FACTORS ASSOCIATED WITH DELAYS IN DIAGNOSIS AND TREATMENT INITIATION AMONG TUBERCULOSIS PATIENTS IN MOMBASA COUNTY, KENYA

BY

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DECLARATION

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DEDICATION

This work is dedicated to my parents, my daughter Hope and my friend Japheth who supported me through their prayers and thoughts.

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This work was a success due to the immense contribution and support I received from individuals I deeply appreciate. Foremost, I would like to thank God for seeing me through my study period. My sincere gratitude to Tharaka Nithi County government for giving me the study leave to undertake this course. I also wish to express my gratitude to my supervisors Dr. Richard K. Biegon and Mr. Tura Boru Galgalo for their guidance, time and support to ensure I successfully completed this project. I also wish to express my gratitude to the Field Epidemiology and Laboratory Training Program (FELTP-Kenya) for technical support and US Centers for Disease Prevention and Control for the financial support. I also extend my gratitude to the sub county tuberculosis coordinators and Mombasa County Department of Health staff for their support and lastly the study respondents for accepting to take part in this study.

ABSTRACT

Background: Delay in diagnosis remains a major gap in TB control and leads to increased transmission of TB, resulting in increased TB mortality.

Objectives: This study was conducted the study to determine the median time to diagnose and initiate TB treatment and identify the risk factors for delays in pulmonary TB (PTB) diagnosis and treatment initiation in Mombasa County.

Methods: A facility based cross-sectional study among PTB patients on intensive phase of treatment was carried out. Interviews were conducted using structured pre-tested questionnaires. Data on demographic, clinical and laboratory factors, health seeking behaviors and health services offered to PTB patients were collected. Median time (days) of diagnosis was calculated based on time of onset of TB symptoms to when TB diagnosis was confirmed. Delay in diagnosis was defined as time period exceeding the calculated median time. Delay in treatment initiation was defined as time period >2 days from diagnosis to treatment initiation based on the national TB program target of initiating treatment within 2 days of diagnosis. Using STATA version 13, I calculated proportions and frequencies, crude and adjusted-odds-ratios (AOR) at 95% confidence-intervals (CI) and factors with p-value of ≤0.05 in the final logistic regression model were considered as risk factors.

Results: Interviewes were conducted for 354 patients; median age was 33 years (range 3–81 years), 72% (255/354) were male, 51.7% (183/354) were married, 24.9% (88/354) were HIV positive, 85.9% (304/354) presented with a cough, and 42.4% (150/354) first sought care from a private health facility. The median for diagnosis was 67 days (range 3 – 411 days) and 61.6% (218/354) of the patients had experienced delay in diagnosis and 38.4% (136/354) had no delays in diagnosis. From diagnosis to treatment initiation, the duration ranged from 0 – 63 days with 36.7% (130/3534) having delays and 63.3% (224/354) had no delays in treatment initiation. The difference between those who experienced delay in diagnosis and those who did not experience delay in diagnosis as well as between those who experienced delay in treatment initiation and those who did not experience delay in treatment initiation were statistically significant (p<0.001). Factors independently associated with delay in diagnosis included; delays in getting laboratory results due to Xpert MTB/RIF referrals (aOR 4.59, CI= 2.17, 9.71) compared to other reasons; those on treatment for other conditions (aOR 3.74, CI=1.42, 9.86) unlike those who had no other comorbidity and distance to the nearest health facility more than one kilometer (aOR 3.01, CI=1.64, 5.53) compared to less than one kilometer. Factors independently associated with delays in treatment initiation were; using a motorcycle as compared to walking as transport means (aOR 1.99, CI=1.16, 3.42) and being male (aOR 2.07 CI=1.22, 3.52) compared to being female.

Conclusion: Over half of the patients experienced diagnosis delays and a third experienced treatment delays. Patient and health care system related factors were associated with diagnosis and treatment initiation delays. I recommend strengthening of TB active case finding in the community, public private partnerships, laboratories sample networking and equipping more facilities with the Xpert MTB/RIF machines to reduce the turnaround time for the results.

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OPERATION DEFINITIONS

The definitions were adopted from the World Health Organization (WHO) revised definitions for Tuberculosis (WHO, 2013);

i. Pulmonary tuberculosis (PTB) - any bacteriologically confirmed or clinically diagnosed patient of TB involving the lung parenchyma or the tracheobronchial tree.

ii. Extra-pulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed patient of TB involving organs other than the lungs, e.g. Pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

iii. Bacteriologically confirmed patient of TB was a patient from whom a biological specimen had a detectable TB bacillus by smear microscopy, culture or WHO-approved rapid diagnostic test (such as Xpert MTB/RIF).

iv. Intensive phase of treatment includes the first two months of treatment of a TB patient.

v. Multidrug-resistant tuberculosis (MDR-TB) is a form of TB resistance to at least both isoniazid and rifampicin.

vi. Tuberculosis treatment site is any health institution with health care providers formally engaged in any of the following TB program functions (DOTS): referring patients with presumptive TB or confirmed TB patients, laboratory diagnosis, TB treatment and patient support during treatment

vii. A TB zone is an administrative zone allocated for purposes of coordinating TB prevention and control activities within a given county as assigned by the ministry of health.

viii. Various delays as defined in our study were modified from a WHO region-based study (WHO-Regional Office for the Eastern Mediterranean, 2006) as follows:

- Delay in diagnosis; duration in days from onset of symptoms to diagnosis of tuberculosis.
- Delay in treatment initiation; duration from when the diagnosis was made to the treatment initiation.
- Delay in seeking health care (patient delay); duration from onset of any TB-related symptom (patient ever having felt sick of any symptom such as coughing, chest pain, fever, weight loss, haemoptysis and night sweat) until the first visit to a health care provider.
- Health care system delay; duration in days from first visit to a health provider to when TB treatment was initiated.

ACRONYM AND ABBREVIATIONS

AFB	Acid Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
AOR	Adjusted Odds Ratio
BCG	Bacille Calmette Guerin
CDC	Centers for Disease Control
CFR	Case Facility Rate
CI	Confidence Interval
COR	Crude Odds Ratio
CXR	Chest X-Ray
DOTS	Directly Observed Therapeutic Services
DRTB	Drug Resistant Tuberculosis
EPTB	Extra Pulmonary Tuberculosis
FBO	Faith Based Organization
FELTP	Field Epidemiology and Laboratory Training Program
HCS	Health care system
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IPT	Isoniazid Preventive Therapy
IQR	Interquartile range
KAP	Knowledge, Attitude, and Practices
KDHS	Kenya Demographic Health Survey
LPA	Line Probe Assay
LTBI	Latent Tuberculosis Infection
MCH	Maternal Child Health

MDR-TB	Multidrug resistant tuberculosis
MTB	Mycobacteria tuberculosis
NGO	Non-governmental organization
NTLD-P	National Tuberculosis, Leprosy and Lung disease program
NTP	National Tuberculosis program
OR	Odds Ratio
PD	Patient delays
PLWHA	People living with HIV/AIDS
PTB	Pulmonary Tuberculosis
PTB+	Pulmonary tuberculosis positive
RR-TB	Rifampicin Resistant Tuberculosis
SDG	Sustainable Development Goals
TB	Tuberculosis
TSR	Treatment success rate
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis* (MTB) (Ahmed et al., 2003) that typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB) (WHO, 2018b) The classic symptoms of active TB are a chronic cough with blood- containing sputum, fever, night sweats, weight loss and a wide range of symptoms from extra pulmonary TB (EPTB) (WHO, 2018b). The disease is spread through droplets when the bacteria are expelled into the air from a sick person by coughing, sneezing or spitting (WHO, 2018b). Diagnostic tests for TB disease include sputum smear microscopy, rapid molecular tests such as Xpert®MTB/RIF assay, line probe assays (LPAs) and Culture which is used as the Gold standard test (Ryu, 2015). Some of the high-risk groups for TB include household, workplace and social contacts of people diagnosed with active TB (WHO, 2018b); Health Care workers (HCWs) (Tudor et al., 2016); human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS), overcrowding, smoking (Yonge et al., 2016) people on dialysis; diabetic patients and prisoners among others. Other risk factors include substance abuse, undernourished people, indoor air pollution, poor housing and sanitation and exposure to silicosis (Godfrey et al., 2016). Prevention measures for TB involves screening the high-risk population, early diagnosis, early treatment and vaccination (WHO, 2018b). Once one is diagnosed with TB, treatment should be started immediately if no other underlying internal organ problems like liver, kidneys and the heart exists which may warrant baseline laboratory work up before starting anti-TB medication (Enos et al., 2018).

In 2017, ten million people developed TB but 4.3 million TB cases were not detected globally (WHO, 2018a). Kenya is among thirty countries with high burden of TB, multi-drug resistant (MDR-TB) and TB/HIV co-infection globally (WHO, 2016). There was a call for reduction in TB deaths and reduction in the TB incidence rate by 90% and 80% respectively by the year 2030 (WHO, 2015b) which is possible if everyone with TB received timely diagnosis and immediate treatment and thereby leading to the Case Fatality Rate (CFR) being low in all countries. The total new cases reported in Africa were 2.7 million and 700,000 deaths of which Kenya reported 81,518 TB cases and among them, 72% were bacteriologically confirmed TB cases (WHO, 2016). In 2017, Mombasa county had the second highest TB burden among the 47 counties in Kenya, with a case notification rate of 326/100,000 population, 2,309/3,854 (60%) of the notified cases were bacteriologically confirmed and the TB/HIV co-infection rate was 29% (MOH-NTLD-P, 2018). The treatment success rate (TSR) in Mombasa County for the year 2017 for TB patients was 83% which was below the national target of 90% (MOH-NTLD-P, 2018).

There are three components of delays in diagnosis and treatment which include patients, health system and total delay. There is no specified and accepted period of delays between onset of symptoms, diagnoses and start of treatments which poses a challenge in defining what is considered as a delay. Diagnosis delay is however defined as the time interval from the onset of the major pulmonary symptoms of TB to diagnosis and treatment delay is the period from the date of diagnosis to initiation of treatment (WHO-Regional Office for the Eastern Mediterranean, 2006). A systematic review of 52 studies on the length of treatment delays showed that average patient delays (28.7 days) and health system delays (25 days) were almost similar and the trend was similar when stratified into low and high income countries (Verhagen et

al., 2010). Other systematic reviews have highlighted the importance of addressing these delays so as to reduce burden of infectious cases and improve TB control (Finnie et al., 2011; Storla et al., 2008). Various determinants such as prevalence of TB, accessibility of health facilities, patient‘s socio-demographic variables, symptoms and signs, presence of refined suspicion index, infrastructures, and organization of the health care system are some of the factors influencing the delays (Eltayeb, 2016). Among the key interventions in TB control are early diagnosis and the immediate start of effective therapy (WHO, 2013b). New diagnostics techniques like Xpert MTB/RIF have also been adopted to increase detection of TB cases, due to their high sensitivity, specificity and shorter turnaround time.

