to TB patients. In this study, patients who reported having another chronic infection posed lower treatment success rates(72.1%) when compared to their counterparts who were not afflicted by another chronic infection(TSR;89.4%). This is consistent with results observed in Ghana, in which TB/HIV co-infected patients had lower TSR and higher mortality rates (Ogyiri *et al*., 2019). In Zambia, TB/HIV patients showed a higher odds of unfavorable treatment outcome (Nanzaluka *et al*., 2019). Diabetes, liver diseases, renal failure, hepatitis, and silicosis are other co-infections that have been documented to be associated with unsuccessful TB treatment (Azeez *et al*., 2018). Co-infection for TB patients in an ongoing challenge with reported drug-drug interactions, toxicities and the emergence of drug resistance despite adherence (Narendran & Swaminatha, 2016). Other than biological interactions the need to follow two or more treatment regimens can be exhaustive and discouraging for a patient. Such challenges could influence patients' adherence to TB treatment and in turn affect the treatment outcomes. Co-infected patients need special attention, more support, and close monitoring when undergoing TB treatment to increase the chances of successful treatment.

5.1.2.3 Patient access to information on Tuberculosis

Patient knowledge on tuberculosis is important as it influences decision making by the patients with regards to the treatment of the disease. In this study access to information on TB was significantly associated with treatment outcome**.** Low treatment success rate (76%), was observed amongst TB patients who indicated that they did not receive or have access to information on Tuberculosis. Access to information is important in improving patients' knowledge about TB (Freitas *et al*., 2015). It has been shown that patients with poor knowledge of tuberculosis had a higher risk of having adverse treatment outcomes compared to those with good knowledge (Fatiregun *et al*., 2009). Good knowledge of TB has been identified as a protective factor against loss to follow-up which can also adversely affect TB treatment outcomes (Tupasi *et al*., 2016). The inability to recognize TB symptoms, a result of a lack of knowledge on tuberculosis, has been reported as one of the reasons for the delay in seeking TB treatment (Samal, 2016). It is of utmost importance for the TB program to establish a standardized information package that will be availed to all newly diagnosed TB patients. This will ensure that all patients diagnosed with TB have the basic knowledge of Tuberculosis diagnosis, prevention, and treatment. As a consequence, the patients will be in a position to make informed decisions regarding their treatment.

5.1.2.4 Nature of facility

Public, private and faith-based facilities offering TB treatment were included in the study and showed a statistically significant association to TB treatment outcome. Faith-based facilities posted the best treatment success rates at 91 % while private for-profit facilities posted the worst treatment success rates at 81 %. The varying nature of treatment success rates in the study could be attributed to many factors. TB treatment is based on the DOT strategy, which majorly relies on community-based volunteers offering support to TB patients associated with lower costs (WHO, 2003). This strategy does not align with the objectives of for-profit health service providers. On the contrary, faith-based facilities are founded on a subsidized, volunteer-based and cost-effective approach to health service provision (WHO, 2003). The workers in these facilities may be more willing to engage in not-for-profit interventions that contribute to the overall achievement of treatment success. In Nigeria, private-for-profit service providers are reported to diagnose and treat TB patients inappropriately which has often led to poorer treatment outcomes (Dosumu *et al*., 2008; Okeke *et al*., 2006). Supervision of for-profit service providers by the national program for strict adherence to TB treatment guidelines needs to be further investigated to establish the level of conformance to these guidelines. The need to make a profit should not compromise on the quality of services offered to TB patients which can contribute to low treatment success rates.

5.1.2.5 Level of facility according to KEPH classification

Kenyan Health facilities are classified according to KEPH guidelines and showed statistically significant association with treatment outcomes. Level II, III and IV facilities were included in the study. The staffing levels both in number and capacity varied between these levels. This is a localized classification system and hence has not been studied extensively worldwide. It is key to note that Level II facilities in Kenya, post the best treatment outcomes according to the National TB program data. In this study, level II and level II had almost similar treatment success rates differing by only a single percentage point. However, it is good to note that more than 50% of the treatment interruptions occurred in level III facilities. This could be attributed to the presence of a consistent HCW at level II facilities allowing for the development of a personal relationship between the HCW and the TB patients over time. On the contrary, level III and IV, tend to have rotational schedules for HCWs workers which do not allow for the formation of these personal relations with the patients due to familiarity. The non-clinical benefits accrued from the establishment of a personal relationship between the HCW and the TB patient are missed in these other two levels. The national TB program will need to consider recommending the appointment of specific HCWs in each facility to offer TB services consistently. With this approach, HCWs can develop familiarity with patients and further advise them accordingly along their treatment journey towards attaining successful treatment.

5.1.3 Frequency of treatment interruption

In this study, 6.5% of the new SM+ TB patients interrupted their treatment. In Kenya, treatment interruption rates of 4.5% and 8.5% have been reported amongst new and retreatment TB patients' respectively (Masini *et al* 2016). According to NTLD 2015 report, the country's treatment interruption rates were 4.3% for new cases and 3.4 % for retreatment cases (NTLD, 2015). Other studies reported treatment interruption rates of 7.2 % among PTB patients in South Africa (Kigozi *et al*., 2017) and 8.9% in Ethiopia (Zenebe *et al*., 2016) When all forms of TB are considered, reported treatment interruption rates of 11.1% (Gebrezgabiher *et al*., 2016) in Ethiopia, 7.4 % in India (Vasudevan *et al*., 2014) and 11.5% in Kuwait (Zhang *et al*., 2014) have been made. There is a variation in treatment interruption rates between and within countries. These variations could be attributed to the status of TB control programs within the study regions in-country and between countries. Nairobi County specifically has been reported to have a higher treatment interruption risk than the national average (Masini *et al.,* 2016) and this is consistent with the observed results . Therefore different approaches might be required to tame treatment interruption, tailored to specific regional needs. Of great focus might also be behavioral patterns and health-seeking behaviors of persons living in Nairobi. Additionally, adjusting timings for public health care service delivery to accommodate persons living in Nairobi county who consist of workers occupied between 8 am-5 pm might be needed. These work schedules coincide with the public facility service delivery timings locking them out of these services.

5.1.4 Time to treatment interruption

The median time to default was 56 days with the majority of the patients defaulting during the transitory phase between intensive and continuation phases of treatment. The results were consistent with the reported increase in risk for treatment interruption during intensive phase treatment in Kenya (Masini *et al*., 2016). Similar results have been observed in India in which up to 40% of defaults occurred during the same period (Vasudevan *et al*., 2014). In Kuwait, 56% of treatment interruption was observed within the first two months of treatment (Zhang *et al*., 2014). In Moldova, the median time to default was 110 days and the highest risk was observed in the month immediately after the intensive phase of treatment (Jenkins *et al*., 2013). There is a need to address individual and health system changes occurring during the transition phase of treatment to institute appropriate measures that would reduce loss to follow up during this period. These measures should be put in place immediately the patients begin TB treatment as the risk for interruption is highest within the first two months.

5.1.5 Factors associated with treatment interruption

5.1.5.1 Highest level of education

There was a significant association between highest level of education attained by the patients and TB treatment interruption. A three-fold increase in cumulative risk for TB treatment interruption was observed amongst patients with secondary level education when compared to those with primary level education. The findings in this study therefore present a possible presence of a high risk group previously not considered. Further investigation into attitudes and health seeking behaviours in this category of patients need to be evaluated to understand the reason for increased risk in this group. There were no reported treatment interruptions among patients who reported attainment of post-graduate level of education.

5.1.5.2 Alcohol use during treatment

A statistically significant association was observed between continued alcohol use and treatment outcomes. Patients who continued alcohol use during treatment had a 4-fold higher cumulative risk of treatment interruption compared to those who did not consume alcohol. New cases with alcoholism and drug addiction have been shown to have an increased risk of defaulting (Jenkins *et al*., 2013; Raviglione *et al*., 2017). In this study majority of study participants with a history of alcohol use, stopped alcohol consumption during TB treatment. Alcohol use impairs mental capability and this interferes with decision-making capacity including adherence to TB treatment. There has been a call to action to address alcohol use and abuse to achieve optimal results in TB prevention and treatment (Finlay *et al*., 2012). Patients who continue to use alcohol during TB treatment should be considered high risk for treatment interruption. Hence, the need to come up with a closer follow up system to ensure that they complete their treatment regimens. A similar significant association with observed amongst patients who continued smoking during treatment with a five-fold increase in risk for treatment interruption. However further analysis did not identify smoking during treatment as a possible predictor of treatment interruption.

