PREDICTORS OF TREATMENT FAILURE AMONG PATIENTS WITH PULMONARY TUBERCULOSIS ATTENDING PUBLIC HEALTH FACILITIES IN NAIROBI COUNTY, KENYA

FAITH MUTHOKI MWANZUI

MASTER OF SCIENCE IN
PUBLIC HEALTH

JOMO KENYATTA UNIVERSITY
OF
AGRICULTURE AND TECHNOLOGY

2026

Predictors of Treatment Failure among Patients with Pulmonary Tuberculosis Attending Public Health Facilities in Nairobi County, Kenya

Faith Muthoki Mwanzui

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Public Health of the Jomo Kenyatta University of Agriculture and Technology

2026

DECLARATION

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

Signature…….Date……

Faith Muthoki Mwanzui

This thesis has been submitted for examination with our approval as the University Supervisors

Signature……. Date……

Prof, Simon Karanja, PhD

JKUAT, Kenya

Signature……. Date……

Dr. Alex Kigundu Mureithi

JKUAT, Kenya

Signature……. Date……

Dr. Herman Owour Weyenga, PhD

CDC, Kenya

DEDICATION

This study is dedicated to my family, colleagues and friends for their enormous support; it is also dedicated to all patients of pulmonary TB who lost the battle to the disease. May their souls rest in eternal peace

ACKNOWELEDMENT

First of all, I would like to acknowledge the Almighty God for the gift of life, His sustenance and blessings of good health during the study period, for such I will forever remain grateful. With deep gratitude, I acknowledge my supervisors, Prof. Simon Karanja, Dr. Alex Kigundu, and Dr. Harman Weyenga, for their dedication in guiding and supporting me throughout the research work. In particular, I distinguish, Prof. Simon Karanja for his devotion to critical review of my work, which ensured its success. My heartfelt appreciation also extends to all respondents that offered the required information, without whom this research could not have been accomplished. To the statisticians who immensely helped in analysis and preparation of data, I owe a big thank you. Finally, I would like to extend my gratitude to my family, friends and colleagues for the support they accorded me during the study period, their prayers and encouragement made it possible for me to accomplish this task. Finally, I recognize The Jomo Kenyatta University of Agriculture and technology (JKUAT) for granting me the opportunity to undertake this program.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ACRONYMS AND ABBREVIATIONS

AFB	Acid Alcohol Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
AOR	Adjusted Odds Ratio
BCG	Bacilli Chalmette Guerin
BPS	Board of Post Graduate Studies
COR	Crude Odds Ratio
DLTLD	Division of Leprosy Tuberculosis and Lung Disease
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy Short Course
DRTB	Drug Resistant Tuberculosis
DST	Drug Susceptibility Test
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
MDR-TB	Multi Drug Resistant Tuberculosis
MSF	Medicines sans Frontiers International
NAA	Nucleic Acid Amplification
NLTP	National Leprosy Tuberculosis Program

OR	Odds Ratio
PLHIV	People Living with HIV
PTB	Pulmonary Tuberculosis
SD	Standard Deviation
TB	Tuberculosis
TST	Tuberculin Skin Test
USD	United States Dollar
WHO	World Health Organization
XDR-TB	Extensively Drug Resistant Tuberculosis
Z-N stain	Ziehl Nielsen Stain

DEFINITION OF OPERATIONAL TERMS

Bacteriologically confirmed pulmonary TB WHO (2018): This refers to a patient whose two sputum samples test positive for Fast Acid Alcohol Bacilli (AFB) by microscopy, Gene expert, microscopy or culture or at least a chest radiography showing abnormalities, which are consistent with pulmonary TB.

Sputum negative pulmonary TB A patient presenting with signs and symptoms, which are consistent with TB and at least two samples of sputum, which are negative for fast acid alcohol fast acid bacilli by microscopy, Gene expert, or chest radiography consistent with pulmonary TB (WHO, 2015).

Extra pulmonary tuberculosis It is TB of other body organs a part from lungs such as abdomen, lymph nodes, skin, joints and bones, genital-urinary tract, and meninges. The confirmation of extra pulmonary tuberculosis may be done using a fine needle aspiration based on cytology or biochemical analyses of cerebrospinal, ascetic and pleural fluid or histological examination and a strong clinical evidence suggestive of extra pulmonary TB. (WHO, 2015).

A case of TB Will be a patient whose TB has been confirmed through X-ray, bacteriology test or clinical diagnosis. (WHO, 2016).

Bacteriological Response was defined as a positive sputum smear at initial diagnosis turning negative by the fifth month, as recorded in the facility register. Informed consent was required for enrolment in both cases and controls.

The following are case definitions:

i. **New Case**: A patient newly diagnosed with TB who has either never received anti-TB treatment before or has been on treatment for less than four weeks.

ii. **Relapse**: A patient who previously completed TB treatment and was declared cured, or had finished treatment for any type of TB, but returns with a new episode of smear-positive TB.

iii. **Treatment Failure**: A patient who continues to test smear-positive by the end of the fifth month of treatment or thereafter. This also includes individuals who were initially smear-negative but become smear-positive during the course of therapy.

iv. **Treatment after Loss to Follow-Up**: A patient who discontinued TB treatment for over two weeks and subsequently returns to the health facility either with a smear-positive test result or with symptoms indicative of TB.

v. **Transfer-Out**: A patient who initiated TB treatment at one healthcare facility but was transferred to a different facility to continue the treatment for any reason.

vi. **Others**: Patients who do not fall under any of the previously defined categories.

vii. **Cured**: A patient who successfully completed TB treatment and had negative bacteriological test results upon completion.

viii. **Completed Treatment**: A patient who finished the entire TB treatment regimen but lacked bacteriological confirmation at the end of the treatment period (WHO, 2018).

ix. **Died**: A patient who passed away from any cause, regardless of whether it was related to TB, during the treatment period (WHO, 2018).

x. **Transfer-Out**: A patient who was transferred to another facility during treatment, with the final treatment outcome remaining unknown (WHO, 2018).

ABSTRACT

TB treatment failure is defined as the persistence of a positive sputum smear or culture at five months or later during treatment, or the need to change treatment due to lack of clinical or bacteriological response. Tuberculosis (TB) is a major public health challenge in Kenya, which remains among the high TB burden countries despite steady progress in control efforts. In 2023, Kenya notified over 97,000 TB cases and achieved a treatment success rate of approximately 88–89% among patients started on anti-TB therapy, with an estimated 25% HIV co-infection rate among TB cases. However, a proportion of patients still experience poor outcomes, including treatment failure, relapse, loss to follow-up, and death. Identifying factors associated with treatment failure is critical to strengthening TB control and reducing morbidity, mortality, and transmission in Kenya. This study aimed to identify socio-demographic, behavioral, and clinical factors associated with TB treatment failure among TB patients in Nairobi County, Kenya. An unmatched case–control design was utilized, involving 81 TB patients with treatment failure (cases) and 162 TB patients who successfully completed treatment and were declared cured (controls). Controls were selected using simple random sampling from TB registers within the same health facilities as the cases, at a ratio of 1:2.Data was collected using structured data abstraction from patient interviews and medical records, focusing on socio-demographic, behavioral, and clinical characteristics. Statistical analysis was conducted using SPSS version 23. Univariate, bivariate, and multivariate analyses were performed, with 95% confidence intervals (CIs). Odds ratios (ORs) were calculated using unconditional logistic regression to determine factors independently associated with treatment failure. Patients with TB treatment failure were significantly more likely to have a history of prior exposure to first-line anti-TB drugs (OR = 85.0; 95% CI: 29.7–243.3; $p < 0.0001$). A positive sputum smear at two months of treatment, indicating delayed sputum conversion, strongly predicted treatment failure (OR = 20.63; 95% CI: 5.42–78.41; $p = 0.0021$). Poor adherence to treatment, shown by missed doses or appointments, was also significantly associated with treatment failure (OR = 4.7; 95% CI: 2.1–10.6; $p = 0.004$). Conversely, HIV-positive status (OR = 0.34; 95% CI: 0.1–0.9; $p = 0.025$) and participation in the Directly Observed Therapy (DOT) program (OR = 0.23; 95% CI: 0.1–0.6; $p = 0.002$) were associated with a reduced risk of treatment failure, suggesting a protective effect. Ethical approval was obtained from the Jomo Kenyatta University of Agriculture and Technology (JKUAT) Board of Postgraduate Studies and the Kenyatta National Hospital–University of Nairobi Ethical Review Committee. Permission to conduct the study was granted by the Nairobi County Health Department and the National Tuberculosis, Leprosy and Lung Disease Program. Written informed consent was obtained from all participants, and confidentiality of patient information was strictly maintained**.** In the Kenyan context, TB treatment failure is significantly associated with retreatment history, delayed sputum conversion at two months, and poor adherence to therapy, while engagement in DOT and HIV-positive status were protective against failure. To address these challenges, routine bacteriological monitoring (e.g., sputum microscopy or GeneXpert) at two months of treatment should be strengthened, along with enhanced implementation of DOT and comprehensive contact tracing for patients at risk

of treatment failure. These measures are critical to improving treatment outcomes and advancing Kenya's progress toward ending TB by 2030.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Tuberculosis (TB) continues to pose a major public health challenge around the world, particularly affecting developing countries (Baysari et al., 2017). The World Health Organization's (WHO) 2019 Global Report identifies TB as the ninth leading cause of death globally and a key contributor to deaths from infectious diseases, even exceeding HIV/AIDS. In 2018 alone, around 10.1 million individuals were diagnosed with TB, with Africa representing 76% of these cases. Globally, there were approximately 1,524,000 deaths attributed to TB during that year.

The epidemiology of tuberculosis (TB) is closely tied to social and economic determinants, which complicate efforts to prevent, manage, and control the disease. Although significant progress has been made in TB treatment and care, achieving the goals of the End TB Strategy—which aims for a 90% reduction in TB-related deaths by 2030 compared to 2015—demands continued and coordinated action (Goletti et al., 2024). Monitoring treatment outcomes and identifying influencing factors are essential aspects of effective TB management. While the global TB treatment success rate is currently at 83%, it varies significantly across regions and countries (Gebremariam et al., 2024). Research conducted in different areas of Kenya has revealed varying success rates and highlighted several factors that influence treatment outcomes. These include being over 40 years old, having a larger family size, undergoing retreatment, and the presence of comorbid conditions such as HIV, diabetes, and kidney diseases (MOH, 2016, 2018).In Africa, the treatment success rate stands at 75%, indicating room for improvement (WHO, 2018). Kenya, however, has not met the WHO recommendations, which target a 70% case detection rate and 85% treatment success rate. Challenges in TB management include missed cases, long treatment durations, pill burden, drug interactions, and adverse effects, leading to intolerance among patients (MOH, 2018).

Despite the challenges, the true prevalence of TB treatment failure in Kenya remains unknown. However, there is a high potential for progression to drug-resistant TB, including multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Factors contributing to this include prolonged exposure to first-line drugs during retreatment, access to second-line anti-TB drugs, weak health systems, high prevalence of HIV/AIDS among TB patients, and limited access to healthcare, particularly among slum dwellers.

Given the severe repercussions of TB treatment failure, especially in urban slums, there is an urgent need for evidence-based public health interventions that are adapted to local conditions. Identifying the factors that predict treatment failure in Kenya is crucial for developing targeted interventions and policies that enhance TB treatment outcomes. Although many studies on tuberculosis have been conducted in Kenya, none have specifically aimed at identifying the predictors of TB treatment failure in public health facilities in Nairobi County.

This study aims to address this gap by identifying the predictors of TB treatment failure in public health facilities within Nairobi County. Understanding these predictors will help in the early identification of patients at risk of treatment failure, allowing clinicians to offer personalized care and, in turn, enhance TB treatment outcomes and control efforts across the country.

1.2 Statement of the Problem

TB treatment failure poses significant challenges in terms of increased morbidity, mortality, and the potential reversal of gains made in tuberculosis (TB) control efforts. It is associated with prolonged infectivity, amplification of drug resistance, and increased strain on already burdened healthcare systems, particularly in resource-limited settings such as Kenya (Neville et al., 2014). Effective surveillance of TB treatment failure requires robust laboratory infrastructure and adequately trained personnel; however, these

resources are often insufficient in high-burden settings, especially in densely populated urban slums where TB transmission is most intense.

In 2021, Kenya reported a total of 77,854 drug-sensitive TB (DSTB) cases, representing a 6.7% increase compared to the 72,943 cases notified in 2020. The national TB incidence was estimated at approximately 140,000 cases in 2021, suggesting that nearly 44% of incident TB cases were either missed or not notified during that year. This substantial detection gap highlights persistent weaknesses in case finding and surveillance systems (National Tuberculosis, Leprosy and Lung Disease Program [NTLD-P], Republic of Kenya, 2021).

TB burden in Kenya is unevenly distributed across counties, with urban and peri-urban areas disproportionately affected. The top ten counties with the highest number of DSTB cases in 2021 were Nairobi, Meru, Kiambu, Mombasa, Siaya, Nakuru, Turkana, Kitui, Homa Bay, and Machakos. Nairobi County consistently reports the highest number of TB cases nationally, accounting for a significant proportion of the country's notified TB burden. This is largely attributed to high population density, extensive informal settlements, poverty, and increased population mobility. In contrast, counties such as Lamu, Tana River, Wajir, Taita Taveta, Elgeyo Marakwet, Marsabit, Isiolo, Mandera, Nyandarua, and Samburu reported the lowest numbers of TB cases during the same period (NTLD-P, 2021).

Despite sustained national TB control efforts, the prevalence of tuberculosis (TB) remains high in Nairobi County, particularly within informal settlements characterized by overcrowding, poverty, and limited access to healthcare services (NLTB, 2022; Neville et al., 2021). Recent evidence indicates that TB transmission in the county remains persistently high. A community-based survey conducted in selected neighbourhoods of Nairobi County between 2015 and 2022 estimated the prevalence of pulmonary TB at approximately 806 cases per 100,000 populations, with no significant decline observed over the study period. This prevalence is substantially higher than the national average and underscores persistent gaps in TB case detection, treatment monitoring, and

prevention efforts in urban settings. The high burden of TB in Nairobi County highlights the ongoing risk of poor treatment outcomes, including treatment failure and the emergence of drug-resistant TB, particularly among vulnerable populations living in informal settlements.

Recent programmatic reports indicate an increase in TB treatment failure cases, particularly in urban slum settings, without corresponding efforts to systematically identify and address the predictors of treatment failure. The absence of targeted interventions allows individuals with treatment failure to remain within communities, thereby sustaining transmission and increasing the risk of drug resistance. To mitigate the public health consequences of TB treatment failure, there is an urgent need for cost-effective, context-specific interventions tailored to high-burden settings.

Understanding the predictors of TB treatment failure in Nairobi County is therefore critical for informing targeted interventions, strengthening TB treatment monitoring, improving patient outcomes, and guiding policy decisions aimed at reducing TB transmission and drug resistance in Kenya.

1.3 Justification

TB control remains a significant challenge globally, especially in high-burden countries like Kenya. Despite efforts to reduce TB burden, the country has not met WHO targets for case detection and treatment success rates. This failure is evidenced by the doubling of TB prevalence rates in Kenya, highlighting missed TB cases and treatment failures as significant contributors.