1.2 Problem Statement

Many people have undetected TB for too long due to the chronicity of the disease. Despite that most people who develop TB disease can be cured with a timely diagnosis, prompt and correct treatment, TB has remained a major global health problem and still causing more deaths than HIV/AIDS among the infectious diseases (WHO, 2018a). Between the years 2009-2025, it is estimated that about one billion people will be newly infected, 200 million people will get TB and 40 million are likely to die from it if control programs do not improve (Bernard, 2006). In Kenya, data from routine surveillance activities shows that there is inadequate access to treatment for a high number of TB patients as they present with advanced disease on the first visit to a health facility mainly in areas with a higher level of TB burden, like Nairobi and the Coast regions, and more in private owned health facilities (Tollefson et al., 2016). As a result, it is estimated that 40% of people with active TB remain undetected and unreported in Kenya (Enos et al., 2018). These cases could either be patients seeking care and are not diagnosed, not notified and also those diagnosed and

not initiated on treatment also known as pre-treatment defaulters (Enos et al., 2018). Delay in treatment initiation has also been caused by poor linkage between clinical and laboratory services and this has led to pretreatment loss to follow up of TB patients (MOH-NTLDP mid-term review, 2018). Mombasa County has high burden of TB, TB/HIV co-infection and drug resistant TB (DRTB). In 2015, Tuberculosis and TB/HIV coinfections were ranked among the top ten causes of death in Mombasa County where the HIV prevalence was also higher (7.5%) than the national prevalence (5.9%) (National AIDS and STI Control Program, 2016) with lower treatment success rates (83%) than the national targets (90%) which is mainly affected by the high number of deaths (4%) (MOH-NTLD-P, 2018). In unpublished national TB program mortality audit report, the high number of deaths were found to occur more in the intensive phase of treatment or before treatment initiation due to delay in diagnosis (MOH-NTLD-P, 2018).

Tuberculosis delays in diagnosis and treatment initiation increases the period of infectivity in the community with increased risk of transmitting the infection to others, causes the disease to advance resulting in poor outcomes including death, families suffer distress and economic hardship in the process of taking care of their sick family member and reduce the impact of TB interventions among TB control programs (WHO, 2013). Untreated smear-positive patient infects over ten contacts per year on average (Storla et al., 2008). In patients with HIV/TB co-infection, increase in viral load occur when there are delays in diagnosis and treatments making them to not only transmit HIV infection but also rapidly progress immune suppression (Toossi et al., 2001).

Rapid and accurate diagnosis of TB is critical for timely initiation of treatment and control of the disease (Cazabon et al., 2017). It is possible that delay in diagnosis

could be a contributor to delay in initiation of treatment leading to high number of deaths. Since Mombasa county is categorized among counties that have strong health partners with an elaborate network of sputum sample referral there is also high placement of Gene Xpert machines which has led the county to adopt it as a mandatory first TB test for all its presumptive TB patients to enhance diagnosis and improve the case detection in the county. This was expected to mprove on early diagnosis and treatment initiation leading to better outcomes. It is therefore important to understand the factors that could lead to delays in diagnosis and treatment initiation among tuberculosis patients in Mombasa county.

1.3 Justification

Prompt diagnosis is the primary strategy in initiation of treatment and successful control of TB(WHO, 2015b). Delay in diagnosis or initiation of treatment is likely to increase the risk of transmission, especially in an overcrowded urban environment. Delay in timely and proper diagnosis of TB may lead to poor outcomes of treatment including death. In Western, Nairobi and kibwezi regions in Kenya, delays in TB diagnosis, treatment initiation and their associated factors studies have been document (Ayuo et al., 2008; Njau et al., 2012).

There are TB county-specific rates which vary widely across the 47 Kenyan counties. Mombasa County has high burden of TB, TB/HIV co-infection and drug resistant TB (DRTB). The county also has high numbers of intravenous drug users, alcoholism, overcrowding, urbanization, high burden of HIV/AIDS as some of the risk factors that increase transmission of TB infection (Yonge et al., 2016). The county adopted the use of MTB/RIF gene xpert test for diagnosis as the first test for all its presumptive TB cases in 2017 and this is expected to improve on timely diagnosis. In Mombasa the length of time to diagnosis and treatment initiation and factors associated with

delays are not clear for the PTB patients and little data exist on the impact of adoption of MTB/RIF gene Xpert as the initial test in Kenya in reducing such delays. The findings of this study are envisioned to help the county and national TB program to devise focused and targeted strategies towards improving TB detection and reducing overall transmission of TB as the country works toward achieving its goal in ending TB by the year 2030.

1.4 Research Question

i. What is the median time to diagnosis and initiate treatment among TB patients in Mombasa County?
ii. What factors are associated with delay in TB diagnosis in Mombasa County?
iii. What factors are associated with delay in TB treatment initiation in Mombasa County?

1.5 Objectives

1.5.1 Broad objective

To determine the median time to diagnose and initiate TB treatment and determine the factors associated with the delays in TB diagnosis and treatment initiation in Mombasa County.

1.5.2 Specific objectives

i. To assess the duration from onset of symptoms to diagnosis and to treatment initiation of TB patients.
ii. To determine factors associated with delay in diagnosis among bacteriologically confirmed pulmonary TB patients.
iii. To determine factors associated with delay in treatment initiation among bacteriologically confirmed pulmonary TB patients.

CHAPTER TWO

LITERATURE REVIEW

2.1 Situation of Tuberculosis Globally

Tuberculosis is the leading cause of death among infectious diseases (WHO, 2018a) and its burden is decreasing globally though not as was expected in the milestones of the End TB Strategy . There were 10 million people who developed TB globally in 2017 and more than half of them were men (WHO, 2015b). During the same period, an estimated 1.3 million HIV negative persons and 300,000 HIV positive persons died of TB. Drug-resistant TB continues to be a public health problem globally (WHO, 2018a).

Millions of deaths due to TB can be prevented through prompt diagnosis and successful treatment of TB patients. However, there exists gaps in detection and treatment and approximately 3.6 million TB cases go undetected worldwide (WHO, 2018a). This can be attributed to gaps in prompt diagnosis due to inaccessible health care, failure of the health workers and unavailability of laboratory equipments for diagnosis of TB among people seeking care, high cost of health care, latency of TB infection delay seeking of health care and diagnostic tests that are not sufficiently sensitive or specific to ensure accurate identification of all cases (WHO, 2015b).

The World Health Organizations' (WHO) aims at having patient centered care with early diagnosis and early treatment as key strategies to reduce TB deaths and incidence by the year 2030 (WHO, 2013), thereby ending TB in all countries. Strategic placement of Xpert MTB/RIF within HIV care settings and engagement of all care providers in provision of timely and quality-assured TB care are also key strategies so as to reduce delays in accessing diagnosis and treatment(WHO, 2015b).

2.2 Situation of Tuberculosis in Kenya

Tuberculosis services in Kenya are offered freely in the government, faith based and some non-governmental organizations health facilities which are a major milestone in the fight against TB in the country (MOH-NTLP, 2016). Kenya remains a high burden country for TB, MDR TB and HIV (WHO, 2017) and TB is among the leading causes of morbidity in Kenya. The TB incidence in the country was 233 cases/100,000 population with 36 deaths/100,000 population in 2015, a period in which 81,518 cases were notified in the country (MOH-NTLDP, 2015). However, the first post-independence Kenya TB prevalence survey of 2015, found the actual TB prevalence to be much higher than routinely notified. A total of 558 per 100,000 adult population in Kenya translating to 40% of people with active TB who remain undetected and unreported (Enos et al., 2018). Failure to diagnose pulmonary TB using smear examination and inadequate case finding remains a challenge (Van't Hoog *et al*., 2011; WHO, 2015b). The treatment success rate for the country dropped from 87% in 2016 to 81% in 2017 which was attributed to high death rates and loss to follow up of TB patients (MOH-NTLDP, 2018a). Deaths were reported to occur more in the intensive phase of treatment or before treatment initiation which is an indication of late diagnosis with patients presenting with advanced disease at the first time of seeking health care. Delays in diagnosis and treatment initiation can lead to an increased period of infectivity in the community and cause the disease to advance resulting in more morbidity, complications, and mortality while untreated smear-positive patient can infect over ten contacts per year on average (Eltayeb *et al*., 2016). Among patients with HIV/TB co-infection, increase in viral load may result when there are delays in diagnosis and treatments making them to not only transmit HIV but also rapidly progress into immune suppression (Toossi *et al*., 2001).

Finding missed TB cases will work towards the WHO global TB targets as well as achieving the Sustainable Development Goals (SDGs) which also emphasizes the need of ending global TB among other epidemics to ensure healthy lives among all populations (SDG, 2016). Some of the recorded risk factors for TB include overcrowding, alcohol misuse, other drug of abuse, malnutrition, diabetes mellitus, indoor air pollution, contact with people with TB disease, smoking, occupational exposure and exposure to silicosis (Sawadogo, 2015).

2.3 Diagnosis and Treatment of Tuberculosis

In Kenya, TB treatment services are integrated with general health services at all health facilities in the country. When patients present with TB symptoms at a health facility, they are recorded in the TB suspect register and have their sputum examined by direct smear microscopy looking for acid-fast bacilli with a Ziehl-Neelsen stain. Sputum specimens are sent to TB diagnosing centres for sputum-smear microscopy which are often located at selected primary level health facilities (microscopy centres) and some secondary level health facilities (subcounty, county and faith based hospitals) in each county. Smear-positive PTB cases are those with sputum smears positive for acid-fast bacilli (WHO, 2013a). In 2011, Gene Xpert was adopted in Kenya and after the prevalence survey of 2016, it was recommended as the initial TB diagnosis test among all presumptive TB patients (Enos et al., 2018). Sputum samples are collected from the patients in the facility they have been attended to and transported to the Gene Xpert site for processing. Patients with smear-positive sputum or a positive result from Gene Xpert are classified as having microbiologically confirmed PTB and have their results communicated to their respective health facilities by telephone. Upon receiving this communication, these patients are requested to visit the nearest facility for treatment and if they do not get notified, then

a community health worker is tasked to trace them in the community. Once traced, these patients are referred back to their nearest health facility where they are registered in the health facility daily observed treatment (DOT) register and are started on anti-TB treatment.