5.1.5.3 Availability of adequate health care workers

Perceived inadequacy of HCWs to offer DOT was identified as a risk factor for treatment interruption. There was a 3-fold increased cumulative risk for treatment interruption among patients treated in facilities that were perceived to have inadequate HCWs to offer DOT compared to facilities that reported the availability of adequate HCWs to provide DOT support. A functional health system requires sufficient health workers, equitably distributed to improve coverage and accessibility of health care. The need for adequate healthcare workers with the right skills cannot be overemphasized as a requirement for achieving health goals in a population. There is limited literature published about HCW staffing levels and TB treatment outcomes. There is an urgent need to rigorously evaluate the importance of adequate staffing to provide evidence in designing optimal TB treatment

guidelines. The results are supportive of the highlighted need for strategies to transform health workforce capabilities to achieve the target to end TB (WHO, 2016).

5.1.5.4 Nature of facility

Tuberculosis treatment is offered in public and non-public facilities in Kenya. The nature of the facility offering treatment showed a statistically significant association with treatment interruption. Patients who received treatment in public facilities had a 3-fold cumulative risk for treatment interruption when compared to those who received treatment in non-public facilities. Similar results were reported in Nigeria where receiving treatment at a public facility was a predictor of unsuccessful treatment outcomes (Ukwaja *et al*., 2016). While there has been no evidence to show that there are better clinical services in non-public facilities, patients in private facilities reported better interpersonal satisfaction attributed to longer consultations times and higher chances of receiving counseling (Hazarika, 2011; Rannan-Eliya *et al*., 2015). It might, therefore, be important that TB treatment facilities or clinic days be increases to decrease congestion, reduce waiting times and allow HCWs not to rush consultations due to pressure to see all the patients. In Kenya, public health facilities are known to be well-stocked with TB tracer commodities to provide TB services (SARAM, 2013). There is a need to determine whether patient interpersonal satisfaction over and above sufficient clinical services is a risk factor to TB treatment interruption.

5.2 Conclusion

- The research identified the achievement of secondary level education as a risk factor for the achievement of treatment success. The presence of other chronic diseases resulted in lower treatment success rates whilst access to multiple sources of TB information resulted in positive treatment outcomes.
- DOT support system attributes were not associated with TB treatment outcomes.
- The study revealed that the nature of the facility and level per KEPH classification were significantly associated with TB treatment outcomes. Being treated in a public facility increased the risk of non-cure while patients treated in level II facilities had a higher treatment success rate.
- The median time to default was 56 (95% CI 36-105) days. TB treatment interruption was found to be associated with the highest level of education attained by the patient, alcohol consumption and smoking during treatment, perceived availability of sufficient staff to offer DOT services and the nature of the facility offering TB treatment. An increased risk was observed amongst patients who had achieved secondary education as the highest level of education, those who consumed alcohol, patients who smoked during treatment, patients treated in public facilities and facilities perceived to have inadequate HCWs to offer DOT.

5.3 Recommendations

- Newly diagnosed patients should be assessed based on the patient-level factors associated with TB treatment outcome and special measures instituted for those considered to be high-risk for adverse treatment outcomes. These include patients who indicate secondary as the highest level of education, those with co-infection and those with a limited to sources of information on TB.
- There is a need to adopt non-clinical services like the development of interpersonal relations with specific HCWs, allowance of amble consultation times in the facilities and reduced waiting times appreciated by the patient to complement the clinical services that are otherwise optimized in the country. The national TB

program will need to devise ways to supervise the different service providers to ensure that TB management guidelines are strictly adhered to and no compromises in quality are encountered

- With specific regards to treatment interruption, precautionary measures need to be put in place for patients who continue alcohol use during TB treatment to prevent treatment interruption. Health system management changes occurring during the transition between intensive and continuation phases of treatment need to be evaluated to determine the reason for increased treatment interruption during that period of treatment.

5.4 Areas for further research

- Investigate health-seeking behaviors among patients who indicate secondary school as the highest level of education and patients co-infected with other chronic diseases.
- There is a need to understand factors that contribute to the high treatment interruption observed during the transition between the intensive phase and the continuation phase of treatment.

5.5 Limitation of the study

- The study assumed that all the patients recruited into the study were residents of Nairobi County
- The standard definitions used in the study are adopted from WHO guidelines. Deaths are defined as any patient who dies during TB treatment which can be true or not.
- Most of the data collected relied on self-reporting.

REFERENCES

Ahmed, J., Chadha, V. K., Singh, S., Venkatachalappa, B., & Kumar, P. (2009). Utilization of RNTCP services in rural areas of Bellary District, Karnataka, by gender, age and distance from health centre. *Indian Journal of Tuberculosis*, 56, 62-8.

American Thoracic Society. (1990). Diagnostic Standards and Classification of Tuberculosis. *American Review of Respiratory Disease*, 142,725-35.

Amuha, G. M., Kutyabami, P., Kitutu, F. E., Odoi-Adome, R. & Kalyango, J. N. (2009). Non-adherence to anti-TB drugs among TB/HIV co-infected patients in Mbarara Hospital Uganda; prevalence and associated factors. *African Health Sciences*, 9 (1).

Anuwatnonthakate, A., Limsomboon, P., Nateniyom, S., Wattanaamornkiat, W., Komsakorn, S., Moolphate, S., ... & Mock, P. A. (2008). Directly observed therapy and improved tuberculosis treatment outcomes in Thailand. *PLoS One*, *3*(8), e3089.

Atif, M., Sulaiman, S. A., Shafie, A. A., Ali, I., Afif, M., and Babar, Z. (2014). Treatment outcome of new smear positive pulmonary tuberculosis patients in Penang, Malaysia. *BMC Infectious Diseases*, 14:399.

Azeez, A., Ndege, J., & Mutambayi, R. (2018). Associated factors with unsuccessful tuberculosis treatment outcomes among tuberculosis/HIV coinfected patients with drug-resistant tuberculosis. *International Journal of Mycobacteriology*, 7(4), 347.

Bam, T. S., Gunneberg, C., Chamroonsawasdi, K., Bam, D. S., Aalberg, O., Kasland, O., ... & Srisorrachatr, S. (2006). Factors affecting patient adherence to DOTS in urban Kathmandu, Nepal. *The International Journal of Tuberculosis and Lung Disease*, *10*(3), 270-276.

Behr, M. A., Edelstein, P. H., & Ramakrishnan, L. (2018). Revisiting the timetable of tuberculosis. *BMJ*, 362-k2738.

Belo, M.T.C.T., Luiz, R. R., Teixeira, E.G., Hanson, C., & Trajman, A. (2011). Tuberculosis treatment outcomes and socio-economic status: a prospective study

in Duque de Caxias, Brazil; *International Journal of Tuberculosis and Lung Disease*, 15(7), 978-981.

Burton, N. T., Forson, A., Lurie, M. N., Kudzawu, S., Kwarteng, E., & Kwara, A. (2011). Factors associated with mortality and default among patients with tuberculosis attending a teaching hospital clinic in Accra, Ghana. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 105, 675-682.

Cadmus, S.I, Yakubu, M. K., Magaji, A.A., Jenkins, A. O., & van Soolingen, D. (2010). Mycobacterium Bovis, but also mycobacterium africanum present in raw milk of pastoral cattle in north central Nigeria. *Tropical Animal Health and Production*, 42(6), 1047-8.

Cancik, J.A., & Mazepova, N. (1925). Direct Cultivation of the mycobacterium tuberculosis. *American Journal of Public Health* (NY), 15(8), 679-80.

Chang, K. C., Leung. C. C., & Tam, C., M. (2004). Risk factors for defaulting from anti-tuberculosis treatment under directly observed treatment in Hong Kong. *International Journal of Tuberculosis and Lung Disease*, 8, 1492– 1498.

Chiang, C. Y., Lee, J. J., Yu, M. C., Enarson, D. A., Lin, T. P., & Luh, K. T. (2009). Tuberculosis outcomes in Taipei: factors associated with treatment interruption for 2 months and death. *International Journal of Tuberculosis and Lung Disease*, 13(1), 105-111.

Chung, W. S., Chang, Y. C., & Yang, M.C. (2007). Factors influencing the successful treatment of infectious pulmonary tuberculosis. *International Journal of Tuberculosis and Lung Disease*. 11(1), 59-64.

Corbett, E. L., Watt, C.J., Walker, N., Maher, D., Williams, B.G., Raviglione, M.C., & Dye, C. (2003). The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 163(9), 1009–1021.

Daniel, W.W. (1999). Biostatistics A foundation for analysis in the health sciences. 7th Edition, John Wiley & Sons, Inc., Hoboken.

David, J. & Masahiro, N. (2018). Extra pulmonary TB approach. *BMJ Best Practice*.

Dean, G. L., Edwards, S. G., Ives, N. J., Matthews, G., Fox, E. F., Navaratne, L., ... & de Ruiter, A. (2002). Treatment of tuberculosis in HIV-infected persons in the era of highly active antiretroviral therapy. *Aids*, *16*(1), 75-83.