TB treatment failure not only leads to increased morbidity and mortality but also poses a threat of MDR-TB development and community transmission. Early identification and understanding of the factors contributing to treatment failure are essential for meeting treatment targets, reducing the overall disease burden, and preventing the progression to

multidrug-resistant TB (MDR-TB). Although laboratory monitoring with advanced tools such as GeneXpert is ideal, it is often impractical in resource-limited settings like Kenya.

This study aims to identify easily measurable surrogate markers for TB treatment failure, prioritize high-risk individuals for laboratory testing, and inform policymakers on evidence-based strategies to minimize treatment failure cases. Addressing this knowledge gap will aid in resource allocation, surveillance activities, early case detection, and intervention strategies tailored to the local context, ultimately reducing the burden of TB on the healthcare system and the country as a whole.

1.4 Hypotheses

1.4.1 Null Hypothesis

There is no association between modifiable socio-demographic, behavioral, and clinical factors and TB treatment failure among patients attending Public health facilities in Nairobi County.

1.5 Research Questions

1. What are the socio-demographic factors associated with pulmonary TB treatment failure among patients attending Public health facilities in Nairobi County?
2. What behavioral factors are associated with pulmonary TB treatment failure among patients attending Public health facilities in Nairobi County?
3. What clinical factors are associated with pulmonary TB treatment failure among patients attending Public health facilities in Nairobi County?

1.6 Objectives

1.6.1 General Objective

To determine predictors of TB treatment failure among pulmonary tuberculosis patients attending selected Public Health facilities in Nairobi County, Kenya.

1.6.2 Specific Objectives

1. To determine the social demographic factors associated with TB treatment failure among pulmonary Tuberculosis patients attending Public health facilities in Nairobi County, Kenya.
2. To determine behavioral factors associated with TB Treatment failure among pulmonary tuberculosis patients attending selected Public health facilities in Nairobi County, Kenya.
3. To determine clinical factors associated with treatment failure among pulmonary tuberculosis patients attending selected Public health facilities in Nairobi County, Kenya

1.7 Conceptual Framework

Socio-demographic, behavioral, and clinical factors influence adherence to TB treatment and bacteriological response during therapy, which in turn determine TB treatment outcomes. Confounding variables such as age, sex, HIV status, socio-economic conditions, and access to healthcare may modify or distort the relationship between the independent variables and TB treatment failure. These confounders were controlled for during multivariate logistic regression analysis

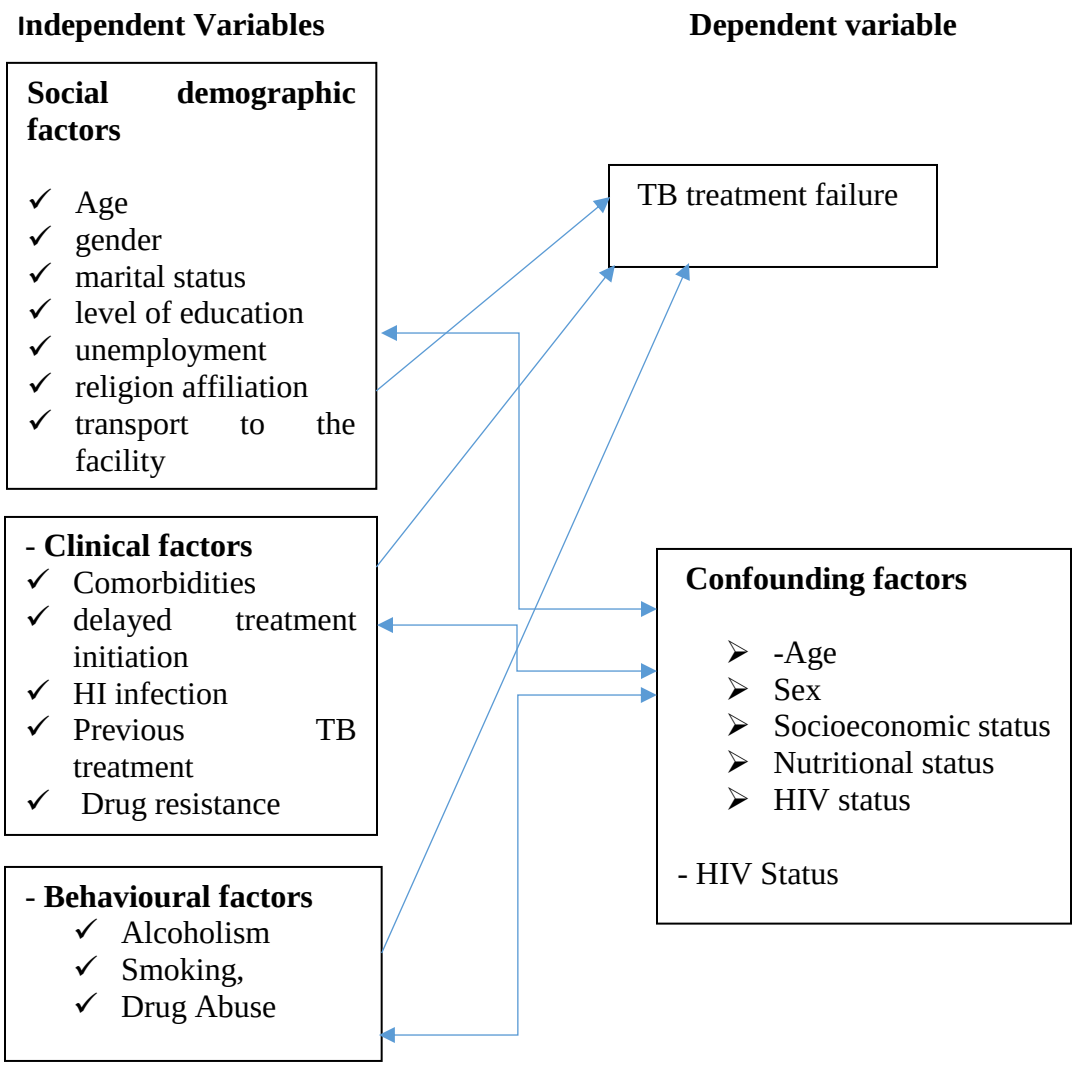


Figure 1.1: Conceptual Framework Showing Predictors of TB Treatment Failure among Patients Attending Selected Health Facilities in Nairobi County, Kenya

CHAPTER TWO

LITERATURE REVIEW

2.1 Pathogenesis of Tuberculosis

Tuberculosis (TB) is caused by *Mycobacterium tuberculosis* and primarily affects the respiratory system. Transmission occurs through inhalation of aerosolized droplet nuclei expelled when individuals with active pulmonary TB cough, sneeze, speak, or sing. These droplets can remain suspended in the air for prolonged periods, increasing the risk of infection among close contacts, particularly in poorly ventilated environments. Factors influencing transmission include the infectious dose, duration and proximity of exposure, ventilation, host immunity, and, rarely, blood transfusion (WHO, 2023).

Once inhaled, *M. tuberculosis* bacilli reach the alveoli, where they are phagocytosed by alveolar macrophages. The bacteria may survive and multiply intracellularly, subsequently spreading to regional lymph nodes and, in some cases, disseminating hematogenously to extra pulmonary sites such as the brain, spine, liver, and bones. Pulmonary TB accounts for the majority of notified cases, while extra pulmonary TB constitutes a significant proportion, particularly among immunocompromised individuals (Pai et al., 2020; WHO, 2023).

Many individuals infected with *M. tuberculosis* remain asymptomatic, a state referred to as latent TB infection. However, latent infection can progress to active TB disease, characterized by symptoms including persistent cough lasting more than two weeks, fever, night sweats, weight loss, and hemoptysis. Progression is influenced by host immune status, notably HIV infection, diabetes mellitus, malnutrition, and other comorbidities (CDC, 2022; Dheda et al., 2022).

Tuberculosis remains a major global public health challenge, accounting for approximately 1.3–1.6 million deaths annually and ranking above HIV/AIDS as a leading cause of death from a single infectious agent (WHO, 2023). Without treatment, TB has a

case fatality rate exceeding 50%. Despite decades of advances in diagnosis and treatment, TB continues to pose a significant burden worldwide, particularly in low- and middle-income countries (Oguh et al., 2021; WHO, 2023).

2.2 Global Impact of TB Treatment Failure

Tuberculosis continues to be a leading cause of morbidity and mortality globally. It is estimated that nearly one-quarter of the world's population is infected with *M. tuberculosis*, placing them at risk of developing active disease (WHO, 2023). Approximately 95% of TB cases and deaths occur in low- and middle-income countries, with the majority affecting individuals in the economically productive age group of 15–49 years (WHO, 2023).

The global incidence of TB increased markedly between 1990 and 2005, largely driven by the HIV/AIDS pandemic, and has since declined slowly in many regions (WHO, 2022). In 2022, an estimated 10.6 million new TB cases and 1.3 million TB-related deaths were reported globally. HIV co-infection remains a major contributor to poor TB outcomes, particularly in sub-Saharan Africa, where the majority of TB/HIV co-infected cases are concentrated (WHO, 2023).

Evidence from TB control programs indicates that HIV-positive TB patients experience less favorable treatment outcomes, including higher rates of treatment failure, default, and mortality, compared to HIV-negative patients (Schnippel et al., 2020; WHO, 2022). The emergence of drug-resistant TB has further complicated TB control efforts. Multidrug-resistant TB (MDR-TB) is defined as resistance to at least rifampicin and isoniazid, while extensively drug-resistant TB (XDR-TB) involves additional resistance to fluoroquinolones and second-line injectable agents (WHO, 2021).

Drug-resistant TB has been reported in all regions of the world and represents a significant threat to global TB control. In 2022, an estimated 410,000 new cases of rifampicin-resistant TB were reported globally, yet less than two-thirds were diagnosed and initiated

on appropriate treatment (WHO, 2023). Limited diagnostic capacity, particularly in resource-constrained settings, remains a major barrier to early detection and effective management of TB treatment failure and drug resistance (Dheda et al., 2022).

2.3 Regional and Local Burden of Tuberculosis

Tuberculosis remains a major public health problem in sub-Saharan Africa, where high HIV prevalence continues to fuel transmission. TB is the leading cause of death among people living with HIV, accounting for approximately 30–40% of AIDS-related deaths globally (WHO, 2023).

Kenya is classified among the high TB burden countries globally. According to the National TB Prevalence Survey and recent WHO estimates, Kenya reports an incidence of approximately 528 cases per 100,000 population (WHO, 2023; NTLD-P, 2022). TB is a leading cause of morbidity and mortality among young adults in their economically productive years, contributing substantially to socioeconomic losses.

Despite progress in TB control, Kenya continues to face challenges related to delayed diagnosis, treatment failure, HIV co-infection, and drug-resistant TB. Continuous surveillance of TB treatment outcomes is therefore essential to inform targeted interventions and strengthen TB control programs (NTLD-P, 2022; WHO, 2023).

2.4 Morbidity and Mortality of Tuberculosis Treatment Failure in Kenya

Tuberculosis treatment failure contributes significantly to morbidity, mortality, and ongoing transmission, particularly in low-income settings. TB-related deaths remain disproportionately high in sub-Saharan Africa due to late presentation, HIV co-infection, and limited access to advanced diagnostic services (WHO, 2022).

Comorbid conditions such as HIV/AIDS, diabetes mellitus, chronic kidney disease, liver disease, cardiovascular disease, chronic obstructive pulmonary disease, and malignancies increase the risk of poor TB treatment outcomes and mortality (Kyu et al., 2020; Harries

et al., 2021). Drug toxicity and adverse reactions further complicate treatment among patients with comorbidities, increasing the likelihood of treatment interruption and failure (Nahid et al., 2020).

Recent studies from Southern and Eastern Africa demonstrate a decline in TB mortality over the past decade; however, TB remains a leading cause of death in the region (Loveday et al., 2020). Prolonged hospitalization, exposure to infectious TB cases in healthcare settings, and delayed diagnosis have been associated with increased TB incidence and mortality (Zetola et al., 2020).

2.6 Factors Associated with Tuberculosis Treatment Failure

2.6.1 Socio-Demographic Factors

Several studies have demonstrated that socio-demographic characteristics significantly influence TB treatment outcomes. Younger adults in the economically productive age group, males, individuals with low socioeconomic status, limited formal education, and unstable housing conditions are more likely to experience poor treatment outcomes (Pradipta et al., 2020; WHO, 2022).

Proximity to TB treatment facilities has been associated with improved adherence and reduced treatment default. Patients living closer to healthcare facilities are less likely to miss appointments or discontinue treatment (Erhabor et al., 2021; Barker et al., 2020). Conversely, poverty, illiteracy, limited access to healthcare, and lack of social support have consistently been linked to treatment default and failure across multiple settings (Comolet et al., 2021).

2.6.2 Behavioural Factors

Behavioural factors such as alcohol use, smoking, illicit drug use, and poor treatment adherence have been strongly associated with TB treatment failure. Studies from Brazil,

South Africa, and Eastern Europe indicate that substance use increases the risk of treatment interruption and default (Jakubowiak et al., 2020; Harries et al., 2021).

Stigma associated with TB has been shown to negatively affect treatment adherence, leading to social isolation, job loss, and reduced income (Erhabor et al., 2021). Mental health conditions, particularly depression, are prevalent among TB patients and have been linked to non-adherence and poor treatment outcomes (Sweetland et al., 2020).

2.6.3 Clinical Factors

Previous TB treatment is one of the strongest predictors of treatment failure and drug resistance. Individuals with a history of TB treatment are at increased risk of MDR-TB due to prior exposure to first-line anti-TB drugs and potential non-adherence (Pradipta et al., 2020; WHO, 2021).HIV co-infection complicates TB management through increased pill burden, frequent clinic visits, drug–drug interactions, and adverse effects, all of which increase the likelihood of treatment interruption (Schnippel et al., 2020). Although some studies report no significant difference in treatment outcomes by HIV status, the majority of evidence supports HIV infection as a key risk factor for TB treatment failure and mortality (WHO, 2023).Diabetes mellitus has also emerged as an important risk factor for TB treatment failure, relapse, and drug resistance. Diabetic patients have impaired immune responses, increasing susceptibility to TB and poor treatment outcomes (Martinez et al., 2021).

2.6.4 Treatment Monitoring and Tuberculosis Treatment Failure

Directly Observed Therapy (DOT) remains a cornerstone of TB control and has been shown to significantly improve adherence and treatment success. Studies conducted in high-burden settings demonstrate that patients not adequately supervised during treatment are substantially more likely to experience treatment failure (Law et al., 2021; WHO, 2022). Monitoring and managing adverse drug reactions throughout the treatment period is essential to prevent treatment interruption. Evidence supports the effectiveness of

universal DOT compared to selective DOT in reducing treatment failure and preventing the emergence of drug-resistant TB (Nahid et al., 2020; WHO, 2022).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Setting

The research was conducted within selected public health facilities in Nairobi County, known for their high caseload of pulmonary tuberculosis (TB). Nairobi County comprises 17 Sub-counties, housing a total of 247 public health facilities that provide TB treatment services. A nationwide TB survey conducted in 2016 estimated Kenya's TB prevalence to be 558 per 100,000 individuals, with males and urban residents bearing a higher burden of the disease. Sub-counties identified with a high TB caseload, based on county records, included Langat, Starehe, Mathare, Embakasi East, and Embakasi West. This high caseload is attributed to the dense population and numerous slum settlements characterized by overcrowding, congestion, and poor ventilation, creating conducive environments for TB transmission. 6,248 TB cases, including 333 pulmonary TB cases, 52 treatment failure cases, and 145 TB-related deaths, were reported in Nairobi County alone in 2018. The County contributes to more than 23% of the country's TB cases, making it the highest TB burden area in the nation. This study in Nairobi County aims to highlight the prevalence of TB treatment failure nationwide.