2.4 Delays in PTB diagnosis and Treatment Initiation

In any national TB program, early diagnosis and timely effective treatment are key to a successful program. Delays in case-finding are common in many developed and developing countries, whether of low or high TB prevalence (WHO-EMRO, 2006). Various causes of delay have been documented: poor index of suspicion leading to TB not suspected, collapse of infrastructure for TB control in low prevalence countries and poor health seeking behavior and delayed diagnosis among physicians in high prevalence countries (Eltayeb *et al*., 2016).

2.4.1 Patient delays

The patient delay has no clear definitions accepted globally. However, it is the time interval from the onset of the pulmonary symptoms of TB until the first time one visits a medical care Centre (WHO 2006). Patient delay is considered to be the main contributor to overall delay Systematic reviews have shown that patient delays ranges from 4.9–162 days for both low and high income countries. However, average patient delays for low income countries has been found to be similar to the high income countries (Sreeramareddy *et al*., 2009). In Western Kenya, delays of up to six weeks in TB diagnosis have been attributed to patients presenting late to the health facilities to seek medical care after onset of symptoms (Ayuo et al., 2008) Other studies in similar settings have reported different findings. In 2012, 58.2% TB presumptive cases were reported to have delayed seeking medical care in Nairobi county (Njau *et al*., 2012).

Factors that are crucial to ensure proper TB control and influence timely access of patients to appropriate health services includes good coverage and access to care (Bassili *et al*., 2008). Several factors that influence patient delays vary in different settings. In western Kenya, marital status, poor TB knowledge, distance to clinic and where help was first sought were reported as factors associated with patient delays (Ayuo *et al*., 2008). In Nairobi region gender, level of education and place of first medical were associated with late seeking of health care services among TB patients care (Njau *et al*., 2012). As much as TB services are offered free in Kenya, indirect costs incurred by the patients in the process of seeking health services like transport among others hampers them from seeking care (MOH-NTLDP, 2018b). Other factors associated with increased patient delay include rural dwellers, first visit to non-formal health provider (Bogale, *et al*., 2017; Finnie, *et al*., 2011), older age, low income (Eltayeb, 2016), longer walking distance to a public facility, urban residence, substance abuse, self-treatment (Gebreegziabher et al., 2016), unemployment, hemoptysis, positive sputum, the individual's attitude of disease (Cai et al., 2015), health seeking behavior, stigma, family support, the severity of the disease, purchase of drugs from medical stores (Deponti et al., 2013; Ukwaja et al., 2013), illiteracy, thinking symptoms will disappear by themselves, having financial constraints and feeling fear of diagnosis or social isolation (Akrim, M. , Bennani, K., Essolbi, A., Sghiar, M., Likos, A., Benmamoun, A., Menzhi Ol., Maaroufi1, 2014). Protective factors from patient delay include adequate TB knowledge, high TB perception, employment and a low crowding index were(Eltayeb, 2016).

2.4.2 Health Care System Delays

Health systems delay is the period from the date of the first presentation of patients to a professional health provider and initiation of treatment but there is no defined

acceptable period of delay from diagnoses and start of treatments (WHO, 2006). The health system delay range from 2–87 days respectively for both low and high income countries (Ref). On average, health system delay in low income countries compares to high income countries (Sreeramareddy et al., 2009). Health services delay contributes to 5% of total median delays in Kenya (Ayuo, 2008) and this ranges from 7-14 days, based on physician‘s practices (Mohamed, 2009). The delay within the health system is influenced by various determinants such as prevalence of TB, accessibility of health facilities, patient‘s socio-demographic variables, symptoms and signs, initial visit to a facility not supported by the national TB program, presence of refined suspicion index, infrastructures, first consultation at a public hospital and organization of the health care system (Eltayeb, 2016) (Ukwaja *et al*., 2013) (Cai *et al*., 2015) (Yimer *et al*., 2005). Travel time for the return visit, (Finnie *et al*., 2011) and consulting first in the private sector or having 3 or more consultations before diagnosis are also associated with health system delay (Akrim *et al*., 2014).

2.4.3 Treatment initiation delays

This is the time interval between TB diagnosis and initiation of anti-TB drugs. Having a diagnosis should lead to treatment immediately but at the same time, it is not a guarantee that treatment will be started immediately with other factors upholding the process. Therefore the time between diagnosis and starting treatment for some patients may be long.

2.5 Conceptual Framework

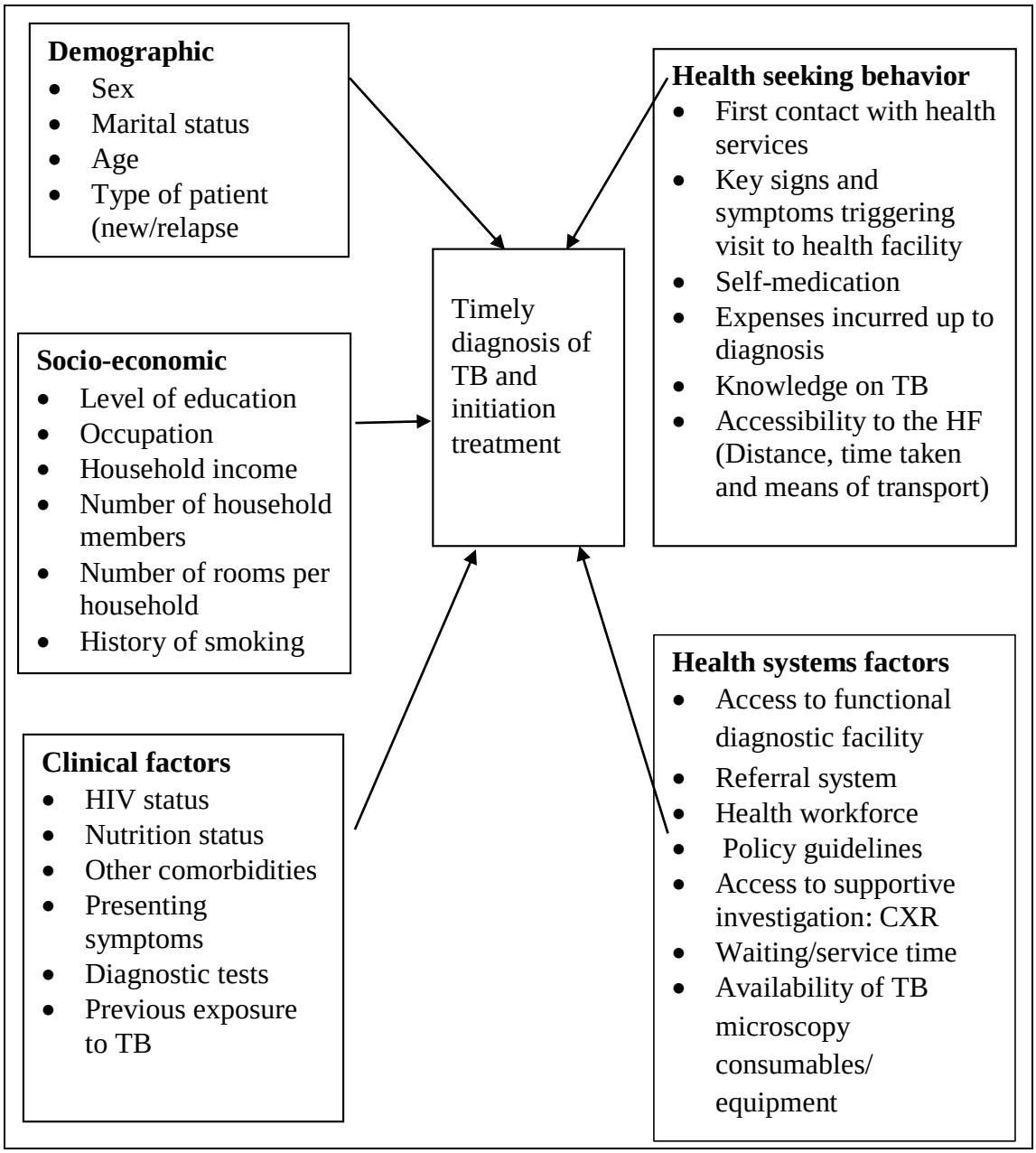

Figure 1.1: Conceptual Framework

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

This study was conducted in Mombasa County. The county is Kenya's second largest city, with a population of 939,370 and a population density of 4,292 people per km^2 (KNBS, 2009). It is located in the South eastern part of the coastal region of Kenya. It borders Kilifi County to the North, Kwale County to the South West and the Indian Ocean to the East. The County has both urban and peri-urban setups with a number of informal settlements. The main economic activity is tourism which contributes to 68% of the wage employment. The county's poverty index is 38% (Mombasa County Government, 2013). It has 6 sub counties namely Kisauni, Likoni, Mvita, Nyali, Changamwe, and Jomvu. There are 52 public health facilities comprising of one referral and teaching hospital, two county hospital, eight sub county hospitals and 41 dispensaries. It also has 13 faith based organizations (FBO) facilities, 270 private facilities and 12 NGOs. The county has eight defined TB zones with 92 TB treatment sites (both public and private), 51 diagnostic sites doing smear microscopy for acid fast bacilli (AFB) test and 9 Gene Xpert® ® sites for molecular testing. Tuberculosis and TB/HIV coinfections are among the top ten causes of death in Mombasa County (National HIV and STI Control Program, 2016).