Division of Leprosy, Tuberculosis and Lung Disease. 2009. DLTLD Kenya Annual Report. Nairobi, Kenya.

Division of Leprosy, Tuberculosis and Lung Disease. 2010. DLTLD Kenya Annual Report. Nairobi, Kenya.

Division of Leprosy, Tuberculosis and Lung Disease. 2013. DLTLD Guidelines on management of Leprosy and Tuberculosis. DLTLD. Nairobi, Kenya.

Division of Leprosy, Tuberculosis and Lung Disease. 2015. NTLD Kenya Annual Report. Nairobi, Kenya.

Division of Leprosy, Tuberculosis and Lung Disease .2016. NTLD Kenya Annual Report. Nairobi, Kenya.

Division of Leprosy, Tuberculosis and Lung Disease. 2017. NTLD Kenya Annual Report. Nairobi, Kenya.

Dooley, S.W., Castro, G.K., Hutton, D. M., Mullan, J.M., Polder, A. J., & Snider, E.D. (1990). Guidelines for preventing transmission of Tuberculosis in Health-care settings, with special Focus on HIV-Related Issues. *Morbidity and Mortality Weekly Report*, 39(RR-17), 1-29.

Dosumu, E.A. (2008).Survey of knowledge, attitudes, and practices regarding tuberculosis among general and private medical practitioners in Nigeria. *African Journal of Respiratory Medicine*, 17–9.

Dowdy, D. W., Grant, A. D., Dheda, K., Nardell, E., Fielding, K., & Moore, D. A. (2017). Designing and evaluating interventions to halt the transmission of tuberculosis. *The Journal of infectious diseases*, *216*(suppl_6), S654-S661.

Duarte, E.C., Bierrenbach, A.L., Barbosa da Silva Jr, J., Tauil, P. L., & Duarte, E. F. (2009). Factors associated with deaths among pulmonary tuberculosis patients: a case–control study with secondary data. *Journal of Epidemiology and Community Health*, 63:233-238.

Fatiregun, A. A., Ojo, A. S. & Bamgboye, E. (2009). Treatment outcomes among pulmonary tuberculosis patients at treatment centers in Ibadan, Nigeria. *Annals of African Medicine*, 8(2), 100-104.

Feng, J. Y., Su, W. J., Chiu, Y. C., Huang, S. F., Lin, Y. Y., Huang, R. M., ... & Yu, K. W. (2011). Initial presentations predict mortality in pulmonary tuberculosis patients-a prospective observational study. *PLoS One*, *6*(9), e23715.

Finlay, A., Lancaster, J., Holtz, T. H., Weyer, K., Miranda, A. & Walt, M. V. (2012). Patient-and provider-level risk factors associated with default from tuberculosis treatment, South Africa, 2002: a case-control study. *BMC Public Health*, 12 (1).

Freitas, I. M. D., Popolin, M. P., Touso, M. M., Yamamura, M., Rodrigues, L. B. B., Neto, M. S., … & Arcêncio, R. A. (2015). Factors associated with knowledge about tuberculosis and attitudes of relatives of patients with the disease in Ribeirão Preto, São Paulo, Brazil. *Revista Brasileira De Epidemiologia,* 18(2), 326–340.

Gebrezgabiher, G., Romha, G., Ejeta, E., Asebe, G., Zemene, E., & Ameni, G. (2016). Treatment Outcome of Tuberculosis Patients under Directly Observed Treatment Short Course and Factors Affecting Outcome in Southern Ethiopia: A Five-Year Retrospective Study. *Plos One,* 11(2).

Getahun, B., Ameni G., Medhin, G. & Biadgilign, S. (2013). Treatment outcome of tuberculosis patients under directly observed treatment in Addis Ababa, Ethiopia: *Brazzilian Journal of Infectious Diseases,* 17,521-8.

Getahun, B., Ameni, G., Biadgilig, S., & Medhin, G. (2011). Mortality and associated risk factors ina a cohort of tuberculosis patients treated under DOTS programme in Addis Ababa, Ethiopia. *BMC Infectious Diseases,* 11:127.

Girardi, E., Raviglione, M.C., Antonucci, G., Godfrey-Faussett, P., & Ippolito, G. (2000). Impact of the HIV epidemic on the spread of other diseases: the case of tuberculosis. *AIDS,* 14(3), S47–S56.

Glover, R. E. (1941). Infection of adult cattle with Mycobacterium tuberculosis avium. *Journal of Hygiene*, 41, 290-296.

Hazarika, I. (2011). Role of private sector in providing tuberculosis care: Evidence from a population-based survey in India. *Journal of Global Infectious Diseases*, 3(1), 19-24.

Hill, P. C., Stevens, W., Hill, S., Bah, J., Donkor, S. A., Jallow, A., & Lienhard, C. (2005). Risk factors for defaulting from tuberculosis treatment: a prospective cohort study of 301 cases in The Gambia. *International Journal of Tuberculosis and Lung Disease, 9*(12), 1349–1354.

Holtz, T. H., Lancaster, J., Laserson, K. F., Wells, C. D., Thorpe, L., & Weyer, K. (2006). Risk factors associated with default from multidrug-resistant tuberculosis treatment, South Africa, 1999–2001. *International Journal of Tuberculosis and Lung Disease*, 10(6), 649– 55.

Jamlick, K., & Paul, G. (2015). Directly observed therapy for treating tuberculosis. *Cochrane Database Systematic Review*, (5) 1–56.

Jasmer, R.M., Seaman, C.B., Gonzalez, L.C., Kawamura, L.M., Osmond, D.H., & Daley, C.L. (2004). Tuberculosis Treatment Outcomes Directly Observed Therapy Compared with Self-Administered Therapy. *American Journal of Respiratory and Critical Care Medicine*, 170, 561–566.

Jenkins, H. E., Ciobanu, A., Plesca, V., Crudu, V., Galusca, I., Soltan, V. & Cohen, T. (2013). Risk factors and timing of default from treatment for non-multidrug-resistant tuberculosis in Moldova. *The International Journal of Tuberculosis and Lung Disease,* 17(3), 373-80.

Jianzhao, H., van den Hof, S., Lin, X., Yubang, Q., Jinglong, H., & van der Werf, M. J. (2011). Risk factors for non-cure among new sputum smear positive tuberculosis patients treated in tuberculosis dispensaries in Yunnan, China. *BMC Health Services Research*, 11, 97.

Kaona, F.A.D., Tuba, M., Siziya. S., & Sikaona, L. (2004). An assessment of factors contributing to treatment adherence and knowledge of TB transmission among patients on TB treatment. *BMC Public Health*, 4, 68.

Kapella, B. K., Anuwatnonthakate, A., Komsakorn, S., Moolphate, S., Charusuntonsri, P., Limsomboon, P., ... & Varma, J. K. (2009). Directly observed treatment is associated with reduced default among foreign tuberculosis patients in Thailand. *The International Journal of Tuberculosis and Lung Disease*, *13*(2), 232-237.

Kenya Ministry of Health. 2014. Kenya Health Sector: Human Resources Strategy 2014-2018. MoH. Nairobi, Kenya.

Kenya Ministry of Health. 2012. Kenya National Health Accounts 2012/2013. MoH. Nairobi, Kenya.

Kenya Ministry of Health. 2009. Kenya National Health Accounts 2009/2012. MoH. Nairobi, Kenya.

Kenya Ministry of Health. 2013. Kenya Service Availability and Readiness Assessment Mapping (SARAM). MoH. Nairobi, Kenya.

Kenya Ministry of Health. 2017. Kenya Tuberculosis Patient cost survey. MoH. Nairobi, Kenya.

Kenya tuberculosis prevalence survey 2016: Challenges and opportunities of ending TB in Kenya. *Plos One*, 14(1).

Kigozi, G., Heunis, C., Chikobvu, P., Botha, S., & Rensburg, D. V. (2017). Factors influencing treatment default among tuberculosis patients in a high burden province of South Africa. *International Journal of Infectious Diseases*, 54, 95-102.

Kim, H. J., Lee, C. H., Shin, S., Lee, J. H., Kim, Y. W., Chung, H. S., ... & Kim, D. K. (2010). The impact of nutritional deficit on mortality of in-patients with pulmonary tuberculosis. *The international journal of tuberculosis and lung disease*, *14*(1), 79-85.

Kim, J. Y., Shakow, A., Castro, A., Vande, C., & Farmer, P. (2003). Tuberculosis control. *Global public goods for health: health economic and public health perspectives. Oxford University Press for the World Health Organization, New York*, 54-72.