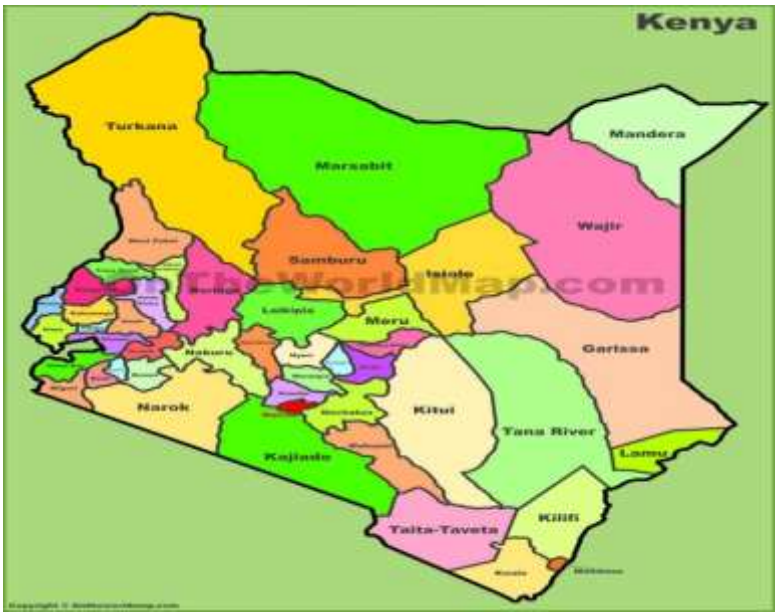


Figure 3.1a: Map of Kenya Showing the 47 Counties

Figure 3.1b: Map of Nairobi County Showing the 17 Sub-Counties

3.2 Study Design

An unmatched case-control research design was employed in this study to identify the predictors of TB treatment failure among pulmonary TB patients receiving care at public health facilities in Nairobi County. This design was chosen for its ability to assess associations between multiple risk factors and TB treatment failure by comparing cases with controls. Additionally, this design allowed for the efficient utilization of resources within a limited timeframe. The study utilized patient records and data from the Kenya National TB register, which serves as the primary repository for disease notification data nationwide. This register contains information on patient demographics, treatment initiation dates, TB type, provided treatment, diagnosis dates, treatment adherence, comorbidities, and treatment outcomes. It has been updated to include TB/HIV data, with all TB patients routinely screened for HIV during enrolment and vice versa. This investigation is intended to determine the factors associated with TB treatment failure among pulmonary TB patients being managed at selected public health facilities in Nairobi County.

3.3 Study Population

The study included all surviving tuberculosis (TB) treatment failure patients confirmed through Gene pert, microscopy, or culture testing between 2018 and 2022, as well as a selected group of sputum smear-positive TB patients from the same sites as the treatment failure cases. Both cases and controls were aged 15 years and above.

A case was defined as a sputum smear-positive TB patient who remained smear-positive at the fifth month of treatment with first-line anti-tuberculosis drugs. Treatment failure patients were identified using line lists available at the county TB coordinator’s offices and were traced to their respective sub-counties. A control was defined as a sputum smear-positive TB patient who showed both clinical and bacteriological improvement, with a negative sputum smear at the fifth month of treatment with first-line anti-tuberculosis drugs, and was selected from the same site as the corresponding case.

3.3.1 Inclusion Criteria

- Cases consisted of all patients confirmed to be sputum-positive via GeneXpert, microscopy, or culture at the initiation of TB treatment.
- Tests were carried out in the fifth month after the initiation of first-line anti-tuberculosis therapy.
- Controls included patients who were initially sputum smear-positive but later exhibited both clinical and bacteriological improvements in response to first-line anti-tuberculosis drugs.

3.3.2 Exclusion Criteria

- The study excluded patients who were sputum smear-positive at initial diagnosis without laboratory confirmation of sputum conversion at the fifth month
- Those with sputum smear-negative and extra-pulmonary TB at initial diagnosis
- Patients with incomplete records or those who declined to consent for the study were also excluded

3.4 Sample Size Determination

A minimum sample size of 243 participants (81 cases and 162 controls) was calculated using the Fleiss formula (Fleiss et al., 1981). The proportion of pulmonary TB cases and controls with smear-positive TB relapse was estimated at 79% and 21%, respectively (Zhang, *et al.*, 2024). The minimum odds ratio detectable by this study was set at 3.0, with a two-tailed level of significance (α) of 5% and a study power (1-β) of 80% (β = 0.20). The sample was independently and randomly selected. The formula used for sample size determination is as follows: using the formula:

$$n_1 = \frac{\left[Z_{\alpha/2} \sqrt{(r+1)\overline{pq}} + Z_{1-\beta} \sqrt{r p_1 q_1 + p_2 q_2} \right]^2}{r(p_1 - p_2)^2}$$

$$n_2 = r \times n_1 \quad \text{and} \quad P_1 = \frac{P_2(OR)}{1+[P_2(OR-1)]}$$

$$\bar{P} = \frac{p_1 + r \times p_2}{r+1} \quad \text{and} \quad \bar{q} = 1 - \bar{p}$$

Definition of Symbols Used in Sample Size Determination

Symbol	Description
n	Sample size per group
P₁	Proportion of exposure among cases
P₂	Proportion of exposure among controls
Z_{α/2}	Standard normal deviate corresponding to the desired confidence level
Z_β	Standard normal deviate corresponding to the desired study power
α	Probability of Type I error
β	Probability of Type II error
OR	Odds ratio

Table 3.1: Sample Size Computation

Step	Computation	Result
1	$(Z\alpha/2 + Z\beta)^2 = (1.96 + 0.84)^2$	7.84
2	$P_1(1 - P_1) = 0.79 \times 0.21$	0.1659
3	$P_2(1 - P_2) = 0.21 \times 0.79$	0.1659
4	$P_1(1 - P_1) + P_2(1 - P_2)$	0.3318
5	$(P_1 - P_2)^2 = (0.79 - 0.21)^2$	0.3364
6	$n = (7.84 \times 0.3318) / 0.3364$	$77.3 \approx 81$ cases

Assumptions were made regarding the representativeness of the sample size, small sampling error, viability within the constraints of available funds and time, control of systemic bias, and the generalizability of results from the sample study (see Appendix 1 for detailed symbol descriptions).

3.5 Sampling Procedure

All TB treatment failure patients listed in the county Data base by December 2022 were traced to their respective sub-counties, and accessible surviving patients were retrospectively enrolled until 81 cases were reached National Tuberculosis, (National Tuberculosis, Leprosy and Lung Disease Program Report (ROK, 2020). Two controls per case were randomly selected from the same facility as the case using a simple random sampling method. In facilities where suitable controls were not available, additional controls were selected from randomly chosen facilities that treat ordinary TB patients referred from the facility managing treatment failure cases. The facility TB register served as the sampling frame for all controls.

3.6 Study Variables

3.6.1 Independent Variables

Sociodemographic: age, gender, education, co-morbidities: tuberculosis and HIV, diabetes, renal disease, type of tuberculosis: smear-positive, smear-negative pulmonary, extra-pulmonary Category of patients: new cases, re-treatment cases.

3.6.2 Dependent Variables

Tuberculosis treatment failure

3.7 Data Collection

A pre-tested structured interviewer-administered questionnaire (see Appendix 2) was utilized to collect data from each study participant, including both cases and controls. The same questionnaire format was employed to extract and abstract data from patients' records. Additionally, the presence of a BCG scar was examined in all participants.

Sub-county TB coordinators were informed in advance of patient interviews and were asked to provide schedules of monthly clinic days for the facilities under their supervision.

They were also tasked with tracing TB treatment failure cases before the interviewers' visits. Prior to data collection, interviewers underwent training on data collection procedures to ensure consistency. Data were collected from medical records, patients' charts, and clinic cards, alongside direct patient interviews. A structured questionnaire was employed to gather data on various parameters, including age; sputum microscopy or GeneXpert results at baseline, 2 months, and 5 months (or later) into treatment; administered drug doses; and the presence of comorbid conditions (such as HIV and diabetes). Data on various factors, including gender, marital status, highest level of education attained, estimated distance to the TB clinic, history of alcohol or substance use, persistence of fever after two weeks of TB treatment, weight loss or inadequate weight gain despite treatment, sputum smear microscopy results, and diabetes mellitus (DM) status were collected through a questionnaire. A standardized treatment regimen was followed by all patients, consisting of two months of rifampicin, isoniazid, ethambutol, and pyrazinamide, followed by four months of rifampicin and isoniazid. Predictors of treatment failure were defined as factors linked to unsuccessful treatment outcomes, which could be used to identify individuals at elevated risk. These predictors included socio-demographic, clinical, laboratory, and treatment-related variables. Treatment adherence was assessed through detailed history-taking to identify missed doses, supported by self-reports from patients and a review of treatment cards to minimize recall bias. Non-adherence was inferred if patients missed two or more scheduled clinic appointments. Alcohol abuse was evaluated using the CAGE questionnaire, with a score of two or more indicating alcohol misuse. Changes in body weight were assessed by comparing patients' initial weight at the start of treatment with their weight at the time of diagnosis of treatment failure or when declared cured. HIV test results were obtained from medical records, using unique participant identifiers to ensure confidentiality.3.8 Data Management and Analysis

Microsoft Excel version 2016 was used for data entry for ease of management and transferability to statistical software. Double data entry was done on daily basis to minimize errors, and data cleaning was also done prior to analysis. The cleaned data were then imported into the Statistical Package for Social Sciences (SPSS) version 23 for

analysis. Descriptive statistics, such as frequency distributions, means, standard deviations, and quartiles, were computed for selected socio-demographic characteristics. The analysis was guided by the use of dummy tables, through which records were categorized into those showing treatment failure (cases) and those without treatment failure (controls). A dummy table on demographic characteristics was utilized for this purpose.

Univariate analysis A descriptive analysis was done based on frequency distribution of selected socio demographic characteristics. Means, standard deviations and quartiles of selected study variables were obtained. Dummy tables were used to guide the analysis. The records were categorized into those that have treatment failure (cases) and those who do not have as (controls). Dummy Table: Demographic characteristics

Table 3.2: Dummy Table Demographic Characteristics

Respondent Characteristics	**Age**	**Education**	**Marital Status**	**Occupation**	**Gender**
Number(N)					
Percentage (%)					

Simple descriptive analysis comparing the frequency and distribution of the identified potential confounders between the exposure groups was performed using measures of central tendency and presented in graphs and pie charts

Bivariate analysis

Was performed to establish any existing associations between the specific individual predictor variables and the outcome measure variable (TB treatment failure), by odds ratio and chi-square statistic. For categorical variables (nominal data) at 95% confidence interval (CI) and alpha level of significance set at 0.05 was used as measures of association in the analysis of factors associated with treatment failure T-test at the same confidence interval and significance level was used for numerical variables. An odds ratio (OR) of < 1 was considered protective while odds ratio of > 1 was considered a risk factor. An odds

ratio equal to 1 indicated that there is no difference between cases and controls. Confidence interval was used to assess variability of the odds ratio. A 95% confidence interval that included less than 1was interpreted to be not significant. Risk factor variables with P<0.05 was considered as having significant association with TB treatment failure. Variables with P<0.05 was considered as having significant association with TB treatment failure.

Table 3.3: Bivariate Analysis

Variable x	**Treatment failure**	**No treatment failure**	**Total**	
YES	A	B	a+b	a/a+b
NO	C	D	c+d	c/c+d
Total				

Logistic regression A multinomial logistic regression analysis was performed for confounding in the relationship between the variables. Unadjusted risk estimates (uRR). Only potential confounders that changed the OR by more than 10%, with less than <10% missing data, will be included in final multinomial logistic regression model. Estimates will be reported with 95% confidence intervals (CI) and significance level was set at alpha of 0.05 and used for all statistical analysis.

Table 3.4: Dummy Table: Multivariate Analysis of Predisposing Factors of Outcome Variable (both Full and Reduced Model)

Variables	**AOR**	**95% C.I**		**P-Value**
		Lower	**Upper**	
Full Model				
IRIS				
1. X				
2. Y				
3. Z				
4. ETC….				
Reduced Model				
1.Z				
2.Y				
ETC…..				

3.9 Ethical Consideration

Ethical clearance was obtained from the Ministry of Higher Education, Science, and Technology, JKUAT Board of Postgraduate Studies, and the KNH-UON Ethical Review Committee. Permission to collect data was granted by the County TB coordinator and the Ministry of Health research committee. Informed consent was obtained from all participants, the study posed no risks of harm to the participants. The benefits of the study included improved understanding, prevention and treatment of TB treatment failure in future. There were no costs or payment by the participants involved. Data collectors were trained on infection prevention measures. Respirators and surgical masks were provided for interviewers and participants, and interviews were conducted in open areas with good ventilation to reduce TB transmission risk. Data confidentiality was ensured, with questionnaires kept secure and accessible only to authorized personnel.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents the results on the findings. Particularly the results on the research objectives.

4.2 Demographic Characteristics of Study Participant

From January 2018 to December 2022, the study recruited a total of 243 participants, consisting of 81 cases and 162 controls. These individuals were recruited from 21 TB treatment facilities across four sub-counties within Nairobi County: Starehe, Langata, Embakasi West, and Embakasi East. The distribution of cases across most sub-counties was generally comparable (Figure 4.1).

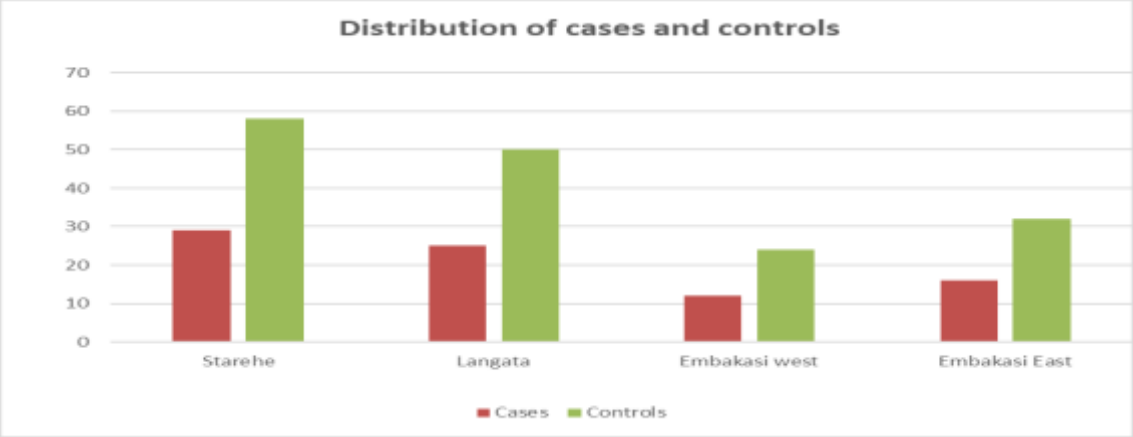


Figure 4.1: Distribution of Cases and Controls by Sub County in Nairobi County

4.2.1 Distribution of Cases and Controls by Age

The cases had an average age of 32.4 years (standard deviation = 10.4) and a mean of 31 years (interquartile range = 26.0-37.0). Those in the control group had an average age of

34.7 years (standard deviation = 12.6) and a middle value of 32.0 years (interquartile range = 26.0-40.0). Most of the participants in the study fell within the economically active age range of 15-44 years (Table 4.1).