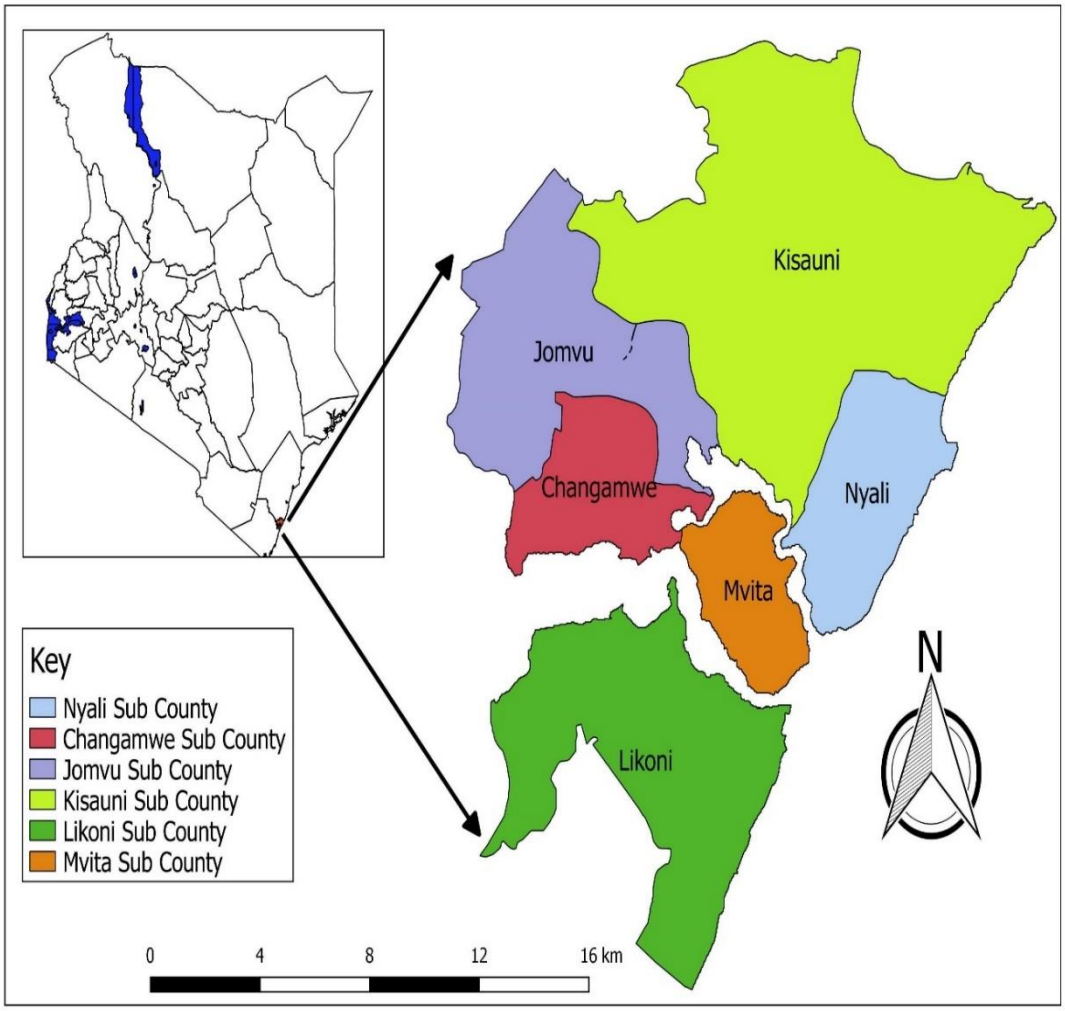

Figure 3.1: Map of Mombasa County, Kenya
Source; *QGIS 2.18.1 browser*

3.2 Study Design

This was a facility-based cross-sectional study that was conducted between May and August 2018.

3.3 Study Population

The target population was all bacteriologically confirmed drug sensitive Pulmonary TB (PTB) patients. The study population was a patient of any age on intensive phase of treatment receiving directly observed treatment shot (DOTS) in Mombasa county health facilities.

3.3.1 Case definitions

Delay in diagnosis was defined as any duration above the median time in days from onset of any TB-related symptom (cough, chest pain, fever, weight loss, hemoptysis, night sweat) up to the time of TB diagnosis (WHO-Regional Office for the Eastern Mediterranean, 2006). Time less than or equal to median was considered as "without delay" and greater than median was considered as "with delay". Delay in treatment initiation was defined as duration beyond the national target of two days from when the diagnosis was made to start of treatment where the time less than or equal to Two (2) days was considered as "without delay" and more than 2 days was "with delay".

3.3.2 Inclusion criteria

i. A Patient of any age recorded and reported to have drug sensitive PTB as confirmed by a laboratory test.
ii. Patients in the intensive phase (first two months) of treatment for PTB in Mombasa County during period of the study.
iii. The patient's TB diagnosis must have been done and treatment initiated in a facility within Mombasa County.

3.3.3 Exclusion criteria

i. A mentally challenged TB patient since their condition might affect memory and recall.
ii. Patients with clinically diagnosed PTB.
iii. Drug resistant TB since most of them may have had treatment for drug sensitive TB and therefore affect the memory of specific times for onset of symptoms and visits to the health facility.

3.4 Sample Size Determination

I used Cochran's formula (Cochran, 1963) to calculate the sample size required to estimate proportion of patients who had delays in TB diagnosis and treatment initiation in the study area. The following assumptions were made during sample size estimation:

- Precision of the study of 0.05 (5%)
- Confidence level of 1.96 (95%)
- Proportion of TB patients who delayed seeking health care in western Kenya was 64% (Ayuo et al., 2008).
- Response rate of 100%.
- Sample size (n) = $\frac{Z^2\, p\,(1-p)}{d^2} = \frac{1.96^2 * 0.64 * 0.36}{0.05^2} = 354$

The minimum sample obtained a sample size of 354 participants.

3.5 Sampling Strategy

Patients were selected from the health facilities with three and more notified bacteriologically confirmed TB patients from all the eight TB zones. Based on patients notified in the national electronic system for TB (TIBU) from January to March 2018, I applied probability-proportional-to-size sampling to determine the sample size for each TB zone and subsequently the health facility. Our sampling interval was based on the number of bacteriologically confirmed TB patients notified on the daily entries in the facility TB4 register in March 2018. A table of random numbers was used to select the first participant for interview and thereafter every 2nd patient in each facility proportionately allocated per the number of reported cases for interview following informed and voluntary consent. If a randomly-selected

participant was not eligible for interview or refused to be part of the study, the next eligible participant on the list was selected.

3.6 Data Collection

The TB treatment health facilities from were visited Monday to Friday, 8.00 am to 5.00 pm for data collection from the patients attending TB clinics. The questionnaire was pretested at Jomvu Health Centre before embarking on data collection at the other selected health facilities. This was conducted to familiarize with the process of data collection, assess the feasibility of the study, determine the accuracy of the tools and identify challenges so as to do the necessary adjustments based on the findings. Face-to-face interviews using the pretested questionnaire were used to collect data which was entered in an electronic tool in a tablet or laptop. The variables collected included: Patient clinical and laboratory information (type of TB patient, presenting symptoms, HIV status, nutrition status, other comorbidities and previous exposure to TB); socio-demographic characteristics (TB zone, age, sex, education, marital status, employment status, history of smoking, number of household members); health-seeking behavior (places of initial healthcare provider visited, number of healthcare services contact. Distance, time and means of travel to reach TB diagnostic/treatment centre. Questions were also asked about the factors that might influence patients' health-seeking behavior, such as fear of social isolation, stigma, and knowledge of TB (cause, transmission, prevention methods, curability, treatment duration and existence of vaccine).Variables for measuring stigma included feeling ashamed of having TB, having to hide TB diagnosis from others and having problems with family relations, work performance, marriage prospects, family responsibilities, infertility, or pregnancy. Date of onset of any TB symptoms, date of first encounter with a health worker and number of visits to a health facility prior to starting treatment. Information

on the date of diagnosis and when treatment was initiated was verified by looking through the patient's patient notes and their TB treatment card. Data collection was done using Epi info software uploaded in Android phones.

3.7 Data Analysis

Data were double checked for errors and missing information, and cleaned using Epi Info™ 7.0 (CDC, Atlanta, GA, USA). Data analysis was performed using STATA version 13. Frequencies and proportions were calculated for categorical variables and means and medians for continuous variables. The cutoff points for patient delays and health care system (HCS) were defined as the median value calculated and for treatment delay was based on the expected turnaround time for Gene Xpert® results in Mombasa County which is 48 hours (2 days). For patient and HCS delays, less than or equal to the median value was considered as "without delay" and greater than the median was considered as "with delay" while for treatment delays, less than or equal to 2 days was considered as "without delay" and more than 2 days was "with delay". Delay in diagnosis and delay in treatment initiation and their relationship to sociodemographic characteristics of the participants, clinical factors, health seeking behavior and health services received in the health facility were assessed. At bivariate analysis I calculated prevalence odds ratios (PORs) and their 95% confidence intervals (CI) and variables with p-value ≤ 0.1 were included in a logistic regression model. The model was built using a backward stepwise elimination method and variables that remained in the final model with p value <0.05 were considered statistically significant for delay in diagnosis and treatment initiation.

3.8 Ethical Considerations

A written consent was secured from every selected eligible TB patient before inclusion into the study. For children, the study objectives and the process were explained and those above 10 years gave a written assent and parental permission while for those below 10 years the closest accompanying relative gave the informed assent. Confidentiality was maintained by using codes for patients' identifiers and data was stored in password protected computers. Since this study did not involve any invasive procedures such as blood or specimen collection there was minimal risk from administering the questionnaire. There was no payment or incentives offered to the participant for taking part in the study and continued to receive care and treatment as before regardless of whether they participated in the study. Permission to conduct the study was also sought from the department of health, Mombasa County (appendix I). The study was approved by the institutional research and ethics committee, Moi University/MTRH – approval number FAN: IREC 3014 (appendix II).

CHAPTER FOUR

RESULTS

Mombasa county notified 597 (N) bacteriologically confirmed PTB patients between January and March 2018 from 52 health facilities. The facilities that reported ≥3 AFB confirmed cases were 39 (75%) and were included in the study. Three hundred and fifty four (n=354) AFB confirmed patients were interviewed. The response rate was 100%.

4.1 Social Demographic Characteristics

Of the participants (n=354), 88.1% (312/354) were new patients while 11.9% (42/354) were relapse cases. Males were 72% (255/354), 53.1% (188/354) had attained primary school level of education, 50% (177/354) had no formal employment and 51.7% (183/354) were married. The median age of participants was 33 years (range 3 – 81 years) and 32.2% (114/354) were in age group 25 – 34 years. Among patients with history of smoking, 30.5% (108/354) had quit smoking while 9.6% (34/354) were currently smoking. The median smoking pack years for those currently smoking was 6.2 pack years (range 0.3 – 43 pack years) and for those who had quit smoking was 2.3 pack years (range 0.1 – 40 pack years). The median number of household members was 3 (range 1 – 3) and 59% (209/354) had three or less members in the household. The households had a median of one room per house with 57.3% (203/354) of the households sharing one room (Table 4.1).