Kittikraisak, W., Burapat, C., Kaewsa-ard, S., Watthanaamornkiet, W., Sirinak, C., Sattayawuthipong, W., ... & Varma, J. K. (2009). Factors associated with tuberculosis treatment default among HIV-infected tuberculosis patients in Thailand. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *103*(1), 59-66.

Kliiman, K., & Altraja, A. (2010). Predictors and mortality associated with treatment default in pulmonary tuberculosis. *International Journal of Tuberculosis and Lung Disease,* 14(4), 454-463.

Kuuire, V. Z., Bisung, E., Rishworth, A., Dixon, J., & Luginaah, I. (2015). Health-seeking behaviour during times of illness: a study among adults in a resource poor setting in Ghana. *Journal of Public Health*, 38(4), e545–e553.

Latunji, O.O., & Akinyemi, O.O. (2018). Factors influencing health-Seeking behaviour among civil servants in Ibadan, Nigeria. *Annals of Ibadan Postgraduate Medicine*, 16(1), 52–60.

Laxminaraya, R., Klein, E., Dye, C., Floyd, K., Darley, S., & Adeyi, O. (2007). Economic Benefit of Tuberculosis Control.*Policy Research Work paper*, 4295.

Liefooghe, R., Baliddawa, J. B., Kipruto, E. M., Vermeire, C., & Munynck, A. O. (1997). From their own perspective. A Kenyan community's perception of tuberculosis. *Tropical Medicine & International Health, 2*(8), 809–821.

Lienhardt, C. (2001). From Exposure to Disease: The Role of Environmental Factors in Susceptibility to and Development of Tuberculosis. *Epidemiologic Reviews*, 23(2), 288–301.

Liew, S. M., Khoo, E. M., Ho, B. K., Lee, Y. K., Mimi, O., Fazlina, M. Y., ... & Jiloris, F. D. (2015). Tuberculosis in Malaysia: predictors of treatment outcomes in a national registry. *The International Journal of Tuberculosis and Lung Disease*, *19*(7), 764-771.

Maher, D. (2009). The natural history of Mycobacterium tuberculosis infection in adults: Tuberculosis: A Comprehensive Clinical Reference. *Elsevier Health Sciences*, 129–132.

Malone, K. M., & Gordon, S. V. (2017). Mycobacterium tuberculosis Complex Members Adapted to Wild and Domestic Animals. Advances in Experimental Medicine and Biology Strain Variation in the Mycobacterium Tuberculosis Complex: Its Role in Biology. *Epidemiology and Control*, 135–154.

Marian, K. A., Karanja, S., & Mohammed, K. (2017). Factors associated with tuberculosis treatment outcomes among tuberculosis patients attending tuberculosis treatment centres in 2016-2017 in Mogadishu Somalia. *Pan African Medical Journal*, 28,197.

Masini, E. O., Mansour, O., Speer, C. E., Addona, V., Hanson, C. L., Sitienei, J. K., . . .& Mungai, B. N. (2016). Using Survival Analysis to Identify Risk Factors for Treatment Interruption among New and Retreatment Tuberculosis Patients in Kenya. *Plos One*, 11(10).

McPhendran, F. M., & Opie, E.L. (1935). The spread of Tuberculosis in families. *American Journal of Epidemiology*, 22(3), 565–643.

Munro, S. A., Lewin, S. A., Smith, H. J., Engel, M. E., Fretheim, A., & Volmink, J. (2007). Patient Adherence to Tuberculosis Treatment: A Systematic Review of Qualitative Research. *PLoS Medicine*, 4(7).

Nahid, P., Jarlsberg, L. G., Rudoy, I., de Jong, B. C., Unger, A., Kawamura, L. M., ... & Daley, C. L. (2011). Factors associated with mortality in patients with drug-susceptible pulmonary tuberculosis. *BMC Infectious diseases*, *11*(1), 1.

Nanzaluka, F. H., Chibuye, S., Kasapo, C. C., Langa, N., Nyimbili, S., Moonga, G. … & Chongwe, G. (2019). Factors associated with unfavourable tuberculosis treatment outcomes in Lusaka, Zambia, 2015: a secondary analysis of routine surveillance data. *Pan African Medical Journal*, 32, 206.

Narasimhan, P., Wood, J., Macintyre, C. R., & Mathai, D. (2013). Risk Factors for Tuberculosis. *Pulmonary Medicine*, 2013, 1–11.

Narendran, G., & Swaminathan, S. (2016). TB-HIV co-infection: a catastrophic comradeship. *Oral Diseases*, 22, 46–52.

Nguyen, L. T., Hamilton, C. D., Xia, Q., & Stout. J. E. (2011). Mortality before or during treatment among tuberculosis patients in North Carolina, 1993-2003. *International Journal of Tuberculosis and Lung Disease,* 15(2), 257-262.

O'Boyle, S. J., Power, J. J., Ibrahim, M.Y., & Watson, J. P. (2002). Factors affecting patient compliance with anti-tuberculosis chemotherapy using the directly observed treatment, short-course strategy (DOTS). *International Journal of Tuberculosis and Lung Disease,* 6(4), 307-12.

Ogyiri, L., Lartey, M., Ojewale, O., Adjei, A. A., Kwara, A., Adanu, R. M., & Torpey, K. (2019). Effect of HIV infection on TB treatment outcomes and time to mortality in two urban hospitals in Ghana-a retrospective cohort study. *Pan African Medical Journal,* 32.

Okanurak, K., Kitayaporn, D., & Akarasewi, P. (2008). Factors contributing to the treatment success among tuberculosis patients: a prospective cohort study in Bangkok. *International Journal of Tuberculosis and Lung Disease,* 12(10), 160-165.

Okeke, T. A., & Aguwa, E. N. (2005). Evaluation of the implementation of directly observed treatment short course by private medical practitioners in the management of tuberculosis in Enugu, Nigeria. *Tanzania Journal of Health Research,* 8(2).

Rannan-Eliya, P., Wijemanne, N., Liyanage, K., Jayanthan, J., Dalpatadu, S., Amarasinghe, S., & Anuranga, C. (2015). The quality of outpatient primary care in public and private sectors in Sri Lanka--how well do patient perceptions match reality and what are the implications. *Health Policy and Planning,* 30 Suppl. 1, 59-74.

Rao, V. K., Iademarco, E. P., Fraser, V.J., & Kollef, M. H. (1998). The impact of comorbidity on mortality following in-hospital diagnosis of tuberculosis. *Chest* 114, 1244–1252.

Raviglione, M., & Poznyak, V. (2017). Targeting harmful use of alcohol for prevention and treatment of tuberculosis: a call for action. *European Respiratory Journal*, 50 (1).

Reichman, L. B. (1996). Tuberculosis elimination – What's to stop us?. *International Journal of Tuberculosis and Lung Disease*, 1(1), 3-11.

Riley, R. L. (1974). Airborne infection. *The American Journal of Medicine*, 57(3), 466–475.

Ruru, Y., Matasik, M., Oktavian, A., Senyorita, R., Mirino, Y., Tarigan, L. H. … & Alisjahbana, B. (2018). Factors associated with non-adherence during tuberculosis treatment among patients treated with DOTS strategy in Jayapura, Papua Province, Indonesia. *Global Health Action*, 11(1), 1510592.

Salles, C. L. G., Conde, M. B., Hofer, C., Cunha, A. J. L. A., Calçada, A. L., Menezes, D. F., ... & Kritski, A. L. (2004). Defaulting from anti-tuberculosis treatment in a teaching hospital in Rio de Janeiro, Brazil. *The International Journal of Tuberculosis and Lung Disease*, *8*(3), 318-322.

Samal, J. (2016). Health Seeking Behaviour among Tuberculosis Patients in India: A Systematic Review; Journal of Clinical and diagnostic Research. *Journal of clinical and diagnostic research*, 10(10), LE01–LE06.

Santha, T., Garg, R., Frieden, T., Chandrasekaran, V., Subramani, R., Gopi, P., ... & Narayanan, P. (2002). Risk factors associated with default, failure and death among tuberculosis patients treated in a DOTS programme in Tiruvallur District, South India, 2000. *The International Journal of Tuberculosis and Lung Disease*, *6*(9), 780-788.

Sengul, A., Akturk, U.A., Aydemir, Y., Kaya, N., Kocak, N.D., & Tasolar, F.T. (2015). Factors affecting successful treatment outcomes in pulmonary tuberculosis: a single-center experience in Turkey, 2005-2011. *The journal of infection in developing countries*, 9(8).

Shaw, J.B., & Wynn-Williams, N. (1954). Infectivity of pulmonary TB in relation to sputum status. *The American Review of Respiratory Disease*, 69,724–732.