Table 4.1: Age Distribution of Cases and Controls by Age

Age in Years	Cases (Frequency, n=81)	Cases (Percentage, %)	Age In Years	Controls (Frequency, n=162)	Controls (Percentage, %)
<15	2	0.2	< 15	3	1.8
15-24	19	23.4	15-24	29	17.9
25-34	26	32	25-34	62	38.2
35-44	21	25.9	35-44	38	23.4
45-54	7	8.6	45-54	15	9.2
55-64	4	4.9	55-64	11	6.7
>65	2	2.4	> 65	4	2.4

4.2.2 Demographic Characteristics of TB Treatment Failure Cases and Controls

One hundred and forty-six (60%) study participants were male. A total of 130 (54 %) of the study participants were living in some form of marital union (married or cohabiting) while, 138 (91.5%) had completed at least the primary school education. No statistically significant differences were observed in these variables among cases and controls, although a larger proportion 65 (80.2%) of cases were unemployed atthe time of the interview compared to the time before illness (Table 4.3).

Table 4.2: Demographic Characteristics of TB Treatment Failure Cases and Controls

Variables	Cases (N=81)	%	Controls (N=162)	%
Demographic				
Mean age in Years (SD)	32.4	(10.4)	34.7	(12.6)
Gender				
Male	50	(62)	96	(59)
Female	31	(38)	66	(41)
Education level				
None	11	(13.6)	8	(4.9)
Primary	34	(42.)	74	(45.7)
Secondary	24	(29.6)	54	(33.3)
Tertiary	12	(14.8)	26	(16)
Marital Status				
Single	27	(33.3)	49	(30.8)
Separated	10	(12.3)	9	(5.6)
Divorced	3	(3.7)	4	(2.5)
Widowed	4	(4.9)	7	(4.3)
Married	36	(44.4)	91	(56.2)
Cohabiting	1	(1.2)	2	(1.2)
Current Employment				
Employed	15	(18.5)	68	(42)
Not employed	65	(80.2)	89	(54.9)
In school	1	(1.2)	5	(3.1)
Employment before illness				
Employed	35	(43.2)	70	(43.2)
Not employed	45	(55.6)	88	(54.3)
In school	1	(1.2)	4	(2.5)

4.3 Socio-Demographic Factors Associated with TB Treatment Failure

During treatment, the cases typically traveled approximately twice the distance to the TB treatment facility compared to controls (OR=1.5, 95%CI=-0.9-3.9; P=0.158), a pattern also seen in the duration of travel for both groups (OR=2.5,95%CI=1.1-4.7; P<0.001). Living within a 3-kilometer radius of the TB treatment facility significantly reduced the risk of TB treatment failure (OR=0.4, 95%CI=0.2-0.7; P=0.002). Although cases traveled farther, there was no statistically significant difference in the means of transportation used

by cases and controls (OR=1.3, 95%CI=0.7-2.4; P=0.353). While pre-illness, unemployment did not correlate with TB treatment failure, there was a significant threefold increase in unemployment among patients with TB treatment failure compared to controls (OR=3.31, 95% CI=1.67-6.65; P<0.001). Cases were three times more likely to lack formal education (OR=3.0, 95% CI=1.2-7.9; P=0.030). However, receiving messages about TB during the last episode of ordinary TB treatment was protective (OR=0.28, 95% CI=0.16-0.50, P=0.001), a finding that held true regardless of the participants' level of formal education (Table 4.4**).**

Table 4.3: Socio-Demographic Factors Associated with TB Treatment Failure

Exposure variable	Cases No	(%)	Controls No	%	COR	P-Value	
Mean duration (minutes) of travel to HP(SD)	42.	(41.0)	25.	(22.3)	2.56	1.19-4.71	**0.001**
Mean No. of family members (SD)	3.4	(3.7)	3	(2.7)	0.41	0.27-0.77	0.104
Use of public transport (Yes)	29	(35)	47	(29)	1.36	0.77-2.41	0.353
Travelling < 3km to hospital (Yes)	29	(35)	93	(57.4)	**0.41**	0.23-0.72	**0.002**
Marital status (married)	37	(45.7)	93	(57)	0.62	0.36-1.07	0.111
Living with family (Yes)	53	(65.4)	92	(74.7)	0.64	0.36-1.14	0.170
Religion (Christian)	50	(61.7)	11	(70.4)	0.68	0.39-1.19	0.226
Gender (Female)	31	(38.3)	66	(35.8)	0.90	0.52-1.56	0.820
Employment before illness (None)	24	(29.6)	42	(25.9)	1.20	0.67-2.18	0.650
Current employment (None)	65	(80.2)	89	(54.9)	3.31	1.67-6.65	**0.001**
Type of house lived in (Permanent)	43	(53.1)	83	(51.9)	1.07	0.63-1.83	0.890
Homelessness (Yes)	10	(12.3)	11	(6.8)	1.9	0.78-4.76	0.220
Formal Education (None)	11	(13.6)	8	(5.8)	**3.03**	1.17-7.85	**0.030**
Received TB Messages (Yes)							
All participants (Yes)	43	(53.1)	13	(80.2)	0.28	0.16-0.50	**<0.001**
Education≤ Primary (Yes)	21	(46.7)	59	(72)	0.34	0.16-0.73	**0.009**
Education ≥ Secondary (Yes)	19	(52.8)	67	(83.8)	0.22	0.09-0.52	**0.001**

T test used for numerical variables and Yates corrected chi square test for categorical variables.
NB: *LL= Lower limit *UP = Upper limit

4.4 Behavioral Factors Associated with TB Treatment Failure

While a smaller percentage of cases 34 (42.3%) acknowledged ever consuming alcohol compared to controls 81(50%), this variance did not reach statistical significance (OR=0.7,95%, CI=0.4-1.34; P=0.28). Similarly, the history of cigarette smoking did not yield a statistically significant difference, despite cases reporting a higher prevalence

(OR=1.1,95%CI=0.6-2.1; P=0.678). Notably, an equal proportion of cases and controls admitted to substance abuse. (Table 4.5**).**

Table 4.4: Behavioural Factors Associated with TB Treatment Failure

Exposure	Cases (No, %)	Controls (No, %)	COR	95% CI(LL-UL)	P value
Those who have ever smoked (Yes)	33 (39.5)	52 (31.2)	1.15	0.64 - 2.15	0.678
Smoked in the past 2 years (Yes)	17 (19.5)	36 (21.6)	0.74	0.36 - 1.6	0.534
Living with smoker (Yes)	37 (43.0)	61 (37.2)	1.36	0.71 - 2.14	0.456
Ever consumed alcohol (Yes)	35 (42.3)	81 (50)	0.75	0.44 - 1.34	0.280
Taken alcohol in past 2 years (Yes)	10 (12.4)	18 (11.2)	2.24	0.72 - 7.35	1.118
Any Substance abuse (Yes)	18 (22)	33 (21.7)	1.12	0.53 - 1.92	1.112
Size of the family <3 people (Yes)	30 (54.7)	83 (66.2)	0.61	0.33 - 1.18	0.22
Ever travelled out of Kenya (Yes)	19 (26.1)	28 (20.2)	1.59	0.83 - 3.34	0.372
Cough hygiene (Yes)	46 (61.2)	90 (60.2)	1.13	0.62 - 1.91	0.978
Well ventilated house (Yes)	10 (13.1)	10 (6.4)	2.06	0.84 - 5.21	0.132
Ever imprisoned (Yes)	23 (29.9)	45 (28.2)	1.21	0.64 - 2.25	0.865

Note: T test used for numerical variables and Yates corrected chi square test for categorical variables.
NB: *LL= Lower limit *UP = Upper limit

4.5 Clinical Factors Associated with Cases and Controls

Clinical data from the facility's TB treatment register categorized sputum smear results into four groups based on bacillary load: scanty, 1+, 2+, and 3+ (refer to Appendix 3). The likelihood of cases having a bacillary load of 2+ or higher was four times greater compared to controls (odds ratio [OR] = 4.1, 95% CI = 1.9-9.8; P = 0.002). Conversely, cases were less likely to have undergone directly observed therapy (DOT) compared to controls (OR = 0.38, 95% CI = 0.21-0.66; P < 0.001). Controls were more prone to being HIV seropositive compared to cases (OR = 0.42, 95% CI = 0.23-0.77; P = 0.007) (Table 4.6)

Table 4.5: Clinical Factors Associated with Cases and Control

Exposure Variables	Cases (No, %)	Controls (No, %)	COR	95%CI (LL-UL)	P value
Bacillary load (<2+)	69 (84.4)	93 (57.6)	4.19	1.78-9.83	0.002
Sero positive HIV status	19 (23.5)	66 (42.4)	0.43	0.24-0.78	0.007
On ARVs before TB diagnosis	72 (88.7)	87 (55.6)	6.41	1.38-30.12	0.002
DOT recorded	52 (83.8)	155 (95.6)	2.61	1.70- 4.01	0.645
DOT self-recorded	36 (48.4)	115 (71.2)	0.36	0.21-0.66	<0.001
DOT once a week	19 (23.5)	34 (20.9)	1.13	0.55-1.91	1.113
Hospital Admission	17 (20.7)	21 (14.1)	1.65	0.82-3.34	0.230
Known diabetic	4 (4.8)	6 (3.7)	1.5	0.28-8.29	0.869
Chronic chest condition	7 (8.5)	5 (3.08)	2.1	0.53-8.34	0.57

T test used for numerical variables and Yates corrected chi square test for categorical variables.
NB: *LL= Lower limit*UP = Upper limit

4.6 Past Medical History and Its Association with for Cases and Control

Previous tuberculosis treatment was strongly linked to TB treatment failure (OR = 68.5, 95% CI = 26.91-174.39; P < 0.001). Additionally, cases were two and a half times more likely to lack a BCG scar (OR = 2.5, 95% CI = 1.35-4.63; P = 0.005). Poor adherence to treatment, including missed clinic appointments and doses, was also associated with TB treatment failure (OR = 63.7, 95% CI = 21.01-114.03; P = 0.003) and (OR = 68.5, 95% CI = 1.69-2.67; P = 0.0031) respectively. However, there was no statistically significant difference in reported history of contact with known TB or chronic cough between cases and controls (OR = 1.24, 95% CI = 0.71-2.15; P = 0.536).

Nevertheless, among the treatment failure cases, six individuals (7.4%) reported contact with a household case of TB treatment failure, despite not having suffered from TB or being exposed to TB drugs before (see Table 4.7). These cases are detailed below: A thirty-year-old HIV-positive man and a 15-year-old HIV-negative girl, both BCG vaccinated, resided in the same single room with a known case of treatment failure who had a history of defaulting from treatment twice.

A HIV-positive 23-year-old man, not vaccinated with BCG, shared a room with his wife, diagnosed with treatment failure after being treated for sputum smear-positive TB twice without a bacteriological response. A 19-year-old HIV-negative girl, BCG vaccinated,

shared a room with her HIV-positive aunt, who passed away during the 6th month of treatment. A 24-year-old HIV-negative man of foreign origin, not vaccinated with BCG, reported contact with a case of TB treatment failure. There was no statistically significant difference in clinical, socio-demographic, or behavioral factors between cases with known exposure to TB treatment failure and those without exposure.

Table 4.6: Past Medical History and Its Association with for Cases and Control

Exposure Variables	Cases (No, %)	Controls (No, %)	COR	95%CI(LL-UL)	P value
Positive sputum smear past 2 months	36(41.3)	6 (3.7)	40.19	17.8-113.7	0.001
Treated previously for TB	79(96.3)	26 (17.4)	65.43	34.21-78.43	<0.001
BCG Scar absent	28(38.7)	29 (17.6)	2.41	1.38-4.12	0.005
Missed clinic appointment	25(38.8)	3 (15.6)	63.7	21.07-116.1	0.0045
Missed doses for >2 weeks	17 (30)	21 (13.8)	4.8	1.61-2.66	<0.0041
DOT in previous treatment	32(39.1)	14 (60.9)	0.59	0.25-1.51	0.400
Contact with known TB case	31(38.7)	56 (34.1)	1.45	0.72-2.24	0.536

T test used for numerical variables and Yates corrected chi square test for categorical variables.

NB: *LL= Lower limit*UP = Upper limit

4.7 Multivariate Analysis Logistic

A multivariate analysis was conducted by incorporating variables found to be associated with TB treatment failure at a significance level of $p \leq 0.1$ in the bivariate analysis into an unconditional logistic regression model (refer to Appendix 7). These variables encompassed the distance from the health facility to the patient's home, provision of TB messages, HIV status, and bacillary load, previous treatment with anti-tuberculosis drugs, a positive sputum smear at 2 months into TB treatment, presence of a DOT observer, lack of formal education, missed doses and clinic appointments, and absence of a BCG scar.

From the model, five variables emerged as independently linked with TB treatment failure in the study. Notably, a history of previous treatment with anti-TB drugs, a positive sputum smear at 2 months of TB treatment, poor adherence to treatment. Conversely,

receiving TB treatment under the DOT program and being HIV positive were found to be protective against TB treatment failure at a significance level of 0.05 alpha (see Table 4.8)

Table 4.7: Optimal Unconditional Logistic Regression Analysis on Predictors of TB Treatment Failure

Term	AOR	95%	C.I.	Z-Statistic	P-Value
On DOT	0.2310	0.0923	0.5783	-3.1298	0.0017
Positive HIV	0.3416	0.1333	0.8756	-2.2366	0.0253
Previous TB treatment	85.0237	29.7063	243.3497	8.2809	0.0001
a positive sputum smear at 2 months of TB treatment	75.0237	19.7063	43.3247	6.2459	0.0021
Missed doses and clinic appointment	65.0237	17.7063	39.1127	4.3421	0.0041

CHAPTER FIVE

DISCUSSION CONCLUSIONS AND RECOMMENDATION

5.1 Discussion

Despite the availability of anti-TB drugs for over seven decades, tuberculosis remains a significant global health challenge, with an estimated one-third of the world's population infected with *M. tuberculosis* (WHO, 2023). Factors such as weak health systems, the HIV pandemic, and the emergence of drug-resistant strains continue to pose substantial threats to TB control efforts (Dean et al., 2020; WHO, 2023). Additionally, poverty, poor living conditions, and overcrowding contribute significantly to the tuberculosis epidemic (Trauner et al., 2021). This study aimed to identify predictors of TB treatment failure in selected public health facilities in Nairobi County, Kenya, to address knowledge gaps and inform cost-effective interventions tailored to the country's needs.