Table 4. 1 Social demographic characteristics of the bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Frequency	Percent
Type of patient		
New	312	**88.1**
Relapse	42	11.9
Age group in years		
<15	11	3.1
15 – 24	71	20.1
25- 34	114	**32.2**
35 - 44	87	24.6
45 - 59	60	16.9
≥60	11	3.1
Sex		
Male	255	**72.0**
Female	99	28.0
Education level		
Primary [a]	188	**53.1**
Secondary [b]	107	30.2
Tertiary [c]	41	11.6
None	18	5.1
Employment status		
No formal employment	177	**50.0**
Formal employment	155	43.8
Student	22	6.2
Marital status		
Married	183	**51.7**
Single	171	48.3
Smoking status		
Never	212	**59.9**
Quit smoking	108	30.5
Current smoker	34	9.6
No. of household members		
<3	209	**59.0**
≥3	145	41.0
Number of house rooms		
1	203	**57.3**
>1	151	42.7

[a] About eight years of schooling, [b] about 14 years of schooling, [c] more than 14 years of school as per the Kenyan system of education. PTB (pulmonary Tuberculosis)

4.2 Clinical Characteristics of PTB Patients

Patients who had a history of exposure to TB before their current illness were 31.4% (111/354). The exposure was mainly from a family member 53.2% (59/111) a friend who was ill 27.9% (31/111) and 16.2% (18/111) of them having had an episode of TB disease in the past. HIV negative patients were 70.1% (248/354), HIV positive

patients were 24.9% (88/354) and 5.1% (18/354) had unknown HIV status. The nutrition status for the participants showed 44.1% (156/354) had moderate acute malnutrition (MAM) while 21.8% (77/354) were severely malnourished (SAM) (Table 4.2).

Table 4.2: Clinical characteristics of the bacteriologically confirmed PTB patients, Mombasa county - 2018 (n=588)

Factor	Frequency	Percent
History of previous exposure to TB		
No	243	**68.6**
Yes	111	31.4
Source of TB exposure (n=111)		
Family member	59	**53.2**
Close friend	31	27.9
Past illness	18	16.2
Another patient	1	0.9
Neighbor	1	0.9
Workplace	1	0.9
HIV status		
Negative	248	**70.1**
Positive	88	24.9
Unknown	18	5.1
Other comorbidities (n=13)		
Asthma	6	**46.2**
Hypertension	5	38.5
Diabetes mellitus	3	23.1
Nutrition status		
Moderate malnutrition	156	**44.1**
Normal	121	34.2
Severe malnutrition	77	21.8

[a] Cardinal symptoms are cough, drenching night sweats, fever and weight loss, [b] Vomiting, loss of appetite, headache, nausea and body weakness, [c] Health centre and dispensary facilities which offer basic health care services, [d] Sub county and county hospitals which also offers more specialized health services, [e] unregulated health service providers

4.3 Reported Major Symptoms Before Seeking For Treatment

The patients presented to a health facility with various clinical symptoms; 85.9% (304/354) presented with a cough, 46.9% (166/354) had weight loss, 45.8% (162/354) had a fever and 45.5% (161/354) reported chest pains (Table 4.3) The median number of visits to a health provider before PTB diagnosis was wade was two visits where

58.2% (206/354) of the patients had visited a health facility twice or less and 41.8% (148/354) made more than two visits to a health provider before diagnosis was made.

Table 4.3: Reported symptoms before seeking for treatment of the bacteriologically confirmed PTB patients, Mombasa county - 2018 (n=354)

Symptom	Yes	Percent
Cough	304	85.9
Weight loss	166	46.9
Fever	162	45.8
Chest pain	161	45.5
Night sweats	144	40.7
Hemoptysis	38	10.7
Body weakness	19	5.4
Difficulty in breathing	7	2.0
Vomiting	4	1.1
Headache	3	0.8
Others*	14	4.0

*Loss of appetite, dizziness, headache, hoarseness of voice, difficult in swallowing, chills, joint pains

4.4 Place Health Care was First Sought with the Onset of the Symptoms

One hundred and fifty patients (42.4%) first sought care from a private clinic/hospital, 27.1% (96/354) went to a chemist/pharmacy, 11.9% (42/354) visited a public dispensary, 8.5% (30/354) sought care from a county/sub county public hospital, 7.6% (27/354) in a health centre, 2% (7/354) to a non-governmental organization and 0.6 (2/354) visited an informal private provider (Figure 4.1).

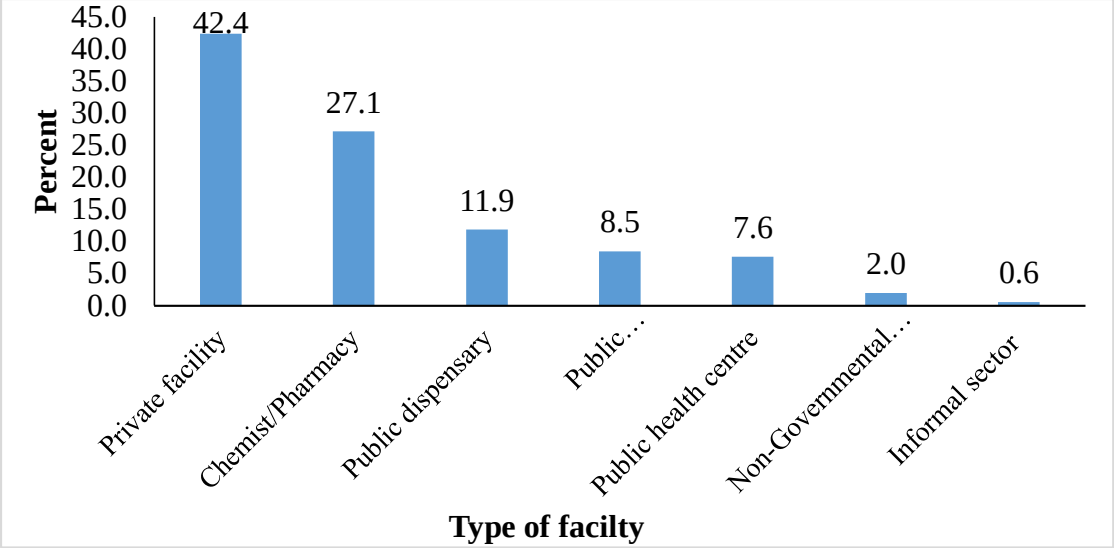

Figure 4.1: Type of health care facility first visited by the bacteriologically confirmed PTB patients, Mombasa county - 2018 (n=354)

4.5 Reasons for Choosing the type of Health Service Providers at the Initial Visit for Seeking Treatment

Different reasons were given for visiting the various mentioned destinations for health services at the initial visit which included; accessibility of the health facility 269/588 (45.8%), patients having faith in the health facility to get good treatment hence cured, 189/588 (32.2%), having been advised by somebody 102/588 (17.4%) and availability of services all the time, 90/588 (15.4%) (Table 4.4).

Table 4.4: Reasons for choosing the type of facility at first visit (n=354)

Reason	Frequency	Percent
Distance to the health facility far	151	**42.7**
Long waiting time and ques in the public hospital	134	37.9
Confidence in getting good services and cure	125	35.3
Advised by a friend/relative	72	20.3
Services available anytime	69	19.5
Free services	21	5.9
Was once referred by a health provider to that facility for other services so decided to just start there	18	5.1
Thought it was a minor problem bought tablets/syrup and didn't warrant serious investigations or care	4	1.1
Symptoms became worse at home	3	0.8
Insurance cover dictated the type of facility	2	0.6

4.6 Duration From Onset of Symptoms, Diagnosis and Treatment Initiation

The median time from onset of symptoms to first visit to a health facility was 40 days (Range 2 – 275 days) with 49.2 (174/354) of patients experiencing delays in seeking health care. The median time from the onset of symptoms to when PTB diagnosis was made was 67 days (range 3 – 411 days) and 61.6% (218/354) of the patients experience delays in diagnosis. From the first visit to a health provider to treatment initiation, the median duration was 30 days (range 0 – 235 days days) with 48.3% (171/354) patients experiencing delays. From diagnosis to treatment initiation, the duration ranged from 0 – 63 days with 36.7% (130/3534) having treatment initiated after two days from diagnosis (Table 4.5).

Table 4.5: Duration of seeking health care to diagnosis and to treatment initiation among bacteriologically confirmed PTB patients in Mombasa county, 2018 (n=354)

Duration/Time interval in days	Median time (days) (range)	With delay [a] # (%)	Without delay # (%)
From onset of symptoms to seeking health care (first visit)	40 (2 – 275)	174 (49.2)	180 (50.8)
Duration from onset of symptoms to diagnosis (**Delay in PTB diagnosis**)	67 (3 – 411)	**218 (61.6)**	136 (38.4)
Duration from first visit to a health facility to when diagnosis was made	22 (0 – 199)	175 (49.4)	179 (50.6)
Duration from diagnosis to treatment initiation (**Delay in treatment initiation of treatment**)	2 (0 - 63)	**130 (36.7)**	224 (63.3)
Duration from first visit to treatment initiation (Health care system delays)	30 (0 - 235)	171 (48.3)	183 (51.7)
Duration from onset of symptoms to treatment initiation (**total delays)**	71 (5 – 416)	175 (49.4)	179 (50.6)

[a] Delay defined as having days more than the median

4.7 Perceived Patients Reasons for not Seeking Care Early in Health Facility

One hundred and forty three (40.4%) patients hoped that symptoms would go away, 16.4% (58/354) were on treatment for other conditions and 12.4% (44/354) lacked

time or were busy and therefore did not seek care promptly from health facilities (Table 4.6).

Table 4. 6: Perceived reasons for not seeking care immediately among the bacteriologically confirmed PTB patients, Mombasa county - 2018 (n=354)

Reason for not seeking care	Frequency	Percent
Hoped that symptoms would go away	143	**40.4**
Already on treatment for other conditions	58	16.4
Lack of time or busy at work	44	12.4
Fear of what would be found on diagnosis	30	8.5
Did not know where to seek services	28	7.9
Poor quality of health services	22	6.2
Economic constraints	21	5.9
Previous bad experience in a health facility	14	4.0
No reason	11	3.1
Far distance to the health facility	7	2.0
Believe that it was witchcraft	6	1.7

4.8 Type of Facility Where Diagnosis of TB was Made

For bacteriological confirmation, 36% (128/354) of the patients had their PTB diagnosis made in public health centers, 28% (98/354) in public county or sub county hospital, 19% (66/354) in public dispensaries, 13% (47/354) in private clinic/ hospital/provider and 4% (15/354) in a non-governmental organization provider (Figure 4.2).