Slama, K., Chiang, C.Y., Enarson, D.A., Hassmiller, K., Fanning A., Gupta, P., & Ray, C. (2007). Tobacco and Tuberculosis: a qualitative systematic review and meta-analysis. *International Journal of Tuberculosis and Lung Disease*, 11(10), 1049-1061.

Snider, D.E., Kelly, G.D., Cauthen, G.M., Thompson, N.J., & Kilburn, J.O. (1985). Infection and disease among contacts of tuberculosis cases with drug-resistant and drug-susceptible bacilli. *The American Review of Respiratory Disease 1985*, 132,125–132.

Sutherland, I. (1968). The Ten-Year Incidence of Clinical Tuberculosis Following "Conversion" in 2550 Individuals Aged 14 To 19 Years. *The Hague, Netherlands*.

Tekle, B., Mariam, D.H., & Ali, A. (2002). Defaulting from DOTS and its determinants in three Districts of Arsi Zone in Ethiopia. *International Journal of Tuberculosis and Lung Disease*, 6(7), 573–579.

Tiemersma, E. W., Van der Werf, M. J., Borgdorff, M. W., Williams, B. G., & Nagelkerke, N.J. D. (2011). Natural History of Tuberculosis: Duration and Fatality of Untreated Pulmonary Tuberculosis in HIV Negative Patients: A Systematic Review. *PLoS One* 4, 6(4), e17601.

Tupasi, T. E., Garfin, A. M. C. G., Kurbatova, E. V., Mangan, J. M., Orillaza-Chi, R., Naval, L. C., ... & Lew, W. J. (2016). Factors associated with loss to follow-up during treatment for multidrug-resistant tuberculosis, the Philippines, 2012–2014. *Emerging infectious diseases*, *22*(3), 491.

Turner, R. D., Chiu, C., Churchyard, G. J., Esmail, H., Lewinsohn, D. M., Gandhi, N. R., & Fennelly, K. P. (2017). Tuberculosis Infectiousness and Host Susceptibility. *The Journal of Infectious Diseases*, 216(suppl_6).

Ukwaja, K. N., Oshi, S. N., Alobu, I., & Oshi, D. C. (2016). Profile and determinants of unsuccessful tuberculosis outcome in rural Nigeria: Implications for tuberculosis control. *World Journal of Methodology*, 6(1), 118-125.

Vasankari, T., Holmström, P., Ollgren, J., Liippo, K., Kokki, M., & Ruutu, P. (2007). Risk factors for poor tuberculosis treatment outcome in Finland: a cohort study. *BMC Public Health,* 7, 291.

Vasantha, M., Gopi, P. G., & Subramani, R. (2008). Survival of tuberculosis patients treated under DOTS in a rural tuberculosis unit (TU), South India. *International Journal of Tuberculosis and Lung Disease,* 55, 64-69.

Vasudevan, K., Jayakumar, N., & Gnanasekaran, D. (2014). Smear Conversion, Treatment Outcomes and the Time of Default in Registered Tuberculosis Patients on RNTCP DOTS in Puducherry, Southern India. *Journal of Clinical and Diagnostic Research*, 8(10).

Vijay, S., Kumar, P., Chauhan, L. S., Rao, S. V. N., & Vaidyanathan, P. (2011).Treatment Outcome and Mortality at One and Half Year Follow-Up of HIV Infected TB Patients under TB Control programme in a District of South India. *PLoS ONE* 6(7), e21008.

Watt, C. (2009). The global epidemiology of tuberculosis. *Tuberculosis*, 17–27.

Wen, C. P., Chan, T. C., Chan, H. T., Tsai, M. K., Cheng, T. Y., & Tsai S. P. (2010). The reduction of tuberculosis risks by smoking cessation. *BMC Infectious Diseases,* 10,156.

World Health Organization. 2015. Implementing END TB strategy: THE ESSENTIALS. World Health Organization, Geneva

World Health Organization. 1994. Global Tuberculosis Programme. Framework for effective tuberculosis control. WHO/TB/94.179. World Health Organization, Geneva.

World Health Organization. 2001. Global tuberculosis control report. HO/CDS/TB/2001.287. Communicable Diseases, World Health Organization, Geneva.

World Health Organization. 2003. Community contribution to TB care: practice and policy. WHO/CDS/TB/2003.312. World Health Organization, Geneva.

World Health Organization. 2003. Treatment of Tuberculosis: Guidelines for National Programmes. WHO. Third edition. World Health Organization, Geneva

World Health Organization. 2006. Regional Office for South-East Asia. Alcohol use and abuse. What you should know. Alcohol Control. Series no. 4. World Health Organization, Geneva.

World Health Organization. 2008. Global tuberculosis control: surveillance, planning, financing. WHO report. World Health Organization, Geneva:

World Health Organization. 2010. Global Tuberculosis Control 2010, 15th Edition. World Health Organization, Geneva.

World Health Organization. 2010. Treatment of tuberculosis: guidelines – 4th ed. World Health Organization, Geneva.

World Health Organization. 2010. Treatment of Tuberculosis: guidelines for national programmes -4th Edition. World Health Organization, Geneva.

World Health Organization. 2011. Automated Real-time Nucleic Acid Amplification Technology for Rapid and Simultaneous Detection of Tuberculosis and Rifampicin Resistance: Xpert MTB/RIF System. World Health Organization, Geneva.

World Health Organization. 2011. Global Tuberculosis Control 2011, 16th Edition. World Health Organization, Geneva.

World Health Organization. 2012. Tuberculosis Factsheet No. 104: World Health Organization, Geneva.

World Health Organization. 2013. Definitions and reporting – 7 framework for tuberculosis – 2013 revision. World Health Organization, Geneva.

World Health Organization. 2016. Global strategy on human resources for health: Workforce 2030. World Health Organization, Geneva.

World Health Organization. 2016. Global Tuberculosis Report 2016. World Health Organization, Geneva.

World Health Organization. 2017. Global tuberculosis report 2017. World Health Organization, Geneva.

World Health Organization. 2018. Treatment guidelines for isoniazid resistant tuberculosis. Supplement to the WHO treatment guidelines for drug-resistant tuberculosis. The End TB strategy. Online Annexes. WHO. Geneva.

World Health Organization. 2018. Global tuberculosis report 2018. World Health Organization, Geneva.

World Health Organization. Definitions and reporting framework for tuberculosis: 2013 revision (updated December 2014). World Health Organization, Geneva.

Xu, W., Lu, W., Zhou, Y., Zhu, L., Shen, H., & Wang, J. (2009). Adherence to anti-tuberculosis treatment among pulmonary tuberculosis patients: a qualitative and quantitative study. *BMC Health Services Research*, 9, 169.

Zenebe, T., & Tefera, E. (2016). Tuberculosis treatment outcome and associated factors among smear-positive pulmonary tuberculosis patients in Afar, Eastern Ethiopia: a retrospective study. *The Brazilian Journal of Infectious Diseases*, 20(6), 635–636.

Zhang, Q., Gaafer, M., & Bayoumy, E. (2014). Determinants of Default from Pulmonary Tuberculosis Treatment in Kuwait. *The Scientific World Journal*, 2014.

APPENDICES

Appendix I: KEMRI CRDR SSC approval

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-209901, 0733-400003; Fax: (254) (020) 2720000
E-mail: director@kemri.org info@kemri.org Website: www.kemri.org

ESACIPAC/SSC/101547

5th April, 2013

Violet Rotich

Thro'
Director, CRDR
NAIROBI

REF: SSC No. 2525 (Revised) – Factors associated with tuberculosis treatment outcomes among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear positive: case study of facilities within Nairobi County.

Thank you for your letter dated 19th March, 2013 responding to the comments raised by the KEMRI SSC.

I am pleased to inform you that your protocol now has formal scientific approval from SSC.

The SSC however, advises that work on the proposed study can only start after ERC approval.

Sammy Njenga, PhD
SECRETARY, SSC

Appendix II: KEMRI-ERC approval

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-206901, 0733-400003; Fax (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

KEMRI/RES/7/3/1 **August 13, 2013**

TO: **MS. VIOLET JEPCHUMBA ROTICH (PRINCIPAL INVESTIGATOR)**

THROUGH : **DR. EVANS AMUKOYE;**
DIRECTOR, CRDR
NAIROBI

forwarded
27/8/13

Dear Madam,

RE: **SSC PROTOCOL NO. 2525 – REVISED (*RE-SUBMISSION*): FACTORS ASSOCIATED WITH TUBERCULOSIS TREATMENT OUTCOMES AMONG PATIENTS NEWLY DIAGNOSED AS *MYCOBACTERIUM TUBERCULOSIS* SPUTUM SMEAR POSITIVE: CASE STUDY OF FACILITIES WITHIN NAIROBI COUNTY**

Reference is made to your letter dated July 1, 2013. The ERC Secretariat acknowledges receipt of the revised proposal on August 2, 2013.