5.1.1 Socio-Demographic Predictors of TB Treatment Failure

The age distribution of TB cases was comparable to that of controls and consistent with national TB program data for smear-positive TB patients (NTLD-P, 2022). However, a notable proportion of cases became unemployed following illness onset, in contrast to the period before illness when no such difference was observed. Loss of employment among cases may worsen socioeconomic conditions, increasing vulnerability to TB transmission and compromising treatment adherence.

Residing within three kilometers of a TB treatment facility showed a protective trend against TB treatment failure, although this association did not reach statistical significance in multivariate analysis. Proximity to healthcare facilities has been associated with improved adherence to anti-tuberculosis therapy (Erhabor et al., 2021), whereas greater distance has been linked to increased mortality in rural South Africa (Barker et al., 2020). Patients living closer to treatment centers are less likely to miss medication refills or discontinue therapy.

Formal education was associated with improved health-seeking behavior. In this study, any level of formal education was linked to reduced risk of TB treatment failure in bivariate analysis. Similarly, receipt of targeted TB health messages was associated with lower risk of treatment failure at the bivariate level, although neither remained statistically significant in multivariate analysis. Health education interventions enhance adherence to anti-TB treatment (Karumbi & Garner, 2020), supported by systematic reviews evaluating adherence-promoting strategies (Karumbi & Garner, 2020). The protective effect of TB health messages was more pronounced among individuals with secondary or tertiary education, suggesting variations in comprehension and uptake. Tailoring TB education to literacy levels may reduce treatment failure (Sweetland et al., 2020)

5.1.2 Behavioural Predictors of TB Treatment Failure

In this study, most behavioral factors including alcohol consumption, cigarette smoking, family size, drug use, travel outside Kenya, and living conditions were not statistically significant predictors of TB treatment failure.

Behavioral factors are key determinants of TB treatment outcomes, consistently linked to poor therapy response, non-adherence, and treatment failure. Alcohol use is a frequently documented risk factor for unsuccessful TB treatment outcomes, with meta-analytic evidence demonstrating higher odds of treatment failure among alcohol users (Rehm et al., 2021; Naidoo et al., 2022). Alcohol impairs immune function and contributes to missed doses and clinic visits (Leung et al., 2021). Similar patterns have been observed in Kenya (WHO, 2023).

Cigarette smoking negatively affects treatment outcomes by impairing lung function and immunity. Meta-analyses show smokers are more likely to experience treatment failure than non-smokers (Leung et al., 2021; Bates et al., 2020), delaying sputum conversion and prolonging infectiousness (WHO, 2023). Smoking also correlates with poor adherence behaviors (NTLD-P, 2022). However, in this study smoking was not significantly associated with treatment failure.

Illicit drug use has been linked to poor adherence and treatment interruption, increasing the risk of treatment failure (Rehm et al., 2021). Drug abuse often coexists with unstable living conditions and mental health disorders, which undermine adherence. In this study, drug use was not statistically significant.

Inadequate cough hygiene contributes to persistent transmission of *M. tuberculosis* (WHO, 2023). Poor cough etiquette increases reinfection risk during treatment, complicating recovery and potentially leading to failure. Similarly, poor ventilation and overcrowded living conditions exacerbate transmission and prolong recovery (WHO, 2023).

5.1.3 Clinical Predictors of TB Treatment Failure

A history of prior TB treatment ($P < 0.001$) and a positive sputum smear at two months ($P < 0.0021$) were the strongest predictors of treatment failure. These findings align with retrospective and cohort studies in South Africa and other high-burden settings (Dean et al., 2020; Gupta et al., 2021). Prior exposure to first-line TB drugs promotes selection of drug-resistant strains (WHO, 2022).

Patients who relapse after first-line treatment face higher risk of subsequent failure (Dean et al., 2020). Positive sputum at two months is a cost-effective early marker of treatment failure (Horne et al., 2020).

Persistence of smear positivity may indicate primary drug resistance or emerging mutant strains, particularly with poor adherence (WHO, 2022). High bacillary load at baseline was not independently associated with failure, consistent with recent findings in India and other comparable settings (Nguyen et al., 2021).

Poor adherence was another significant predictor, consistent with prior studies (Karumbi & Garner, 2020). DOT was protective, reinforcing its role in preventing drug resistance.

Unlike European studies, contact with known TB cases was not significant in this study (WHO, 2023). MDR-TB strains may be less transmissible due to reduced virulence, though Beijing strains remain highly virulent and transmissible (Abebe, 2021; Trauner et al., 2021). HIV remains a major factor in TB treatment failure globally (Gupta et al., 2021; WHO, 2023). In this study, a higher proportion of HIV-positive individuals were observed among controls, likely reflecting diagnostic challenges, under-detection, and early mortality among HIV-positive patients (WHO, 2023). Bacillary load of ≥2+ at diagnosis was associated with failure but not independently predictive, consistent with recent studies (Trauner et al., 2021). BCG vaccination showed a protective effect in bivariate analysis but was not independently predictive (Abebe, 2021; WHO, 2023).

5.2 Recommendations

1. The National TB Program should strengthen social support mechanisms, including linkage to social protection services and decentralized TB services, to minimize indirect barriers such as loss of income and transport costs that may compromise treatment adherence.
2. TB programs should prioritize patients with a history of previous TB treatment and those who remain smear-positive at two months for intensified follow-up, including early drug susceptibility testing and consideration of extended or modified treatment regimens in line with national guidelines.
3. The Ministry of Health should strengthen implementation and monitoring of DOT, particularly for patients identified as high-risk, including those with prior TB treatment, poor adherence history, or delayed sputum conversion. Community-based DOT models should be expanded to improve accessibility and continuity of care.
4. There is a need to strengthen TB treatment failure surveillance among HIV-infected patients through improved diagnostic capacity, routine monitoring, and integration of TB and HIV services to ensure timely identification and management of treatment failure.

5. TB health education should be intensified and tailored to patients' literacy levels, with emphasis on treatment adherence, early reporting of symptoms, and the importance of sputum follow-up examinations.

5.3 Conclusions

This case–control study identified key predictors of tuberculosis treatment failure among patients enrolled in the national TB control program. A history of prior TB treatment and persistent sputum smear positivity at two months of treatment emerged as the strongest independent predictors of treatment failure. Poor adherence to treatment significantly increased the risk of failure, while the presence of a Directly Observed Therapy (DOT) observer was protective.

Socio-demographic factors such as loss of employment following illness, distance from TB treatment facilities, and lower levels of education demonstrated associations with TB treatment failure at the bivariate level, although these associations were attenuated after adjustment for confounders. HIV status showed a complex relationship with TB treatment failure, with fewer HIV-positive patients identified among cases, likely reflecting diagnostic and surveillance limitations rather than a true protective effect.

Overall, the findings highlight the importance of early treatment monitoring, adherence support, and programmatic interventions targeting high-risk patients, particularly those with previous TB treatment and delayed sputum conversion.

5.4 Methodological Implications

Given the case–control design of this study, the identified associations do not imply causality. However, the findings provide strong evidence for targeted programmatic interventions among high-risk groups. Future prospective cohort studies and molecular epidemiological investigations are recommended to further explore causal pathways and transmission dynamics of TB treatment failure in Kenya

5.4 Limitations of the Study

5.4.1 Misclassification

Confirmation of diagnosis among the controls relied on sputum smear microscopy rather than culture and drug susceptibility testing (DST) to definitively rule out TB treatment failure. This could potentially lead to misclassification of controls who may have actually experienced treatment failure. However, it's important to note that the proportion of TB treatment failure cases in Nairobi County is relatively small. Additionally, the observed clinical and bacteriological response among the controls is assumed to be attributed to the efficacy of first-line anti-tuberculosis drugs rather than the natural healing process of tuberculosis, which could occur in approximately 50% of patients if left untreated over a two-year period. It's unlikely that this misclassification would significantly bias the results, as it would tend towards null findings and therefore not explain any significant differences observed in the study.

5.4.2 Cause-Effect Relationship

Establishing a cause-effect relationship is challenging in this study, as both the exposure and outcome had already occurred at the time of conducting the study.

5.4.3 Recal Bias

Cases had a longer mean duration of illness compared to controls and had undergone multiple unsuccessful TB treatments. Consequently, they may have been more likely to recall events surrounding their illness compared to controls. Efforts were made to mitigate this bias by focusing on exposures that do not change rapidly over time. It was assumed that cases were less likely to recall exposures compared to controls, so any existing recall bias would likely affect both groups equally, potentially underestimating the strength of association.

5.4.4 Sampling and Representativeness

As a case-control study, the selection of study sites was based on the presence of treatment failure cases rather than a random selection of facilities offering TB care. This may have led to varying levels of representativeness across different areas, with some areas having more selected facilities than others. However, efforts were made to include all available cases, while controls were randomly selected within the chosen facilities to mitigate this limitation

REFERENCES

Abbas, U., Masood, K. I., Khan, A., Irfan, M., Saifullah, N., Jamil, B., & Hasan, Z. (2022). Tuberculosis and diabetes mellitus: Relating immune impact of co-morbidity with challenges in disease management in high burden countries. *Journal of Clinical Tuberculosis and Other Mycobacterial Diseases, 29*, 100343. https://doi.org/10.1016/j.jctube.2022.100343

Abebe, F. (2021). The role of Bacillus Calmette–Guérin (BCG) vaccine in the prevention of tuberculosis. *Tuberculosis*, *127*, 102046. https://doi.org/10.1016/j.tube.2021.102046

Bates, M., et al. (2020). Tobacco smoking and tuberculosis treatment outcomes: A systematic review. *PLOS ONE, 15*(12), e0243796. https://doi.org/10.1371/journal.pone.0243796

Bizuneh, F. K., et al. (2024). Tuberculosis-associated mortality and risk factors for HIV-infected population in Ethiopia: A systematic review and meta-analysis. *Frontiers in Public Health, 12*, 1386113. https://doi.org/10.3389/fpubh.2024.1386113

Dean, A. S., Cox, H., Zignol, M., & Floyd, K. (2020). Epidemiology of drug-resistant tuberculosis. *The Lancet, 395*(10236), 1559–1570. https://doi.org/10.1016/S0140-6736(20)30318-1

Dheda, K., et al. (2022). Global tuberculosis: The role of host-pathogen interactions. *Nature Reviews Microbiology, 20*, 277–292. https://doi.org/10.1038/s41579-021-00650-0

Erhabor, G. E., et al. (2021). Adherence to tuberculosis treatment in Nigeria. *African Journal of Respiratory Medicine, 16*(1), 1–7.

Gandhi, N. R., et al. (2021). HIV and tuberculosis treatment outcomes in high burden settings. *Clinical Infectious Diseases, 73*(7), e1629–e1636. https://doi.org/10.1093/cid/ciaa1605

Goletti, D., et al. (2024). World Tuberculosis Day 2024: Advancing detection, diagnosis, and treatment. *International Journal of Infectious Diseases, 141*.

Gupta, A., et al. (2021). Mortality and treatment outcomes in HIV-associated tuberculosis. *Clinical Infectious Diseases, 73*(7), e1629–e1636. https://doi.org/10.1093/cid/ciaa1605

Horne, D. J., et al. (2020). Sputum monitoring during tuberculosis treatment. *Clinical Infectious Diseases, 71*(5), 1235–1242. https://doi.org/10.1093/cid/ciz1052

Jakubowiak, W., et al. (2020). Behavioral risk factors for tuberculosis treatment non-adherence. *BMC Public Health, 20,* 1056. https://doi.org/10.1186/s12889-020-09038-6

Karumbi, J., & Garner, P. (2020). Directly observed therapy for treating tuberculosis. *Cochrane Database of Systematic Reviews*, CD003343. https://doi.org/10.1002/14651858.CD003343.pub5

Leung, C. C., et al. (2021). Alcohol use, smoking, and TB treatment outcomes: Meta-analysis. *International Journal of Tuberculosis and Lung Disease, 25*(1), 1–12. https://doi.org/10.5588/ijtld.20.0625

Mitchison, D. A. (2020). How drug resistance emerges as a result of poor compliance during short-course chemotherapy for tuberculosis. *International Journal of Tuberculosis and Lung Disease, 2*(1), 10-15.

Muture, B. N., Keraka, M. N., Kimuu, P. K., Kabiru, E. W., Ombeka, V. O., & Oguya, F. (2015). Factors associated with default from treatment among tuberculosis patients in Nairobi province, Kenya: A case-control study.

Naidoo, P., et al. (2022). Alcohol and TB treatment outcomes in high-burden settings. *BMC Public Health, 22*, 1122. https://doi.org/10.1186/s12889-022-13470-z

NASCOP. (2018). *Kenya Population-Based Impact Assessment (KENPHIA) final report*. Nairobi: NASCOP.

Neville, K., Bromberg, A., Bromberg, R., Bonk, S., Hanna, B. A., & Rom, W. N. (2016). The third epidemic: Multidrug-resistant tuberculosis. *Chest, 105*(1), 45-48.

Nglazi, M. D., Bekker, L. G., Wood, R., & Kaplan, R. (2015). The impact of HIV status and antiretroviral treatment on TB treatment outcomes in co-located TB and ART services in South Africa

Nguyen, T. V. A., et al. (2021). Delayed sputum conversion and tuberculosis outcomes. *BMC Infectious Diseases, 21*, 421. https://doi.org/10.1186/s12879-021-06144-8

NLTP. (2016). *National Tuberculosis Survey*.

NTLD-P. (2022). Kenya National Tuberculosis, Leprosy and Lung Disease Programme annual report. Ministry of Health Kenya.

Nunes, E. M., Capitani, D. E., Coelho, E., Joaquim, O. A., Figueiredo, R. O., Cossa, A. M., Panunto, A. C., & Carvalho-Ramos, M. (2016). Patterns of antituberculosis drug resistance.

Odhiambo, J. A., Borgdorff, M. W., Kiambih, F. M., Kibuga, D. K., Kwamanga, D. O., Nga'ng'a, L., & Others. (2019). Tuberculosis and the HIV epidemic: Increasing

annual risk of tuberculosis infection in Kenya. *American Journal of Public Health, 89*(0), 1078-1082.

Oguh, C. E., Obiwulu, E. N. O., Sheshi, I. M., Ameh, S. E., Okpaka, C. O., Oluwadepo, T. J., & Ejiofor, U. M. (2021). The epidemiological pattern of HIV/AIDS: Diagnosis, transmission, and prevention in Nigeria.

Ordway, D. J., Sonnenberg, M. G., Donahue, S. A., Belisle, J. T., & Orme, A. M. (2018). Drug-resistant strains of *Mycobacterium tuberculosis* exhibit a range of virulence in mice. *Infection and Immunity, 2,* 741–743.

Ordway, D., et al. (2021). Beijing strains of *M. tuberculosis*: Virulence, resistance, and transmission. *Frontiers in Cellular and Infection Microbiology, 11,* 650398. https://doi.org/10.3389/fcimb.2021.650398

Ormerod, L. P. (2015). Multidrug-resistant tuberculosis (MDR-TB): Epidemiology, prevention, and treatment. *British Medical Bulletin, 73,* 17-24.

Ormerod, L. P. (2017). Role of surgery in pulmonary multidrug-resistant tuberculosis. *Thorax, 62,* 377.

Pan African Medical Journal. (2023). Cigarette smoking and tuberculosis outcomes. *PAMJ, 44,* 105.