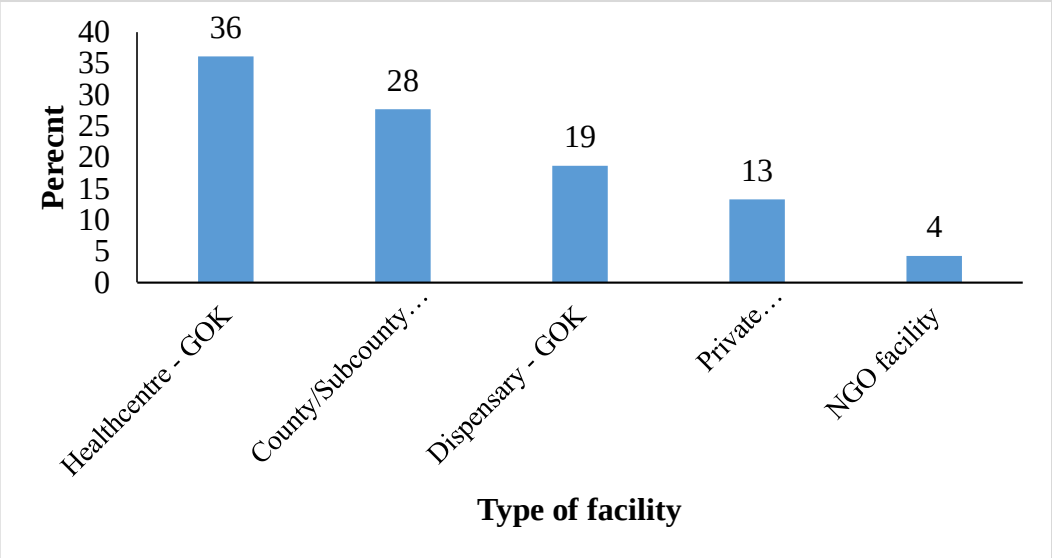

Figure 4.2: Type of health facility where TB diagnosis was made

4.9 Delay in Laboratory Results

One hundred and eight (31%) clients received their laboratory results within one day and 69% (246/354) received results after one day. Among those who received the results after one day (n=246), there were various reasons for the late release of results which included 83% (205/246) due to sample referral to a gene xpert site and 8% (19/246) of the clients decided not to wait for the results to return later (figure 4.3).

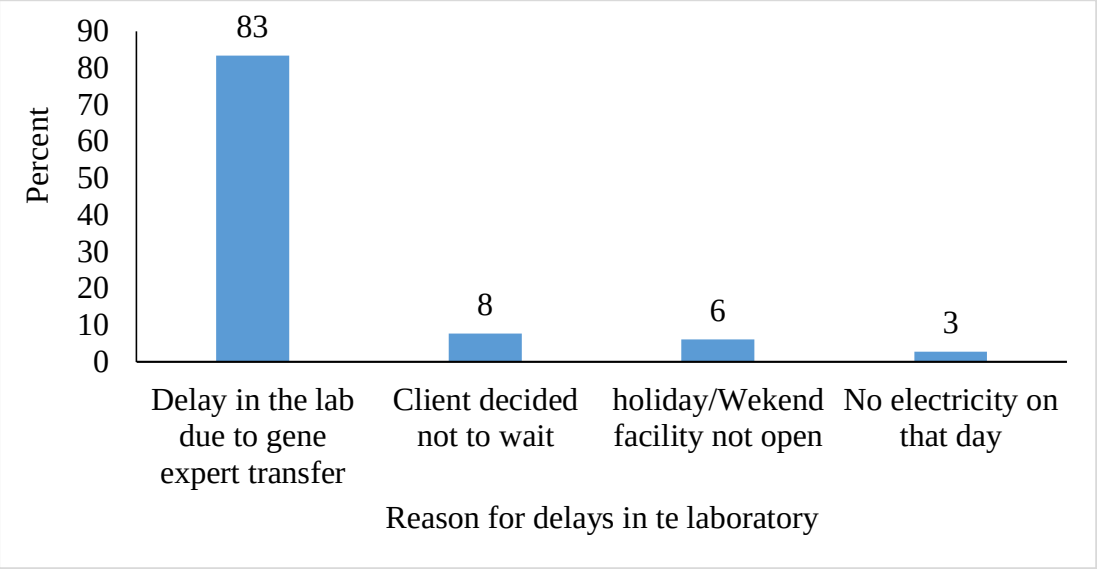

Figure 4.3: Reasons for delay in getting laboratory results

4.10 Bivariate Factors Associated with Delay in Diagnosis and Treatment Initiation Among Bacteriologically Confirmed PTB Cases

4.10.1 Bivariate factors associated with delay in diagnosis

4.10.1.1 Sociodemographic factors associated with delays in diagnosis

At bivariate level, Patients who had quit smoking (POR 1.71, CI=1.05, 2.79) had higher odds of delays in diagnosis compared to those who had never smoked. Patients on formal employment as compared to the unemployed (POR 0.46, CI=0.29, 0.73), age group 15 – 24 years (POR 0.20, CI=0.04, 1.01) had lower odds of delays compared to under 15 years (Table 4.7).

Table 4.7: Sociodemographic factors at bivariate level associated with delays in diagnosis among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Diagnosis delays [a]		POR (95% CI)	P value
	Delay [b] # (%)	No delay # (%)		
Employment status				
Formal employment	53 (24.31)	56 (41.18)	0.46 (0.29, 0.73)	**0.001**
No formal employment	165 (75.69)	80 (58.82)	*	*
Smoking history				
Quit smoking	75 (34.40)	33 (24.26)	1.71 (1.05, 2.79)	**0.033**
Current smoker	22 (10.09)	12 (8.82)	1.38 (0.65, 2.93)	0.404
Never	121(55.50)	91 (66.91)	*	*
Age group in years				
<15	9 (4.13)	2 (1.47)	*	
15 - 24	34 (15.60)	37 (27.21)	0.20 (0.02, 1.11)	**0.052**
25- 34	78 (35.78)	36 (26.47)	0.48 (0.10, 2.34)	0.365
35 - 44	54 (24.77)	33 (24.26)	0.36 (0.07, 1.79)	0.213
45 - 59	38 (17.43)	22 (16.18)	0.38 (0.08, 1.94)	0.247
60+	5 (2.29)	6 (4.41)	0.19 (0.02, 1.70)	0.183
Type of patient				
New	188 (86.24)	124 (91.18)	0.61 (0.30, 1.23)	**0.165**
Relapse	30 (13.76)	12 (8.82)	*	
Marital status				
Single	101 (46.33)	70 (51.47)	0.81 (0.53, 1.25)	0.347
Married	117 (53.67)	66 (48.53)	*	
Sex				
Male	161 (73.85)	94 (69.12)	1.26 (0.79, 2.03)	**0.335**
Female	57 (26.15)	42 (30.88)	*	
Number of household members				
>3	92 (42.20)	53 (38.97)	1.14 (0.74, 1.77)	0.548
≤3	126 (57.80)	83 (61.03)	*	
Education level				
Primary [c]	119 (54.59)	69 (50.74)	0.86 (0.31, 2.40)	0.777
Secondary [d]	62 (28.44)	45 (33.09)	0.69 (0.24, 1.97)	0.488
Tertiary [e]	25 (11.47)	16 (11.76)	0.78 (0.24, 2.50)	0.678
None	12 (5.50)	6 (4.41)	*	*

*****(Reference group), pOR (prevalence odds ratio), aOR (adjusted odds ratio), **[a]** Patient delay defined as duration from onset of symptoms to first visit to a health facility, **[b]** delay defined as having more than 67 days period from onset of symptoms to first visit to a health facility, **[c]** about 8 years of schooling, **[d]** about 14 years of schooling, **[e]** more than 14 years of schooling (as per Kenyan education system)

4.10.1.2 Clinical factors associated with delays in diagnosis

At bivariate level, patients on treatment for other conditions (POR 3.12, CI= 1.56, 6.26) compared to those without other conditions and patients who had a fever (POR 1.68, CI=1.09, 2.59) as the presenting symptom compared to those who had no fever had higher odds of experiencing delays. Patients with history of exposure to TB (POR

0.54, CI=0.33, 0.88) had lower odds of delays than those who had no history of PTB exposure (Table 4.8).

Table 4.8: Clinical factors at bivariate associated with delays in diagnosis among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Diagnosis delays [a]		pOR (95% CI)	P value
	Delay [b] # (%)	No delay # (%)		
On treatment for other condition				
Yes	47 (21.56)	11 (8.09)	3.12 (1.56, 6.26)	**0.001**
No	171 (78.44)	125 (91.91)	*	*
Having fever				
No	129 (59.17)	63 (46.32)	1.68 (1.09, 2.59)	**0.019**
Yes	89 (40.83)	73 (53.68)	*	
History of TB exposure				
Yes	79 (36.24)	32 (23.53)	0.54 (0.33, 0.88)	**0.013**
No	139 (63.76)	104 (76.47)	*	*
Nutrition status				
Severe malnutrition	54 (24.77)	23 (16.91)	1.39 (0.75, 2.56)	0.291
Moderate malnutrition	88 (40.37)	68 (50.00)	0.77 (0.47, 1.25)	0.283
Normal	76 (34.86)	45 (33.09)	*	*
Hemoptysis				
Yes	26 (11.93)	12 (8.82)	1.40 (0.68, 2.88)	0.361
No	192 (88.07)	124 (91.18)	*	*
Body weakness/fatigue				
No	205 (94.04)	132 (97.06)	*	*
Yes	13 (5.96)	4 (2.94)	2.09 (0.63, 8.98)	0.306
HIV status				
Positive	54 (24.77)	34 (25.00)	1.02 (0.62, 1.68)	0.937
Unknown	13 (5.96)	5 (3.68)	1.67 (0.58, 4.83)	0.344
Negative	151 (69.27)	97 (71.32)	*	*
Weight loss				
No	113 (51.83)	75 (55.15)	0.88 (0.57, 1.35)	0.544
Yes	105 (48.17)	61 (44.85)	*	*
Having a cough				
No	29 (13.30)	21 (15.44)	0.84 (0.46, 1.54)	0.574
Yes	189 (86.17)	115 (84.56)	*	
Night sweats				
No	127 (58.26)	83 (61.03)	0.89 (0.58, 1.38)	0.606
Yes	91 (41.74)	53 (38.97)	*	
Chest pains				
Yes	99 (45.41)	62 (45.59)	0.99 (0.65, 1.53)	0.974
No	119 (54.59)	74 (54.41)	*	*