This is to inform you that the Committee determines that the issues raised at the 215th meeting held on 21st May, 2013 have been adequately addressed. The study is granted approval for implementation effective this **13th day of August 2013**. Please note that authorization to conduct this study will automatically expire on **August 12, 2014**. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **July 1, 2014**.

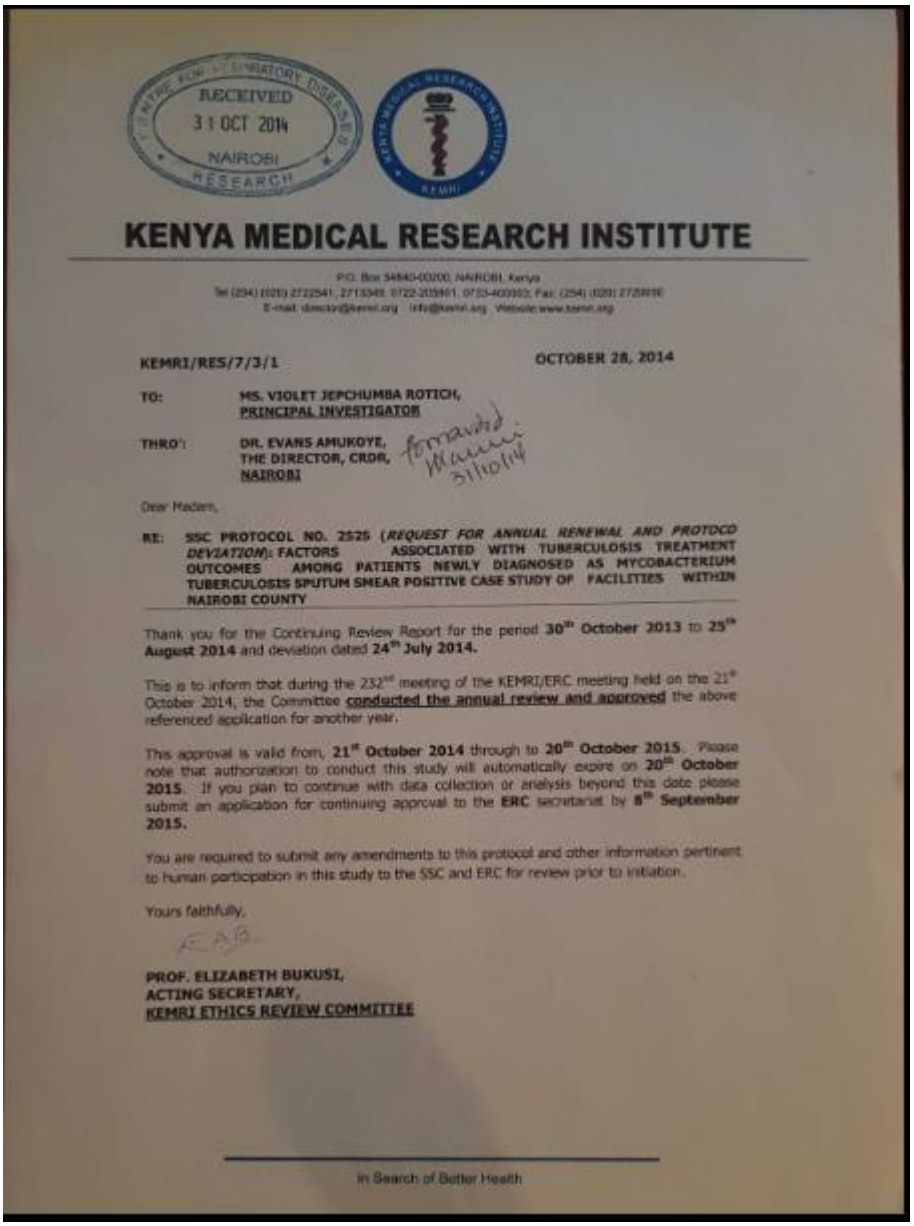
Any unanticipated problems resulting from the implementation of this protocol should be brought to the attention of the ERC. You are also required to submit any proposed changes to this protocol to the ERC prior to initiation and advise the ERC when the study is completed or discontinued.

You may embark on the study.

Yours faithfully,

Dr. ELIZABETH BUKUSI,
ACTING SECRETARY,
KEMRI ETHICS REVIEW COMMITTEE

In Search of Better Health



RECEIVED
31 OCT 2014
NAIROBI
RESEARCH

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-203901, 0733-400900; Fax: (254) (020) 2720816
E-mail: director@kemri.org info@kemri.org Website: www.kemri.org

KEMRI/RES/7/3/1 **OCTOBER 28, 2014**

TO: **MS. VIOLET JEPCHUMBA ROTICH,**
PRINCIPAL INVESTIGATOR

THRO': **DR. EVANS AMUKOYE,**
THE DIRECTOR, CRDR,
NAIROBI

forwarded
31/10/14

Dear Madam,

RE: SSC PROTOCOL NO. 2525 (*REQUEST FOR ANNUAL RENEWAL AND PROTOCO DEVIATION*): FACTORS ASSOCIATED WITH TUBERCULOSIS TREATMENT OUTCOMES AMONG PATIENTS NEWLY DIAGNOSED AS MYCOBACTERIUM TUBERCULOSIS SPUTUM SMEAR POSITIVE CASE STUDY OF FACILITIES WITHIN NAIROBI COUNTY

Thank you for the Continuing Review Report for the period **30th October 2013** to **25th August 2014** and deviation dated **24th July 2014.**

This is to inform that during the 232nd meeting of the KEMRI/ERC meeting held on the 21st October 2014, the Committee **conducted the annual review and approved** the above referenced application for another year.

This approval is valid from, **21st October 2014** through to **20th October 2015**. Please note that authorization to conduct this study will automatically expire on **20th October 2015**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the **ERC** secretariat by **8th September 2015.**

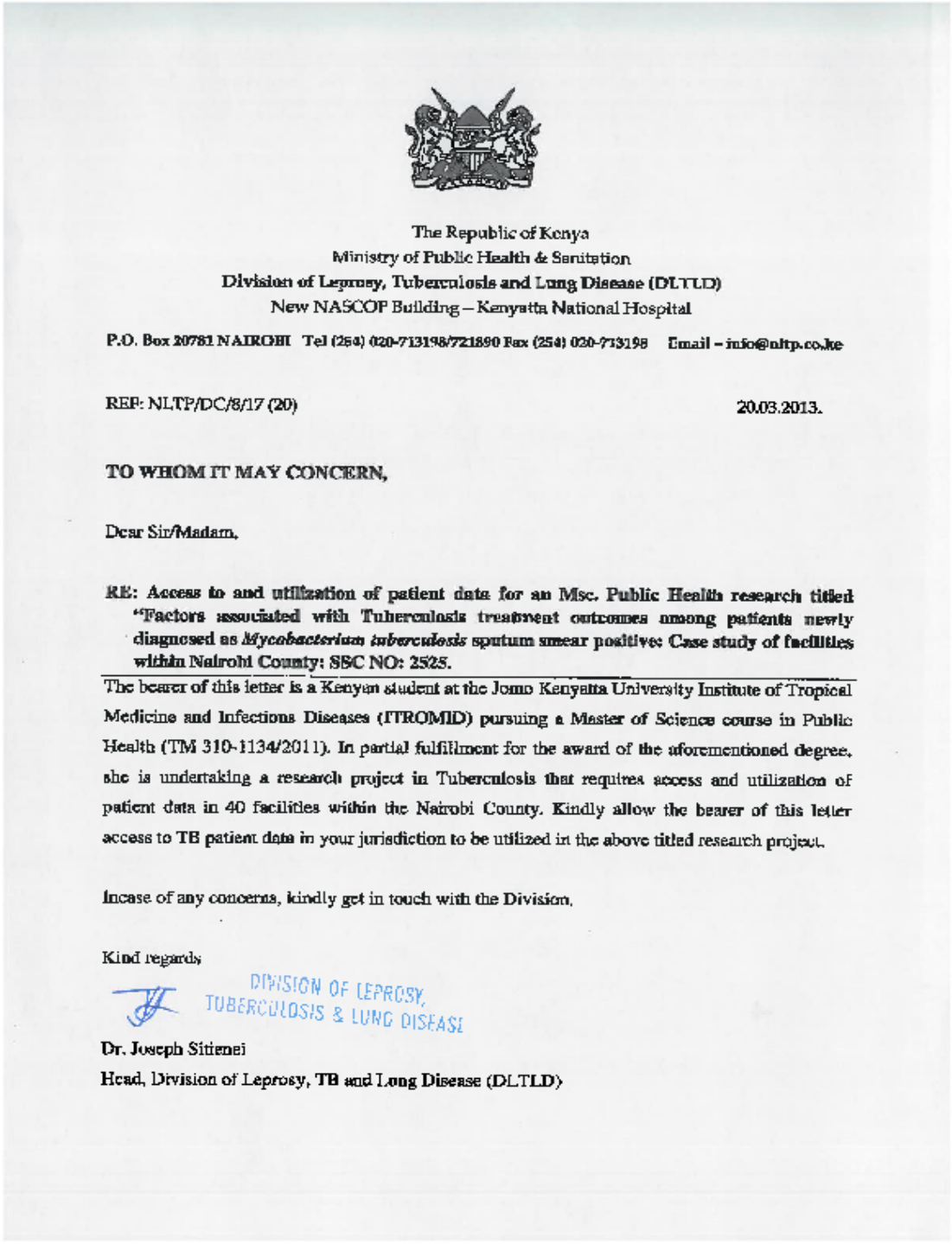
You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SSC and ERC for review prior to initiation.