Pande, J. N., Singh, U. B., Sanjeev, S., Agarwal, R. C., & Singh, S. P. N. (2015). Evaluation of risk factors and prevalence of drug-resistant tuberculosis in North India. *Chest, 128*(4), 405.

Rakotonira, S., Chandrasekar, C., Mahilmaran, A., Kanakaraj, K., Karthikeya, D. S., & Suriakumar. (2015). HIV co-infection among multidrug-resistant tuberculosis (MDR-TB) patients in Lesotho. *Journal of the Indian Medical Association, 107*(5), 281-286.

Raviglione, M. C., Rieder, H. L., Zellweger, J. P., Keizer, S. T., & Migliori, G. B. (1994). Tuberculosis control in Europe and international migration: Report of the working group. *European Respiratory Journal*.

Rehm, J., et al. (2021). Alcohol consumption and tuberculosis treatment outcomes: Systematic review. *BMC Public Health, 21*, 1245. https://doi.org/10.1186/s12889-021-11317-3

Rieder, H. L. (2019). *Interventions for tuberculosis control and elimination*. Paris: IUATLD.

Robah, B., Katherine, F., Christopher, D., & Rob. (2012). Achieving the millennium development goals for health: Cost-effectiveness analysis of strategies for tuberculosis control in developing countries. *BMJ*. https://doi.org/10.1136/bmj.38645.660093.68

Robert, M. J., Christopher, B. S., Gonzalez, L. C., Kawamura, M., Osmond, D. H., & Daley, C. L. (2014). Tuberculosis treatment outcomes: Directly observed therapy compared with self-administered therapy. *American Journal of Respiratory and Critical Care Medicine, 170*, 561-566. https://doi.org/xxxx

Sweetland, A. C., et al. (2020). Mental health and tuberculosis treatment adherence. *Lancet Psychiatry, 7*(9), 761–774. https://doi.org/10.1016/S2215-0366(20)30228-5

Trauner, A., et al. (2021). Within-host population dynamics of tuberculosis. *Nature Medicine, 27*, 167–176. https://doi.org/10.1038/s41591-020-01178-1

WHO. (2009-2018). *WHO Tuberculosis Facts*. Geneva: World Health Organization.

WHO. (2022). *Consolidated guidelines on tuberculosis: Module 4 – Treatment*. Geneva: World Health Organization.

WHO. (2023). *Global tuberculosis report 2023*. Geneva: World Health Organization.

World Health Organization. (2014). *Global Tuberculosis Report*. Geneva: WHO.

Xin, J., Borgdorff, M. W., Pakker, N. G., Chum, H. J., Klokke, A. H., Senkoro, K. P., et al. (2017). HIV-1 infection as a risk factor for the development of tuberculosis: A case-control study in Tanzania. *International Journal of Epidemiology, 22*(6), 1159-1165. https://doi.org/xxxx

Zetola, N. M., Macesic, N., Modongo, C., Shin, S., Ncube, R., & Collman, R. G. (2014). Longer hospital stay is associated with higher rates of tuberculosis-related morbidity and mortality within 12 months after discharge in a referral hospital in Sub-Saharan Africa. *BMC Infectious Diseases, 14*, 1-11. https://doi.org/xxxx

Zetola, N., et al. (2020). Risk of TB infection post-hospital discharge: Cohort study in Botswana. *PLoS ONE, 15*(6), e0233768. https://doi.org/10.1371/journal.pone.0233768

Zhang, L., Han, X., Ge, Q., Shu, W., Sun, Y., Gao, J., & Gao, W. (2024). Treatment outcomes of retreated patients with isoniazid/rifampicin-resistant pulmonary tuberculosis. *BMC Infectious Diseases, 24*(1), 7

Zignol, M., Germet, W., Falzon, D., Sismanidis, C., Glazion, P., Floyd, K., & Raviglione, M. (2012). Global multidrug-resistant tuberculosis and extreme drug-resistant tuberculosis: Situation and trends (2007–2010). *Bulletin of the World Health Organization, 90*, 111–119.

APPENDICES

Appendix I: Consent Form

Title of Study: Predictors of TB treatment Failure in Nairobi County

Investigator: Faith Muthoki Mwanzui

Institution: Jomo Kenyatta University of Agriculture and Technology health and sanitation.

Request: I request you to take part in a research study. The research study aims to determine factors associated with TB treatment failure in Nairobi County. TB treatment failure is becoming a common problem in Kenya. It is expensive to treat and take long to complete treatment. Understanding predictors of the disease may enable us to, control its spread and prevent development of a more serious form of disease. The study session is expected to last about 50 minutes. During this time, you will be asked some questions about the current and past illness and other practices andexperiences your left arm will also be examined for BCG/ TB vaccination scar. The study will not interfere with your current treatment.

Risks and benefits: The study will not pose any risks to you. This study may help to improve our understanding, prevention and treatment of TB treatment failure in future. There will be no costs to you for taking part in this study.

Confidentiality: All Information obtained about you will be kept confidential and will be used only for the purposes of the study. Your name will not be required. The results of the study may be published or disseminated without revealing your identity. **Consent:** You are free to take part or to withdraw from the study, there will be no penalty.

Questions: If you have any questions, concerns or complaints about the study, please call

Faith Muthoki: 0725949928

Signatures: Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of participant……Date……..

Signature of interviewer……..……Date……..

Signature of investigator……..……Date……

Appendix II: Questionnaire

Questionnaire

To be administered to patient in patients own, language. Answer as many questions as possible

1. General Information

Questionnaire number ☐

1. Status of patient
   ☐ Case ☐ Control
2. Date of interview dd / mm / yyyy _____ / _____ / _____
3. Interviewer Name_____
4. Health Facility details
   a) Name of Health Facility _____ Level 2, 3, 4, 5, 6
   ☐ Private ☐ Public ☐ Mission
   b) District _____
   c) Province _____

2. Personal details

1. Patient unique identifier ☐
2. Sex ☐ Male ☐ Female
3. Nationality _____
5. Where have you been living in the past 1 year? Country _____Town or district_____
6. Date of birth dd / mm / yyyy ____/____/_____ Age in years_____*(fill both & check for consistency)*
7. Religion
   ☐ Catholic ☐ Protestant ☐ Muslim ☐ None
   Others specify_____
8. Marital status
   ☐ Single ☐ Married ☐ Cohabiting
   ☐ Separated ☐ Divorced ☐ Widowed others specify_____
9. Level of education (highest level of formal education completed)
   ☐ None ☐ Primary ☐ Secondary ☐ Tertiary
   Others specify_____

10. Current Employment

☐ Salaried employment ☐ Self employed ☐ Not employed

☐ Casual employment ☐ Young in school Specify _____

11. Have you changed your employment since illness?

☐ Yes ☐ *if no go to question 13*

12. if yes what was your employment prior to current illness

☐ Salaried employment ☐ Self employed ☐ Not employed

☐ Casual employment Specify _____

13. What means of transport were you using to travel to the hospital where you were treated for the last TB episode *(Report what the patient is currently using if he/she has never been treated for TB)*

☐ On foot ☐ Motorcycle ☐ Personal car

☐ Bicycle ☐ Matatu

How long does it take to get to hospital _____(Minutes)

Estimated distance _____Kms

4. Clinical information

History of current TB episode

1. When were you diagnosed to have the current episode of TB? dd /mm/ yyyy _____ /_____ /_____Duration of illness to the present date _____month

2. How was the TB diagnosed? ***(check the TB register)***

☐ Clinical examination ☐ Sputum microscopic examination

☐ X ray ☐ Don't Know

3. What type of TB did you have? ***(confirm from the TB facility register)***

☐ New Sputum smears positive PTB ☐ ear negative relapse

☐ New Sputum smear negative PTB ☐ ear positive relapse

☐ Extra-pulmonary TB ☐ atment Failure Others Specify_____

4. For those with sputum smear positive TB check the register for bacillary load on AFB microscopy at month 0?

☐ + ☐ ++ ☐ +++ ☐ Not available

5. For how long were you supposed to take TB drugs during the last episode of ordinary TB?

☐ Six months ☐ Eight months

Other specify _____

6. Was your TB treatment period changed from what you had been informed at the beginning of treatment

☐ Yes ☐ No

What were the reasons for the change_____

_____

7. Were you injected as part of TB treatment

☐ Yes No ☐

8. If yes for how long?_____ months

9. What messages concerning TB were you given before or during treatment for the current episode of TB?

_____

_____

_____

_____

10. Did you have someone to observe you while taking your TB medicine

☐ Yes ☐ No

Confirm DOTS status in treatment register after interviewing the patient

☐ DOTS done ☐ DOTS not done

11. If yes in 10 above who was it?

☐ Health care worker ☐ Family member

☐ Community member ☐ Workmate Others specify_____

Other specify_____

12. How available was the person to observe you while taking treatment

☐ Daily ☐ Once in 2 days ☐ Once in 3 days ☐ Once in 4 days

☐ Once a week ☐ Once in 2 weeks ☐ once a month Other specify_____

13. Were you for any reason during treatment for the current TB episode unable to take your TB medicine or go for injections

☐ Yes ☐ No ☐ Cannot remember ***if no go to question 16***

If yes, What were the reasons_____

14. If yes in (13) above, for how long were you unable to take your medicine

dates from dd/mm/yyyy_____/_____/_____ to _____/_____/_____ estimate the period

☐ less than 1 week ☐ 1 Week ☐ 2 weeks ☐ 3 weeks

☐ 4Weeks ☐ 2 months ☐ 3 months others specify_____

15. Did you continue taking the same medicines you had been taking when you resumed treatment?

☐ Yes ☐ No

16. Was sputum sent to Nairobi or KEMRI for drug resistance testing?

☐ Yes ☐ No ***If No go to question 17***

For those tested, what is drug resistance pattern? (Check the District MDRTB register/ lab request forms)

Drug	Rifampicin	Isoniazid	Ethambutol	Streptomycin	Not Available
Sensitive					
Resistant					

Indicate if ☐ MDR-TB ☐ Non MDR-TB ☐ XDR-TB

For M/X DRTB are you on treatment? ☐ Yes ☐ No

17. Were you admitted in hospital at any time within two years prior to the onset of the current illness?

☐ Yes ☐ No

18. Did you come in contact with someone with TB or a chronic cough prior to the onset of the current illness?

☐ Yes ☐ No ☐ Don't Know

If yes was it MDR-TB? ☐ Yes ☐ No ☐ Don't know

19. Have you ever received treatment (Isoniazid Preventive Therapy) to protect you from developing TB Disease

☐ Yes ☐ No ☐ Don't Know

If yes for what reasons and how long? Reason _____duration _____months

20. Do you have diabetes

☐ Yes ☐ No

21. Did you have any chronic lung condition prior to diagnosis of the TB?

☐ Yes ☐ No ☐ Don't Know

If yes, what was the condition

☐ Asthma ☐ Other chronic lung condition

22. Were you tested for HIV during TB treatment?

☐ Yes ☐ No

23. If yes in 22 above, what were the results

☐ HIV+ ☐ HIV-

24. Confirm HIV testing from TB register

☐ HIV+ ☐ HIV- ☐ Not Tested *If HIV negative or not tested go to page 6*

25. If HIV positive are you on antiretroviral drugs

☐ Yes ☐ No

If on ART, when was it started relative to TB diagnosis? ☐ Before ☐ After

Indicate the difference in period of time_____

26. Was CD4 count done?

☐ Yes ☐ No If yes, what was the number when last done? _____

Previous Medical history

1. Have you ever been treated with anti TB drugs before the current treatment

☐ Yes ☐ No

If No, in 1 above go to question 8

2. If yes, in 1 above how many separate episodes of TB did you have _____

What were the dates, length of treatment and treatment outcomes of each of the episodes?

(Ask the patient what he/ she was told the treatment outcome was for each of the treatments)

a) Date _____length treatment _____outcome_____
b) Date _____length treatment _____outcome_____
c) Date _____length treatment _____outcome_____
d) Date _____length treatment _____outcome_____
e) Date _____length treatment _____outcome_____
f) Date _____length treatment _____outcome_____
g) Date _____length treatment _____outcome_____
h) Date _____length treatment _____outcome_____

3. Were you explained to on how to take the TB medicine during each of the TB treatment?

☐ Yes ☐ No

4. Were you for any reason unable to take TB medicine while undergoing any of the previous TB treatment?

☐ Yes ☐ No

5. If yes for how long were you unable to take the medicine?

dates from dd /mm/ yyyy____/____/_____ to ____/____/_____

☐ Less than I Week ☐ 1Week ☐ 2weeks ☐ 3weeks
☐ 4Weeks ☐ 2 months ☐ 3 months Other specify_____

6. Did you have someone to observe you when taking your medicine during the previous episode of ordinary TB?

☐ Yes ☐ No

7. If yes in 6 above how available was the person to observe you while taking treatment

☐ Daily ☐ Once in 2 days ☐ Once in 3 days ☐ Once in 4 Days
☐ Once a week ☐ Once in 2 weeks ☐ Once a month Others specify_____

8. Did you receive the BCG (TB) vaccine during your childhood or at any other time?

☐ Yes ☐ No ☐ Don't know

I would like to examine your left forearm. *Examination for BCG scar*

☐ Present ☐ Absent

Behavioral and Social Factors

1. Have you ever smoked cigarettes? ☐ Yes ☐ No *If no go to question 6*
2. If yes when did you start (year) _____
3. Are you currently smoking? ☐ Yes ☐ No

   If no when did you stop? Date dd/mm/yyyy_____/_____/_____
4. Duration of smoking_____
5. How many sticks do you or were you smoking per day _____
6. Have ever lived with someone who smokes ☐ Yes ☐ No

   If yes for how long did you live with the person during his/ her active smoking_____
7. Any history of alcohol intake?

   ☐ Yes ☐ No If yes when did you start (Year/ month)_____

   Are you currently taking alcohol? ☐ Yes ☐ No

   If no when did you stop (Year/month)_____

   Duration of alcohol intake_____

   How frequent is or was the alcohol intake?

   ☐ Daily, ☐ Weekly ☐ Monthly, Others specify_____

   What type of alcohol were you or do you take? _____

   How much were you/do you take per day _____ glasses
8. Have you ever used any substance for recreation (e.g. chewable tobacco, Miraa / Khat, injectable drugs etc)

   ☐ Yes ☐ No

   If yes, which one (specify)_____ Is it current? ☐ Yes ☐ No
9. Do you live with your family?

   ☐ Yes ☐ No
10. How many people do you live with _____
11. What type of house do you live in?