*****(Reference group), pOR (prevalence odds ratio), aOR (adjusted odds ratio), [a] Patient delay defined as duration from onset of symptoms to first visit to a health facility, [b] delay defined as having more than 67 days period from onset of symptoms to PTB diagnosis

4.10.1.3 Health care system factors at bivariate associated with delays in diagnosis

Those who visited a health facility more than two times before diagnosis (POR 6.60, CI= 3.92, 11.14) compared to those who had two or less visits, taking more than 30 minutes to reach a nearby health facility (POR 3.01, CI= 1.91, 4.73) compared to 30 minutes and less, distance to a nearest facility more than one kilometer (POR 2.98, CI= 1.90, 4.67) compared to one kilometer and less, delays in getting laboratory results due to gene Xpert referrals and testing (POR 2.33, CI=1.28, 4.26) compared to other reasons, seeking care from a chemist first (POR 2.70, CI= 1.11, 6.56) as compared to a public county or subcounty hospital and long waiting time in the health facility (POR 1.47, CI= 0.94, 2.30) were associated with delays in PTB diagnosis (table 4.9).

Table 4.9: Health care sytem factors at bivariate level associated with delays in diagnosis among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Diagnosis delays [a]		POR (95% CI)	P value
	Delay [b] # (%)	No delay # (%)		
Number of health facilities visited before diagnosis was made				
>2	125 (57.34)	23 (16.91)	6.60 (3.92, 11.14)	**0.0001**
≤2	93 (42.66)	113 (83.09)	*	*
Time taken to reach a health facility				
>30 minutes	125 (57.34)	42 (30.88)	3.01 (1.91, 4.73)	**0.0001**
≤30 minutes	93 (42.66)	94 (69.12)	*	*
Distance to the nearest health facility				
>1 Kilometer	157 (72.02)	63 (46.32)	2.98 (1.90, 4.67)	**0.0001**
≤1 Kilometer	61 (27.98)	73 (53.68)	*	*
Delays in getting lab results				
Gene expert referral	122 (82.99)	67 (67.68)	2.33 (1.28,4.26)	**0.006**
Other reasons	25 (17.01)	32 (32.32)	*	*
Type of facility where care was sought first				
Public healthcentre/dispensary	37 (16.97)	32 (23.53)	0.77 (0.32, 1.84)	0.558
Private clinic/hospital	86 (39.45)	73 (53.68)	0.79 (0.35, 1.74)	0.551
Chemist	77 (35.32)	19 (13.97)	2.70 (1.11, 6.56)	**0.028**
Public County/subcounty	18 (8.26)	12 (8.82)	*	*
Long waiting time				
Yes	90 (41.28)	44 (32.35)	1.47 (0.94, 2.30)	**0.093**
No	128 (58.72)	92 (67.65)	*	*
Means of transport				
Motorcycle	57 (26.15)	32 (23.53)	1.06 (0.62, 1.80)	0.355
Matatu	50 (22.94)	38 (27.94)	0.78 (0.46, 1.32)	0.832
Walking	111 (50.92)	66 (48.53)	*	*
Lack of services				
Yes	6 (2.75)	5 (3.68)	0.74 (0.22, 2.48)	0.627
No	212 (97.25)	131 (96.32)	*	*
Type of facility where diagnosis was made				
Public	180 (82.57)	112 (82.35)	1.02 (0.58, 1.78)	0.959
Private	38 (17.43)	24 (17.65)	*	*
Affordability of services				
Yes	169 (77.52)	105 (77.21)	1.02 (0.61, 1.70)	0.945
No	49 (22.48)	31 (22.79)	*	*

*****(Reference group), POR (prevalence odds ratio), aOR (adjusted odds ratio), [a] Patient delay defined as duration from onset of symptoms to first visit to a health facility, [b] delay defined as having more than 67 days period from onset of symptoms to first visit to a health facility, [c] about 8 years of schooling, [d] about 14 years of schooling, [e] more than 14 years of schooling (as per Kenyan education system)

4.10.2 Factors associated with Treatment initiation delay at bivariate level

4.10.2.1 Sociodemographic and clinical factors associated with treatment initiation delays

At bivariate level, being a current smoker (pOR 2.05, CI= 0.99, 4.26) as compared to those who never smoked and being a male (pOR 0.93, CI= 1.16, 3.23) as compared to female were associated with delays in diagnosis (Table 4.10).

Table 4.10 Sociodemographic factors at bivariate level associated with delays in treatment initiation among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Treatment initiation delays [a]		pOR (95% CI)	P value
	Delay [b] # (%)	No delay # (%)		
Smoking history				
Quit smoking	75 (34.40)	33 (24.26)	0.95 (0.58, 1.55)	0.843
Current smoker	22 (10.09)	12 (8.82)	2.05 (0.99, 4.26)	**0.053**
Never	121(55.50)	91 (66.91)	*	*
Sex				
Male	104 (80.00)	151 (67.41)	1.93 (1.16, 3.23)	**0.012**
Female	26 (20.00)	73 (32.59)	*	
Marital status				
Single	69 (53.08)	102 (45.54)	1.35 (0.88, 2.09)	0.172
Married	61 (46.92)	122 (54.46)	*	*
Type of patient				
New	118 (90.77)	194 (86.61)	0.66 (0.32, 1.33)	0.246
Relapse	12 (9.23)	30 (13.39)	*	*
Education level				
Primary [c]	60 (46.15)	128 (57.14	0.74 (0.27, 1.99)	0.547
Secondary [d]	50 (38.46)	57 (25.45)	1.38 (0.50, 3.83)	0.538
Tertiary [e]	13 (10.00)	28 (12.50)	0.73 (0.23, 2.31)	0.592
None	7 (5.38)	11 (4.91)	*	*
Employment status				
Formal employment	92 (70.77)	153 (68.30)	0.89 (0.56, 1.43)	0.628
No formal employment	38 (29.23)	71 (31.70)	*	*
Age group in years				
<15	4 (3.08)	7 (3.13)	*	*
15 - 24	28 (21.54)	43 (19.20)	1.14 (0.31, 4.25)	0.846
25- 34	43 (33.08)	71 (31.70)	1.06 (0.29, 3.83)	0.929
35 - 44	27 (20.77)	60 (26.79)	0.79 (0.21, 2.92)	0.721
45 - 59	23 (17.69)	37 (16.52)	1.09 (0.29, 4.13)	0.902
60+	5 (3.85)	6 (2.68)	1.46 (0.26, 8.05)	0.665

*****(Reference group), pOR (prevalence odds ratio), aOR (adjusted odds ratio), a treatment initiation delay defined as duration from diagnosis to when treatment was started, b delay defined as having more than 2 days from diagnosis to start of treatment, [c] about 8 years of schooling, [d] about 14 years of schooling, [e] more than 14 years of schooling (as per Kenyan education system)

The clinical factors that were associated with delays in treatment intiation at bivariate level included having hemoptysis (pOR 1.85, CI= 0.94, 3.63) as compared to no hemoptysis and being on treatment for another condition (pOR 0.55, CI= 0.29, 1.03) as compared to not being on any other treatment (Table 4.11).

Table 4.11: Clinical factors at bivariate associated with delays in treatment initiation among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Treatment initiation [a]		pOR (95% CI)	P value
	Delay [b] # (%)	No delay # (%)		
Hemoptysis				
Yes	19 (14.62)	19 (8.48)	1.85 (0.94, 3.63)	0.076
No	111 (85.38)	205 (91.52)	*	*
On treatment for other condition				
Yes	15 (11.54)	43 (19.20)	0.55 (0.29, 1.03)	0.063
No	115 (88.46)	181 (80.80)	*	*
Weight loss				
No	63 (48.46)	67 (51.54)	0.74 (0.48, 1.15)	0.183
Yes	125 (55.80)	99 (44.20)	*	*
HIV status				
Positive	28 (21.54)	60 (26.79)	0.74 (0.44, 1.24)	0.251
Unknown	6 (4.62)	12 (5.36)	0.79 (0.29, 2.18)	0.651
Negative	96 (73.85)	152 (67.86)	*	*
Nutrition status				
Severe malnutrition	24 (18.46)	53 (23.66)	0.82 (0.45, 1.51)	0.527
Moderate malnutrition	63 (48.46)	93 (41.52)	1.23 (0.75, 2.01)	0.411
Normal	43 (33.08)	78 (34.82)	*	*
Having a cough				
No	17 (13.08)	33 (14.73)	0.87 (0.46, 1.63)	0.667
Yes	113 (86.92)	191 (85.27)	*	
Previous exposure to TB				
Yes	42 (32.31)	69 (30.80)	0.93 (0.59, 1.48)	0.769
No	88 (67.69)	155 (69.20)	*	*
Body weakness/fatigue				
Yes	6 (4.62)	11 (4.91)	0.94 (0.34, 2.60)	0.900
No	124 (95.38)	213 (95.09)	*	*
Having fever				
No	71 (54.62)	121 (54.02)	1.02 (0.66, 1.58)	0.913
Yes	59 (45.38)	103 (45.98)	*	
Chest pains				
Yes	52 (40.00)	109 (48.66)	0.70 (0.45, 1.09)	0.974
No	78 (60.00)	115 (51.34)	*	*
Night sweats				
No	77 (59.23)	133 (59.38)	0.99 (0.64, 1.54)	0.979
Yes	53 (40.77)	91 (40.63)	*	*

*****(Reference group), pOR (prevalence odds ratio), aOR (adjusted odds ratio), [a] treatment initiation delay defined as duration from diagnosis to treatment initiation, [b] delay defined as having more than 2 days from diagnosis to start of treatment

4.10.2.2 Health care system factors associated with treatment initiation delays

Use of motorcycle as a means of transport (POR 1.97, CI= 1.17, 3.32) as compared to walking, and affordability of health services (POR 0.49, CI= 0.30, 0.81) were associated with delays in treatment initiation (Table 4.12).