Yours faithfully,

E.A.B.

PROF. ELIZABETH BUKUSI,
ACTING SECRETARY,
KEMRI ETHICS REVIEW COMMITTEE

Appendix III: National TB program approval



The Republic of Kenya
Ministry of Public Health & Sanitation
Division of Leprosy, Tuberculosis and Lung Disease (DLTLD)
New NASCOP Building – Kenyatta National Hospital

P.O. Box 20781 NAIROBI Tel (254) 020-713198/721890 Fax (254) 020-713198 Email – info@nltp.co.ke

REF: NLTP/DC/8/17 (20) 20.03.2013.

TO WHOM IT MAY CONCERN,

Dear Sir/Madam,

RE: Access to and utilization of patient data for an Msc. Public Health research titled "Factors associated with Tuberculosis treatment outcomes among patients newly diagnosed as *Mycobacterium tuberculosis* sputum smear positive: Case study of facilities within Nairobi County: SSC NO: 2525.

The bearer of this letter is a Kenyan student at the Jomo Kenyatta University Institute of Tropical Medicine and Infectious Diseases (ITROMID) pursuing a Master of Science course in Public Health (TM 310-1134/2011). In partial fulfillment for the award of the aforementioned degree, she is undertaking a research project in Tuberculosis that requires access and utilization of patient data in 40 facilities within the Nairobi County. Kindly allow the bearer of this letter access to TB patient data in your jurisdiction to be utilized in the above titled research project.

Incase of any concerns, kindly get in touch with the Division.

Kind regards,

DIVISION OF LEPROSY, TUBERCULOSIS & LUNG DISEASE

Dr. Joseph Sitienei
Head, Division of Leprosy, TB and Lung Disease (DLTLD)

Appendix IV: County research authorization

NAIROBI CITY COUNTY

Telegrams: "PMO MOHHEALTH", Nairobi
Telephone: Nairobi 217131/ 212481
Fax: 217148
E-mail: pmonairobi@yahoo.com

COUNTY HEALTH OFFICE
NAIROBI
NYAYO HOUSE
P.O. Box 34349-00100
NAIROBI

When replying please quote

Ref. No. CDH/NRB/OPR/VOL.2/105 COUNTY HEALTH SERVICES

14th November 2014

Violet Jepchumba

RE: RESEARCH AUTHORIZATION

Following your letter dated 7th August 2014 for conducting research on "**Factors associated with tuberculosis treatment outcomes among patients newly diagnosed as Mycobacterium tuberculosis sputum smear positive: case study of facilities within Nairobi County.**" I am pleased to inform you that you have the support of the County Health Operational Research Technical working group to undertake research in Nairobi County Health Facilities.

On completion of your study, we request that you submit **one hard copy and one copy in PDF** of the research dissertation to our operational research technical working group.

14/11/2014

For COUNTY DIRECTOR OF HEALTH NAIROBI COUNTY

DR. THOMAS OGARO
HEAD OF PRIMARY HEALTH SERVICES/
FOR: COUNTY DIRECTOR OF MEDICAL SERVICES – NAIROBI

C.C.

All Sub-County MOH

Appendix V: Entry Patient Questionnaire

Questionnaire for new smear +ve TB patients on Socio-demographic Characteristics, Knowledge on TB and TB services received to be administered within the **first three weeks of treatment**.

Date of Interview_____

Interviewer_____

Patient Identification Number…….

Patient Register Number..…….

Patient Characteristics

1. Age in years?_____	2. Gender	☐ ☐	Male Female
3. Weight in Kilograms?_____	4. What is the highest formal education level attained?	☐ ☐ ☐ ☐ ☐	Primary Secondary Diploma University under – graduate Masters graduate & above
	5. Do you have a source of income?	☐ ☐	Yes No
	6. What is the source of your income?	☐ ☐	Self employed Employed by other party

	7. What is your average income per month(Ksh)	☐ ☐ ☐ ☐ ☐	<10000 10001-20000 20001-50000 50001-100000 >100000
	8. If employed by third party (number 7 above) how often do you receive your wages?	☐ ☐ ☐	Daily Weekly Monthly
	9. Have you ever smoked?	☐ ☐	Yes No
10. If yes to Number (7) above when was the last time you smoked?			
	11. Have you ever taken alcohol or an alcoholic drink?	☐ ☐	Yes No
12. If yes to Number (9) above when was the last time you indulged?			
13. How many hours does it take you to get to the facility?			

	14. Have you heard of DOT?		
	15. What DOT support system do you utilize?	☐ ☐ ☐ ☐	HCW CHCW Family SAT
16. Why did you choose a particular support system (from 16 above)			
	17. Have you suffered any adverse reaction to TB drugs?	☐ ☐	Yes No
18. If yes to number (18) above what reaction?			
	19. Have your symptoms eased off with TB treatment?	☐ ☐	Yes No
20. If yes to number (20) above what symptoms?			
	21. Do you suffer from any other chronic disease?	☐ ☐	Yes No

22. If yes to number (22) above what disease?			

Tuberculosis General Knowledge

23. Have you ever heard about Tuberculosis?	☐ ☐	Yes No
24. What causes TB	☐ ☐ ☐ ☐ ☐ ☐	Viruses Bacteria Parasites Insects Other Specify_____ Don't know
25. How is TB transmitted?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	Waterborne Airborne Food borne Physical contact Sexually Inherited Other specify_____ Don't know
26. List the main symptoms of TB are? ***(Do not read the choices. Check all that are mentioned, multiple responses possible)***	☐ ☐ ☐ ☐ ☐	Chronic cough Blood stained sputum Night sweats Weight loss Chest pain

	☐ ☐ ☐ ☐ ☐ ☐	Fever Difficulty breathing Swollen lymph nodes Decreased appetite Other (specify)_____ Don't Know
27. What duration of cough is suspicious of TB? ***(Do not read the choices. Let them provide the answer and tick accordingly, multiple responses possible)***	☐ ☐ ☐ ☐ ☐ ☐ ☐	Five days Two weeks and above One month Five months One year Others (specify)_____ Don't know
28. Can TB spread from one person to another?	☐ ☐ ☐	Yes No Don't know
29. Do you know what increases a person's likelihood of getting TB? ***(Do not read. Check all that are mentioned, multiple responses possible)***	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	Contact with a TB patient Living in a congested place Infection with HIV/ other chronic illness Being very old/very young Malnutrition Drinking too much alcohol and smoking Spirits/Curse/Bad Omen People from other tribes

	☐	Other (specify) _____ Don't Know
30. How can you prevent yourself or your family members from getting TB? ***(Do not read. Check all that are mentioned. Prompt after each responses, multiple responses possible.)***	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	Cannot prevent Herbs Wash hands Keep distance from coughers Do not smoke Do not drink too much alcohol Eat healthy food Avoid congested places Ensure appropriate ventilation of closed spaces Other (specify)_____ Don't Know
31. What tests are done to find out if one has TB? ***(Do not read the choices. Check all that are mentioned, multiple responses possible)***	☐ ☐ ☐ ☐ ☐ ☐	Sputum test Chest x-ray Blood test Stool test Urine test Don't know
32. Do all people with TB also have HIV?	☐ ☐	Yes No

33. Is tuberculosis curable?	☐ ☐ ☐	Yes No Don't know
34. Why is it important for people with TB to be treated?	☐ ☐ ☐ ☐ ☐	To prevent / stop TB transmission To get cured To prevent death Don't know / no response
35. Is TB treatment free?	☐ ☐ ☐	Yes No Don't know
36. Do you know where to get TB medicines?	☐ ☐ ☐ ☐ ☐	District hospital only Health centre Dispensary Private clinic Private pharmacy
37. Have you ever heard about MDRTB?	☐ ☐ ☐	Yes No Don't know
38. Where did you get the information concerning TB? ***(Tick as appropriate, multiple responses possible)***	☐ ☐ ☐ ☐ ☐ ☐ ☐	TV spots TV program Radio spot Radio program School lessons From a school child From a drama session

TB services

39. When you were diagnosed with TB did you receive explanation from the health worker regarding TB disease and treatment?	☐ ☐	Yes No
40. If yes to question (39) above has the information informed your decision making	☐ ☐	Yes No
41. Have you received counselling for all your subsequent visits?	☐ ☐	Yes No
42. If no above (48) when was the last time you received counselling?		
43. How do you rate the TB services in the facility?	☐ ☐ ☐ ☐	Excellent Good Average Bad

Appendix VI: Exit Patient Questionnaire

Questionnaire for new smear +ve TB patients on Socio-demographic Characteristics and TB services received to be administered **after 12 weeks of treatment**.