    ☐ Temporary ☐ Semi permanent house ☐ Permanent house
12. Who owns the house

    ☐ Rental ☐ Personal ☐ Accommodated

    If rental, how much rent do you pay per month ?_____shillings
13. How many rooms are there in the house? _____
14. How many windows are there in the room you use_____
15. Do you open it/ them ☐ Yes ☐ No If yes how many hours per day is window open

    ☐ Less than an hour ☐ 1 hour ☐ 2hours ☐ 6 hours ☐ 8 hours

    ☐ 10 hours ☐ 12 hours ☐ 24 hours others specify_____

16. Do you share the room with anyone else?

☐ Yes ☐ No ***(If no go to question 18)***

17. If yes in 15 above, what is the age of those you share the house with? Indicate their Age breakdown

1st ____ 2nd ____ 3rd ____ 4th ____ 5th ____ 6th ____ 7th ____ 8th ____ 9th ____ 10th ____

18. Have you ever been imprisoned or detained in police custody

☐ Yes ☐ No

If yes which one and for how long? Prison/ custody_____ Duration_____ months

19. Have you ever been in a situation where you did not have a house to live in?

☐ Yes ☐ No

20. Have you ever stayed in a refugee camp or internally displaced persons camp?

☐ Yes ☐ No

If yes which one and how for how long? Camp _____ Duration _____Months

21. Have you ever travelled outside of the country?

☐ Yes ☐ If yes which one and _____ for how long_____ months

22. How many meals were you typically having per day prior to developing current episode of TB

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Others specify_____

23. How Did this number of meals influence how you swallowed your TB drugs

_____

_____

24. Could you describe what you do while coughing?_____

Decide if patient practices cough hygiene ☐ Yes ☐ No

25. Have you disclosed the form of TB you have to any one?

☐ Yes ☐ No

If yes to whom have you disclosed? _____

If no what are the reasons for non disclosure? _____

26. What do you recommend to the TB control program regarding TB care?

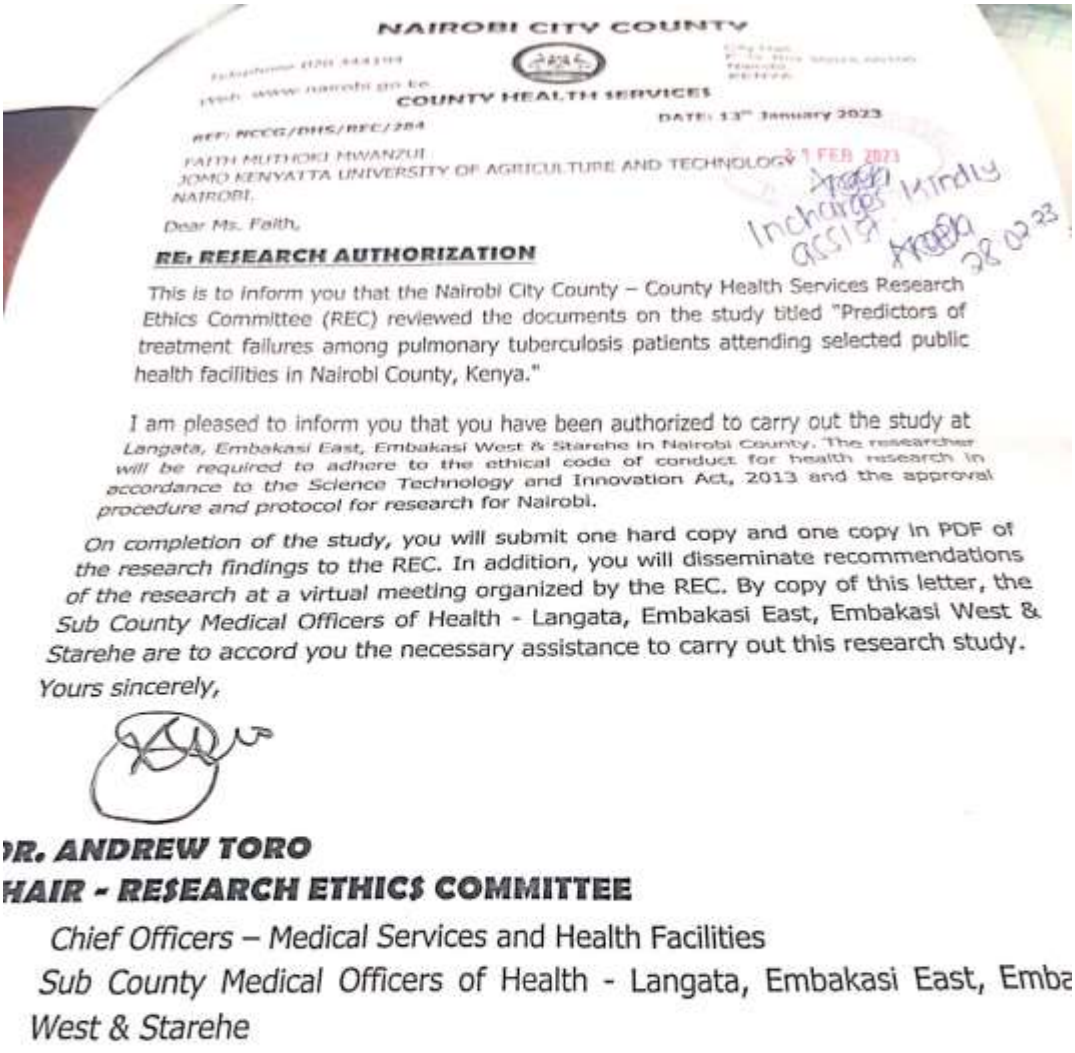
_____

Appendix III: Grading of Sputum Smear for AFB

International Union against Tuberculosis and Lung Disease recommended gradingof sputum smear microscopy results

Number of Acid Fast Bacilli counted	**Recording and Reporting**
Negative	
No AFB in at least 100 fields 0/negative	
1 to 9 AFB in 100 fields* Actual AFB counts in 100 fields	Scanty10 to 99 AFB +
1 to 10 AFB per fields in at least 50 fields	++
> 10 AFB per field in at least 20 fields	+++

Appendix IV: Study Authorization by the County



NAIROBI CITY COUNTY

COUNTY HEALTH SERVICES

REF: NCCG/DHS/REC/284

DATE: 13th January 2023

FAITH MUTHONI MWANZUI
JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY
NAIROBI.

21 FEB 2023

Dear Ms. Faith,

RE: RESEARCH AUTHORIZATION

This is to inform you that the Nairobi City County – County Health Services Research Ethics Committee (REC) reviewed the documents on the study titled "Predictors of treatment failures among pulmonary tuberculosis patients attending selected public health facilities in Nairobi County, Kenya."

I am pleased to inform you that you have been authorized to carry out the study at Langata, Embakasi East, Embakasi West & Starehe in Nairobi County. The researcher will be required to adhere to the ethical code of conduct for health research in accordance to the Science Technology and Innovation Act, 2013 and the approval procedure and protocol for research for Nairobi.

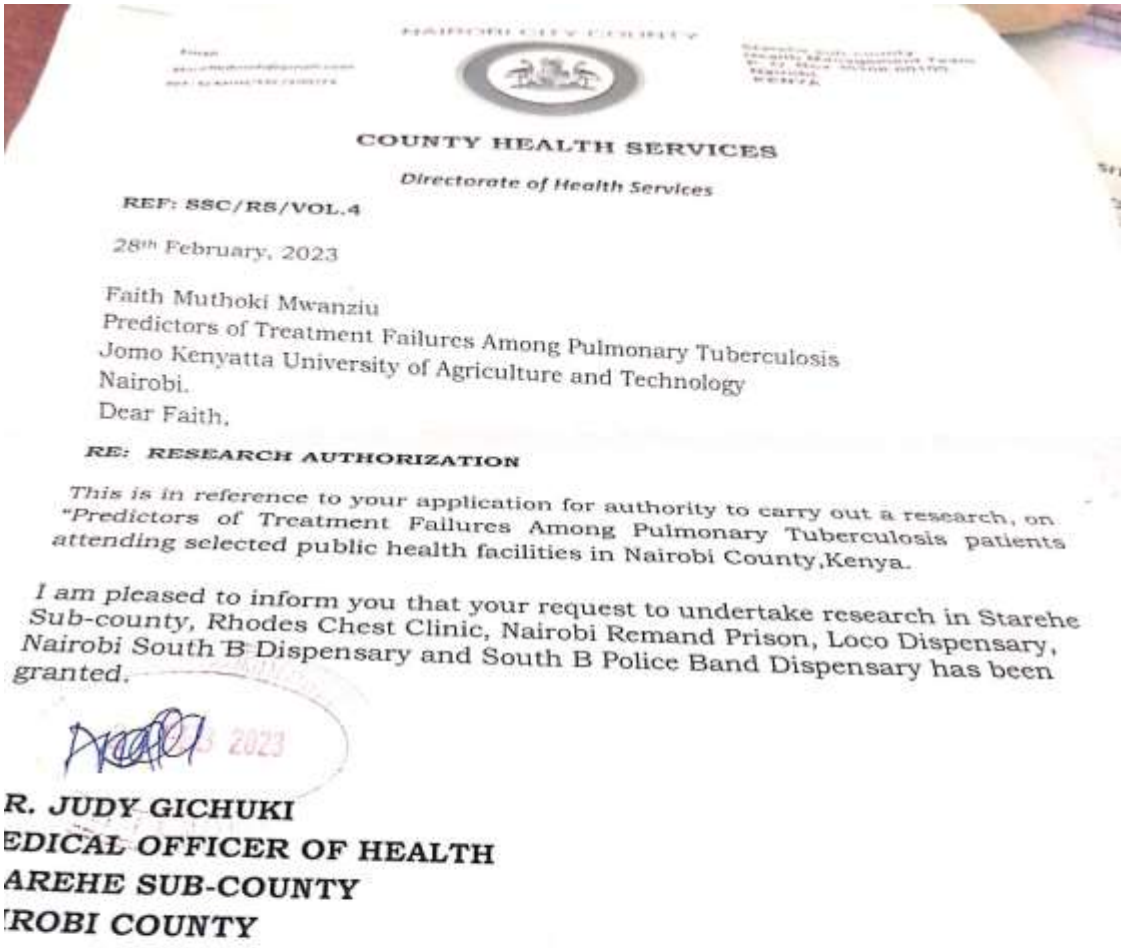
On completion of the study, you will submit one hard copy and one copy in PDF of the research findings to the REC. In addition, you will disseminate recommendations of the research at a virtual meeting organized by the REC. By copy of this letter, the Sub County Medical Officers of Health - Langata, Embakasi East, Embakasi West & Starehe are to accord you the necessary assistance to carry out this research study.

Yours sincerely,

DR. ANDREW TORO
CHAIR - RESEARCH ETHICS COMMITTEE

Chief Officers – Medical Services and Health Facilities
Sub County Medical Officers of Health - Langata, Embakasi East, Emba
West & Starehe

Appendix V: Study Authorization by the Sub-County



COUNTY HEALTH SERVICES

Directorate of Health Services

REF: SSC/RS/VOL.4

28th February, 2023

Faith Muthoki Mwanziu
Predictors of Treatment Failures Among Pulmonary Tuberculosis
Jomo Kenyatta University of Agriculture and Technology
Nairobi.

Dear Faith,

RE: RESEARCH AUTHORIZATION

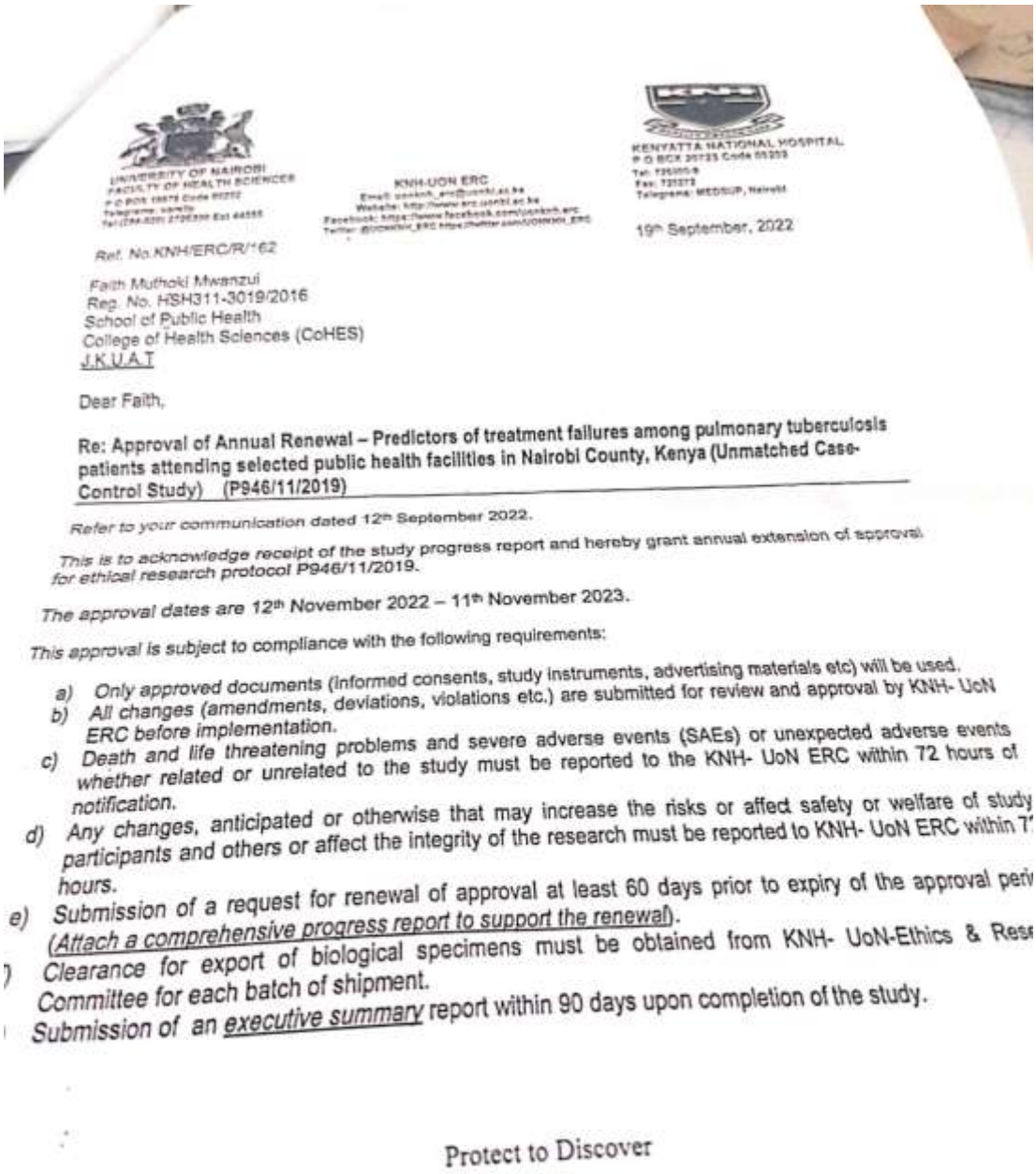
This is in reference to your application for authority to carry out a research, on "Predictors of Treatment Failures Among Pulmonary Tuberculosis patients attending selected public health facilities in Nairobi County,Kenya.

I am pleased to inform you that your request to undertake research in Starehe Sub-county, Rhodes Chest Clinic, Nairobi Remand Prison, Loco Dispensary, Nairobi South B Dispensary and South B Police Band Dispensary has been granted.

2023

R. JUDY GICHUKI
EDICAL OFFICER OF HEALTH
AREHE SUB-COUNTY
ROBI COUNTY

Appendix VI: Study Authorization by KNH-OUN ERC



UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES

KNH-UON ERC

KENYATTA NATIONAL HOSPITAL

Ref. No.KNH/ERC/R/162

19th September, 2022

Faith Muthoki Mwanzui
Reg. No. HSH311-3019/2016
School of Public Health
College of Health Sciences (CoHES)
J.K.U.A.T

Dear Faith,

Re: Approval of Annual Renewal – Predictors of treatment failures among pulmonary tuberculosis patients attending selected public health facilities in Nairobi County, Kenya (Unmatched Case-Control Study) (P946/11/2019)

Refer to your communication dated 12th September 2022.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethical research protocol P946/11/2019.