Date of Interview_____

Interviewer_____

Patient Identification Number…….

Patient Register Number..…….

Patient Characteristics

1. Weight in Kilograms._____			
	2. Have you ever smoked?	☐ ☐	Yes No
3. If yes to Number (2) above when was the last time you smoked?			
	4. Have you ever taken alcohol or an alcoholic drink?	☐ ☐	Yes No
5. If yes to Number (4) above when was the last time you indulged?			

	6. What DOT support system do you utilize?	☐ ☐ ☐ ☐	HCW CHCW Family SAT
	7. Have you suffered any adverse reaction to TB drugs?	☐ ☐	Yes No
8. If yes to number (8) above what reaction?			
	9. Have your symptoms eased off with TB treatment?	☐ ☐	Yes No
10. If yes to number (10) above what symptoms?			

TB Services

1. When you were diagnosed with TB did you receive explanation from the health worker regarding TB disease and treatment?	☐ ☐	Yes No
2. If yes to question (39) above has the information informed your decision making	☐ ☐	Yes No
3. Have you received counselling for all your subsequent visits?	☐ ☐	Yes No

4. If no above (48) when was the last time you received counselling?		
5. How do you rate the TB services in the facility?	☐ ☐ ☐ ☐	Excellent Good Average Bad

Appendix VII:Patient Consent

I have been informed verbally and in writing about the study. I have clearly understood what is involved. I have obtained clear responses to all my questions and I know whom to contact if I need more information. I understand that confidentiality will be preserved. I have also understood that I am free to withdraw from the study at any time without any prejudice or blame. I agree to participate voluntarily in the study under the conditions presented in the information notice. I will be given a copy of this information notice and one of this consent form.

Participant Name

Participant Address

Signature

Date.

Witness statement (if applicable)

I certify that the information in the information notice and in the consent from have been accurately explained to and apparently fully understood by the participant. The informed consent was freely given

Name of witness

Address of witness

Signature

Date

(Print on back of form)

Investigators Statement

I, the undersigned, certify that I have explained to the volunteer, in a language he/she understands, all the information on the study and its procedures. I have informed the volunteer that confidentiality will be preserved, that he/she is free to withdraw from the study at any time without any prejudice or blame. I pledge to comply with the terms of the protocol with respect to confidentiality, respect of individual rights and freedom

Name of Investigator

Signature of Investigator

Date

Fomu ya kukubali

Nimejulishwa kinaganaga kwa kuambiwa na kwa kusoma kuhusu utafiti huu. Nimeelewa kikamilfu kuhusu utafiti huu. Nimepewa maelezo ya kunitosheleza ya mwaswali niliyokuwa nayo na ninafahamu vyema mtu ama watu ninaoweza kuwasiliana nao iwapo ninahitaji maelezo zaidi. Ninaelewa kwamba siri itadumishwa kuhusu mambo yangu. Ninaelewa kwamba ninao uhuru wa kujitoa kwenye utafiti huu wakati wowote bila kuhatarisha haki zangu na bila kulaumiwa. Nimekubali kwa hiari yangu kushiriki kwenye utafiti huu kulingana na mipango niliyoiona kwenye fomu ya maelezo. Ninajua kwamba nitapewa nakala for fomu ya maelezo na fomu hii ya kukubali kushiriki kwenye utafiti huu.

Jina la mshiriki

Anwani ya mshiriki

Saini ya mshirika

Tarahe .

Shahidi(iwapo inafaa)

Ninathibitisha kwamba mshiriki ameelezwa kwa kisawa fomu ya maelezo na ya kukubali ambayo mshirika ameilewa vizuri. Kukubali kwa msihriki huyu kwenye utafiti huu kumetolewa kwa hiari

Jina la shahidi

Anwani ya shahidi

Sani ya shahidi

Tarehe

(print on back of the form)

Kauli la Mtafiti

Mimi, ambaye nimeweka saini yangu hapa, nathibitisha kwamba nimemueleza mshiriki huyu kuhusu utafiti huu, kwa lugha anayoilewa . Nimemueleza mshiriki kwamba siri ya hali ya juu itaimarishwa kwa utafiti huu, na kwamba , mshirika huyu anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kulaumiwa. Nina apa kuzingatia mipangilio iliyowekwa ya utafiti huu. Sitayatoa mambo ya mshiriki huyu niliyoyajua kwa hali ya siri na nitaheshimu haki aliyonayo mshiriki huyu. Pia nitaheshimu uhuru alio nao mshiriki huyu.

Jina la mtafiti

Saini ya mtafiti

Tarehe

Appendix VIII: Teen information (15-17 year olds) for assent

My name is (*Insert interviewer name*), (*Insert credentials and affiliate institution*. I would like to invite you to take part in a research study. Your parent(s)/guardian knows we are talking with you about the study. This form will tell you about the study to help you decide whether or not you want to be in it. In this study, we want to learn about treatment results of Tuberculosis. If you decide to be in the study, we will ask you to respond to questions asked by (*Insert interviewer name*), twice over the duration of your treatment which is six months. Each questionnaire will take 20-30 minutes to be completed.

While we will not provide an incentive to take part in the study, however taking part in this research will help us learn how to help other children of your age get better treatment. We think there are a few risks to you by being in the study, you might become bored, tired worried or sad because of some of the questions we ask. You don't have to answer any of the questions you don't want to answer. If you become upset, let us know and we will get you a counsellor to help you with those feelings.

We won't tell anybody that you are in this study and everything you tell us and do will be private. Your parent/guardian will know that you took part in the study, but we will not tell them anything you said or did, either. When we tell other people or write articles about what we learned in the study, we will not include your name or that of anyone else who took part in the study. You however do not have to participate in the study. The choice is up to you. No one will get angry or upset if you do not want to do this. You can change your mind anytime if you decide you do not want to be in the study anymore.

If you have questions at any time, you can ask us and you can talk to your parents about the study. We will give you a copy of this form to keep. If you want to ask us questions about the study, contact Violet Jepchumba Rotich- 0724 869686, violet.jepchumba@gmail.com or Dr. Juma Rashid- +254 (0)20 2713349**,** erc@kemri.org**.**

Before you say yes to be in this study what questions do you have about the study?

If you are willing to participate in this study, please sign and write your name.

Name : _____ Signature: _____ Date:

Appendix IX: Facility in-charge questionnaire

Questionnaire for health facility in-charges to be administered within the **6 months study period**.

Date of Interview_____

Interviewer_____

Facility Identification Number…….

Facility name..…….

What is the nature of your facility?	☐ ☐ ☐	Public Health Private Faith based
What is the level of the facility under the KEPH classification?	☐ ☐ ☐ ☐ ☐	II III IV V VI
Is the centre a recognized diagnostic & treatment or treatment centre only?	☐ ☐	Diagnostic and treatment centre Treatment centre
Is the laboratory staff trained on TB diagnosis?	☐ ☐	Yes No
If yes in question (4) above how long ago?		
Do you have a space/office/clinic allocated to TB care only?	☐ ☐	Yes No
Have you allocated specific HCW for TB services?	☐ ☐	Yes No

Are the health care workers trained in TB management?	☐ ☐	Yes No
If yes to question (8) above how long ago.		
Do you have sufficient HCW to offer DOT to TB patients?	☐ ☐	Yes No
Do you offer continuous counselling or one time counselling for TB patients during treatment?	☐ ☐	Yes No

Appendix X:TB register review tool

A TB register review tool to be utilized in collecting treatment outcome data of the study subjects from the respective health facilities at the end treatment.

Date of Review_____

Reviewer_____

Facility Identification Number…….

Facility name..…….

Patient Identification Number…….

Patient Register Number..…….

Treatment outcome	☐	Cured
	☐	Treatment Completed
	☐	Transferred out
	☐	Out of control/Default
	☐	Failure
	☐	Death