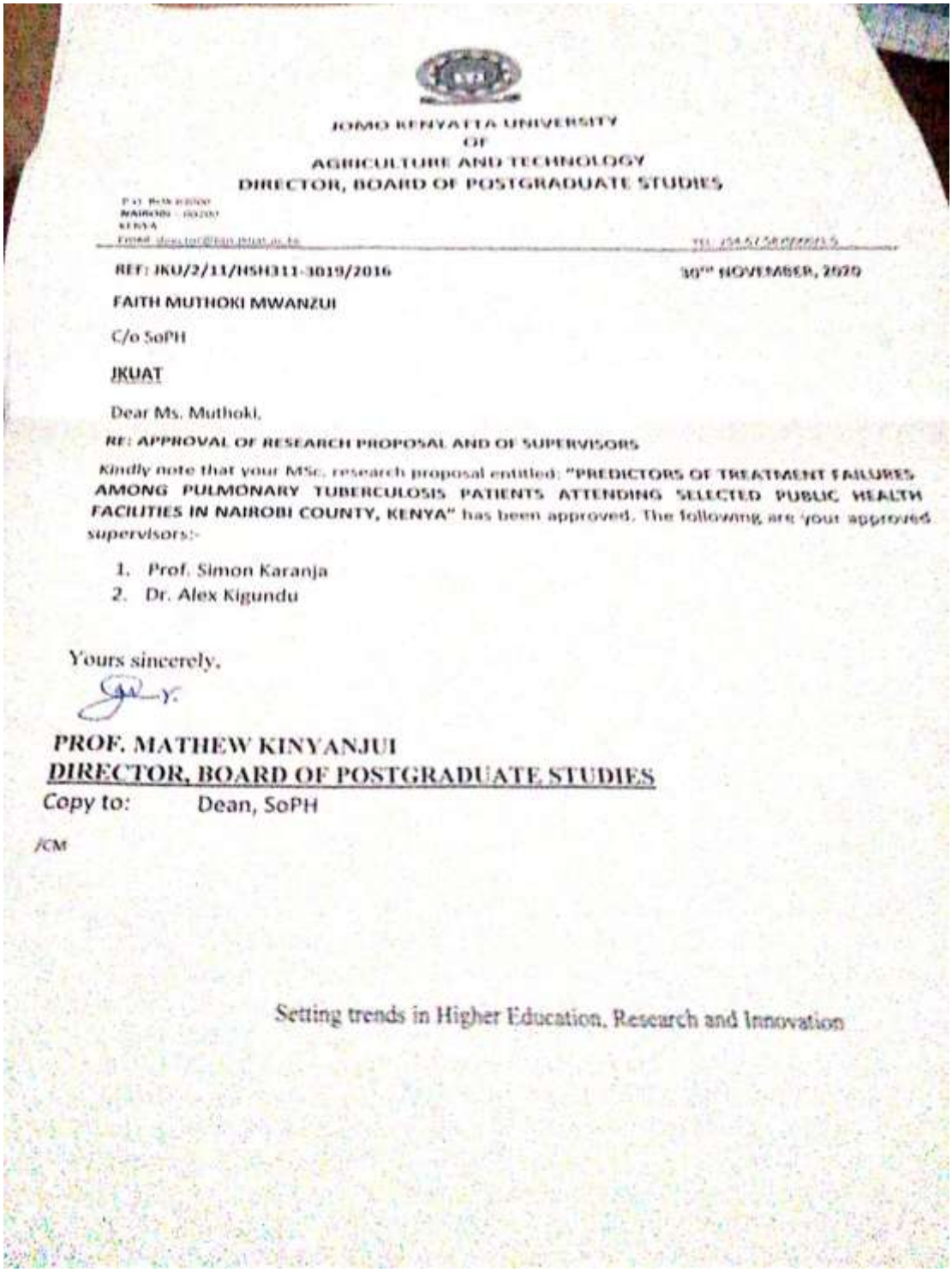
The approval dates are 12th November 2022 – 11th November 2023.

This approval is subject to compliance with the following requirements:

a) *Only approved documents (informed consents, study instruments, advertising materials etc) will be used.*
b) *All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH- UoN ERC before implementation.*
c) *Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH- UoN ERC within 72 hours of notification.*
d) *Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 7 hours.*
e) *Submission of a request for renewal of approval at least 60 days prior to expiry of the approval peri (Attach a comprehensive progress report to support the renewal).*
) *Clearance for export of biological specimens must be obtained from KNH- UoN-Ethics & Res Committee for each batch of shipment.*
Submission of an executive summary report within 90 days upon completion of the study.

Protect to Discover

Appendix VII: Study Authorization by JKUAT



JOMO KENYATTA UNIVERSITY
OF
AGRICULTURE AND TECHNOLOGY
DIRECTOR, BOARD OF POSTGRADUATE STUDIES

NAIROBI
KENYA

REF: JKU/2/11/HSH311-3019/2016 30TH NOVEMBER, 2020

FAITH MUTHOKI MWANZUI

C/o SoPH

JKUAT

Dear Ms. Muthoki,

RE: APPROVAL OF RESEARCH PROPOSAL AND OF SUPERVISORS

Kindly note that your MSc. research proposal entitled: "PREDICTORS OF TREATMENT FAILURES AMONG PULMONARY TUBERCULOSIS PATIENTS ATTENDING SELECTED PUBLIC HEALTH FACILITIES IN NAIROBI COUNTY, KENYA" has been approved. The following are your approved supervisors:-

1. Prof. Simon Karanja
2. Dr. Alex Kigundu

Yours sincerely,

PROF. MATHEW KINYANJUI
DIRECTOR, BOARD OF POSTGRADUATE STUDIES
Copy to: Dean, SoPH

/CM

Setting trends in Higher Education, Research and Innovation

Appendix VIII: Unconditional Logistic Regression Model

Step 1

All variables with P≤ 0.1 were entered into the model with the tabulated results.

Term	AOR	95% C.I.		Coefficient	S. E.	Z-statistic	P-Value
BCG scar Absent (Yes/No)	2.1427	0.6844	6.7088	0.7621	0.5823	1.3087	0.1906
Bacillary load ≥2 + (Yes/No)	0.9186	0.3665	2.3025	-0.0849	0.4688	-0.1810	0.8563
	0.2228	**0.0853**	**0.5821**	-1.5016	0.4901	-3.0639	**0.0022**
DOT (Yes/No)							
Given TB Message (Yes/No)	0.6429	0.2389	1.7299	-0.4417	0.5050	-0.8747	0.3818
Positive HIV status (Yes/No)	0.4207	0.1588	1.1147	-0.8657	0.4971	-1.7415	0.0816
Previous TB treatment (Yes/No)							
Positive smear@2 months (Yes/No)	**60.4082**	**19.7771**	**184.5140**	4.1011	0.5697	7.1987	**0.0000**
Missed clinic appointment (Yes/No)	40.2745	1.7328	14.3731	112.91	3.2862	0.7423	**0.0012**
Travelling <3 KM to hospital (Yes/No)	12.31	4.557	33.3564	14.59	3.0471	7.156	**0.0032**
	0.4830	0.1872	1.24630	-0.7277	0.4835	-1.5050	0.1323

Appendix IX: Unconditional Logistic Regression Model Building Process (Continued)

Step 2

"Bacillary load ≥2+" was removed from the model since it has the highest P- value. The remaining variables were re-entered into the model with the results tabulated below

Term	AOR	95% C.I.		Coefficient	S. E.	Z-statistic	P-Value
BCG scar Absent (Yes/No)	2.1082	0.6816	6.5208	0.7459	0.5761	1.2947	0.1954
	0.2234	**0.0855**	**0.5836**	-1.4988	0.4900	-3.0589	**0.0022**
DOT (Yes/No)	0.6411	0.2386	1.7222	-0.4446	0.5042	-0.8818	0.3779
Given TB Message (Yes/No)	**36.189**	**17.8488**	**151.5027**	3.2862	0.7423	17.348	**0.0032**
Missed appointment (Yes/No)	**0.4267**	**0.1632**	**1.1158**	-0.8517	0.4905	-1.7365	0.0825
Positive HIV status(Yes/No)	**60.6727**	**19.8700**	**185.2627**	4.1055	0.5695	7.2084	**0.0000**
Previous TB treatment (Yes/No)							
Positive sputum @ 2months (Yes/No							
<3 KM to hospital (Yes/No)							

Appendix X: Unconditional Logistic Regression Model Building Process (Continued)

Step 3

"Given TB messages" was removed from the model since it has the highest P-value. The remaining variables were re-entered into the model with the results tabulated below

Term	AOR	95% C.I.		Coefficient	S. E	Z- Statistic	p-Value
DOT (Yes/No)	**0.2208**	**0.0850**	**0.5738**	-1.5104	0.4872	-3.1003	**0.0019**
	2.1082	0.6816	6.5208	0.7459	0.5761	1.2947	0.1954
BCG scar(Yes/No)	**4.7637**	**1.0744**	**21.1222**	1.5610	0.7599	2.0543	**0.0399**
	0.4304	0.1651	1.1215	-0.8431	0.4887	-1.7253	0.0845
Missed appointment (Yes/No)	**61.265**	**20.1111**	**186.634**	4.1152	0.5683	7.2407	**0.0000**
Positive HIV status (Yes/No)	**40.2130**	**1.81772**	**14.3731**	112.98	3,2867	0.7423	**0.0012**
Previous TB treatment (Yes/No)							
Positive sputum @2months Yes/No							
Travelling <3KM to hospital (Yes/No							

Appendix XIII: Glossary

New case: A person diagnosed with tuberculosis who has never received treatment before or has taken anti-TB medication for less than one month.

Relapse: A patient who was previously treated and declared either cured or treatment-complete, but later tests positive again for TB through smear or culture.

Failure: A newly diagnosed, smear-positive TB patient who continues to test smear-positive after five months or more of starting treatment.

Return after default (RAD): A patient who restarts TB treatment after missing it for two or more months and is bacteriologically confirmed to have TB.

Cured: A patient who tests negative for TB in a sputum smear at the end of treatment and on at least one prior test during the course of treatment.

Treatment completed: A person who finishes their TB medication regimen but does not meet the specific standards for being classified as cured or a failure.

Chronic: A TB patient who remains smear-positive even after completing a full standard retreatment course using key anti-TB medications.

Died: Any patient who dies for any reason while still undergoing TB treatment**.**

Default: A TB patient who discontinues treatment for a continuous period of at least two months.

Transferred out: A patient who is moved to another health facility or reporting unit, and whose final treatment outcome is not documented.

Category I: New cases of acid-fast bacillus (AFB) smear-positive pulmonary tuberculosis (TB) and other recently diagnosed individuals who are sputum-negative or have extra-pulmonary TB forms with severe manifestations**.**

Category II: Patients who have previously undergone anti-TB treatment for more than one month, indicating an increased risk of multi-drug resistant TB. This category encompasses individuals with smear-positive relapses, smear-positive treatment failures, and smear-positive patients undergoing retreatment after default. Additionally, Category II includes smear-negative pulmonary and extra-pulmonary TB cases resulting from treatment failure and relapse, albeit infrequently and exceptionally.

Category III: New cases of AFB smear-negative pulmonary and extra-pulmonary TB in individuals who are not severely ill

Appendix XI: Unconditional Logistic Regression Model Building Process (Continued)

Step 4

"BCG scar" was removed from the model since it has the highest P- value.The remaining variables were re-entered into the model with the results tabulated below.

Term	AOR	95%	C.I.	Coefficient	S. E	Z- Statistic	p-Value
DOT (Yes/No)	**0.2208**	**0.0850**	**0.5738**	-1.5104	0.4872	-3.1003	**0.0019**
	4.7637	**1.0744**	**21.1222**	1.5610	0.7599	2.0543	**0.0399**
Missed appointment (Yes/No)	0.4304	0.1651	1.1215	-0.8431	0.4887	-1.7253	0.0845
Positive HIV status (Yes/No)	**61.265**	**20.1111**	**186.634**	4.1152	0.5683	7.2407	**0.0000**
Previous TB treatment (Yes/No)	**40.2130**	**1.81772**	**14.3731**	112.98	3,2867	0.7423	**0.0012**
Positive sputum @2months Yes/No							
Travelling <3KM to hospital (Yes/No							

Appendix XII: Unconditional Logistic Regression Model Building Process (Continued)

Step 5

"Travelling >3K to the hospital" was removed from the model since it has the highest P-value. Variables were re-entered into the model with the results tabulated below

Term	AOR	95% C.I.		Coefficient	S. E.	Z-Statistic	P-Value
DOT (Yes/No)	**0.2171**	**0.0850**	**0.5544**	-1.5274	0.4784	-3.1929	**0.0014**
Positive HIV status (Yes/No)	**0.3577**	**0.1398**	**0.9156**	-1.0279	0.4795	-2.1440	**0.0320**
Previous TB treatment(Yes/No)	**80.2555**	**27.9044**	**230.8217**	4.3852	0.5390	8.1358	**0.0000**
Missed clinic appointment (Yes/No)	**36.7769**	**15.0739**	**87.1647**	3.2525	0.7002	4.2104	**0.0351**
Positive smear sputum@2months (Yes/No)	**64.1696**	**21.1938**	**119.479**	3.7559	0.4516	5.6739	**0.0021**

Appendix XIV: Symbols Description as Used in Fleiss Formulation

Description of Symbols in the formula	Value
Z - Score for two-tailed test based on α level ($z_{\alpha/2}$) ...	1.96
Z - Score for one-tailed test based on β level ($z_{1-\beta}$)	0.84
Ratio of controls: cases (r).....	2:1
Proportion of cases with exposure (P_1)	23%
Proportion of controls with exposure (P_2)	9%

(Unpublished data from MDR-TB surveillance system evaluation)

$1 - P_1$ (q_1)		77%
$1 - P_2$ (q_2).....		91%
Number of cases (n_1).....		81
Number of controls (n_2)	162	
Total sample size ($n_1 + n_2$)		**243**

Appendix XV: Cases and Controls by Facility and Sub-County

Sub county / facility	Cases (No)	Controls(No)	Cases (No) Tracked
Starehe sub count	29(35%)	82	29
1. south B Health center	5	2	
2. police Band	5	2	
3. Rhodes health center	4	2	
4. loco health center	4	4	
5. Mary immaculate	4	8	
6. Remand	7	3	
Langata sub county	25(30%)	32	25
8. Kibera Health Centre	4	2	
9. Mbagathi District hospital	7	2	
16. Langata health center	5	24	
17. Kibera south	5	2	
18. Karen health center	4	2	
Embakasi west	12(15%)	20	12
19. Mama lucy kibaki	5	10	
20. Edarp komarock	3	6	
21. Soweto health center	4	8	
Embakasi East	16(20 %)	10	16
30. Kayole II Health center	4	8	
31. Umoja health center	3	6	
32. Kariobagi health center	4	8	
33. Mukuru kwa njenga	5	10	