Table 4.12: Health care system factors at bivariate level associated with delays in treatment initiation among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor		Treatment initiation [a] Delay [b] # (%)	No delay # (%)	POR (95% CI)	P
Means of transport					
	Motorcycle	43 (33.08)	46 (20.54)	1.97 (1.17, 3.32)	**0.011**
	Matatu	30 (23.08)	58 (25.89)	1.09 (0.63, 1.87)	0.758
	Walking	57 (43.85)	120 (53.57)	*	*
Lack of services					
	Yes	7 (5.38)	4 (1.79)	3.13 (0.90, 10.90)	**0.073**
	No	123 (94.62)	220 (98.21)	*	*
Affordability of services					
	Yes	90 (69.23)	184 (82.14)	0.49 (0.30, 0.81)	**0.006**
	No	40 (30.77)	40 (17.86)	*	*
Knowledge on TB					
	Good	50 (38.46)	104 (46.43)	0.72 (0.46, 1.12)	0.146
	Poor	80 (61.54)	120 (53.57)	*	*
Stigma towards TB					
	Present	68 (52.31)	103 (45.98)	1.29 (0.84, 1.99)	0.251
	Absent	62 (47.69)	121 (54.02)	*	*
Delays in getting lab results					
	Gene expert referral	96 (80.00)	93 (73.81)	1.42 (0.78, 2.58)	0.251
	Other reasons	24 (20.00)	33 (26.19)	*	*
Type of facility where diagnosis was made					
	Public	110 (84.62)	182 (81.25)	1.27 (0.71, 2.27)	0.423
	Private	20 (15.38)	42 (18.75)	*	*
Time taken to health facility					
	>30 minutes	58 (44.62)	109 (48.66)	0.85 (0.55, 1.31)	0.463
	≤30 minutes	72 (55.38)	115 (51.34)	*	*
Type of facility where care was sought first					
	Public healthcentre/dispensary	37 (16.97)	32 (23.53)	1.29 (0.52, 3.16)	0.584
	Private clinic/hospital	86 (39.45)	73 (53.68)	1.21 (0.53, 2.76)	0.647
	Chemist	77 (35.32)	19 (13.97)	1.05 (0.44, 2.50)	0.916
	Public County/subcounty	18 (8.26)	12 (8.82)	*	*
Distance to the nearest health facility					
	>1 Kilometer	82 (63.08)	138 (61.61)	1.06 (0.68, 1.66)	0.783
	≤1 Kilometer	48 (36.92)	86 (38.39)	*	*

*(Reference group), POR (prevalence odds ratio), aOR (adjusted odds ratio), [a] treatment initiation delay defined as duration from diagnosis to when treatment was started, [b] delay defined as having more than 2 days from diagnosis to start of treatment

4.11 Multivariate analysis of factors associated with delay in diagnosis and treatment initiation among bacteriologically confirmed PTB cases

4.11.1 Independent factors associated with delay in diagnosis

At multivariate level, factors independently associated with diagnosis delay included; visiting health facilities more than twice before diagnosis (aOR 5.84, CI= 2., 11.77), delays in getting laboratory results due to gene xpert referrals (aOR 4.43, CI= 2.01, 9.79), on treatment for other conditions (aOR 3.39, CI=1.22, 9.38); having a fever as a symptom (aOR 2.86, CI=1.51, 5.44), distance to the nearest health facility more than one kilometer compared to less than one kilometer (aOR 2.49, CI=1.30, 4.77), patients aged between 15 and 24 years (aOR 0.07, CI=0.01, 0.82) as compared to patients under 15 years and having history of exposure to TB (aOR 0.4, CI= 0.19, 0.82) (Table 4.13).

Table 4.13: Multivariate factors independently associated with delay in diagnosis among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Diagnosis delays [a] Delay [b] # (%)	No delay # (%)	pOR (95% CI)	aOR (95% CI)
Number of visits to a health facility before diagnosis				
>2	125 (57.34)	23 (16.91)	6.60 (3.92, 11.14)	**5.84 (2.9, 11.77)**
≤2	93 (42.66)	113 (83.09)	*	
Delays in getting lab results				
Gene expert referral	122 (82.99)	67 (67.68)	2.33 (1.28,4.26)	**4.43 (2.01, 9.79)**
Other reasons	25 (17.01)	32 (32.32)	*	
Treatment for other condition				
Yes	47 (21.56)	11 (8.09)	3.12 (1.56, 6.26)	**3.39 (1.22, 9.38)**
No	171 (78.44)	125 (91.91)	*	*
Having fever				
No	129 (59.17)	63 (46.32)	1.68 (1.09, 2.59)	**2.86 (1.51, 5.44)**
Yes	89 (40.83)	73 (53.68)	*	*
Distance to nearest health facility				
>1 Kilometer	157 (72.02)	63 (46.32)	2.98 (1.90, 4.67)	**2.49 (1.30, 4.77)**
≤1 Kilometer	61 (27.98)	73 (53.68)	*	*
Age group in years				
<15	9 (4.13)	2 (1.47)	*	*
15 - 24	34 (15.60)	37 (27.21)	0.20 (0.04, 1.01)	0.07 (0.01, 1.82)
25- 34	78 (35.78)	36 (26.47)	0.48 (0.10, 2.34)	0.27 (0.03, 2.86)
35 - 44	54 (24.77)	33 (24.26)	0.36 (0.07, 1.79)	0.16 (0.02, 1.74)
45 - 59	38 (17.43)	22 (16.18)	0.38 (0.08, 1.94)	0.16 (0.01, 1.75)
60+	5 (2.29)	6 (4.41)	0.19 (0.03, 1.29)	0.12 (0.01, 2.55)
Previous exposure to TB				
Yes	79 (36.24)	32 (23.53)	0.54 (0.33, 0.88)	**0.4 (0.19, 0.82)**
No	139 (63.76)	104 (76.47)	*	*
Employment status				
Formal employment	53 (24.31)	56 (41.18)	0.46 (0.29, 0.73)	0.65 (0.31, 1.37)
No formal employment	165 (75.69)	80 (58.82)	*	*
Smoking history				
Quit smoking	75 (34.40)	33 (24.26)	1.71 (1.05, 2.79)	1.08 (0.48, 2.39)
Current smoker	22 (10.09)	12 (8.82)	1.38 (0.65, 2.93)	0.96 (0.33, 2.82)
Never	121(55.50)	91 (66.91)	*	*
Time taken to reach a health facility				
>30 minutes	125 (57.34)	42 (30.88)	3.01 (1.91, 4.73)	0.7 (0.25, 1.95)
≤30 minutes	93 (42.66)	94 (69.12)	*	*
Type of facility where care was sought first				
Public health centre/dispensary	37 (16.97)	32 (23.53)	0.77 (0.32, 1.84)	0.81(0.20, 3.26)
Private clinic/hospital	86 (39.45)	73 (53.68)	0.79 (0.35, 1.74)	0.71 (0.19, 2.69)
Chemist	77 (35.32)	19 (13.97)	2.70 (1.11, 6.56)	1.54 (0.37, 6.38)
County/subcounty hospital	18 (8.26)	12 (8.82)	*	*

*(Reference group), OR (prevalence odds ratio), POR (adjusted odds ratio), [a] Patient delay defines as duration from onset of symptoms to diagnosis, [b] delay defined as having more than 67 days period from onset of symptoms to diagnosis.

4.11.2 Independent factors associated with delay in treatment initiation

Factors independently associated with delays in treatment initiation were; Using a motorcycle as compared to walking as a means of transport (aOR 1.99, CI=1.16, 3.42), being a male compared to a female (aOR 2.07 CI=1.22, 3.52) and free services offered at the health facility unlike where they were charged (aOR 0.54, CI=0.32, 0.92) (Table 4.14).

Table 4.14: Multivariate factors independently associated with delays in treatment initiation among bacteriologically confirmed PTB patients, Mombasa county-2018 (n=354)

Factor	Treatment initiation delays [a]		POR (95% CI)	aOR (95% CI)
	Delay [b] # (%)	No delay # (%)		
Sex				
Male	104 (80.00)	151 (67.41)	1.93 (1.16, 3.23)	**2.07 (1.22, 3.52)**
Female	26 (20.00)	73 (32.59)	*	*
Means of ransport				
Motorcycle	43 (33.08)	46 (20.54)	1.97 (1.17, 3.32)	**1.99 (1.16, 3.42)**
Matatu	30 (23.08)	58 (25.89)	1.09 (0.63, 1.87)	1.15 (0.66, 2.01)
Walking	57 (43.85)	120 (53.57)	*	*
Free services				
Yes	90 (69.23)	184 (82.14)	0.49 (0.30, 0.81)	**0.54 (0.32, 0.92)**
No	40 (30.77)	40 (17.86)	*	*
Hemoptysis				
Yes	19 (14.62)	19 (8.48)	1.85 (0.94, 3.63)	2.00 (0.99, 4.04)
No	111 (85.38)	205 (91.52)	*	*
Lack of services				
Yes	7 (5.38)	4 (1.79)	3.13 (0.90, 10.90)	2.36 (0.64, 8.71)
No	123 (94.62)	220 (98.21)	*	*
Smoking history				
Quit smoking	75 (34.40)	33 (24.26)	0.95 (0.58, 1.55)	1.03 (0.60, 1.77)
Current smoker	22 (10.09)	12 (8.82)	2.05 (0.99, 4.26)	2.06 (0.95, 4.49)
Never	121(55.50)	91 (66.91)	*	*
On treatment for other condition				
Yes	15 (11.54)	43 (19.20)	0.55 (0.29, 1.03)	0.66 (0.33, 1.32)
No	115 (88.46)	181 (80.80)	*	*

*****(Reference group), pOR (prevalence odds ratio), aOR (adjusted odds ratio), [a] treatment initiation delay defined as duration from diagnosis to when treatment was started, [b] delay defined as having more than 2 days from diagnosis to start of treatment

CHAPTER FIVE

DISCUSSION

The median time to diagnosis was ten weeks with over half of the patients experiencing delays in diagnosis. This could be due to the fact that not all health facilities in Mombasa County, have TB diagnostic equipment and so many peripheral facilities refer patients or the sputum samples to the TB diagnostic centers. Therefore, patients are forced to go home and wait for a feedback of their results and some of them will not report back at the appropriate time. The median time for diagnosis delay in our study was longer than six weeks reported in cross sectional studies conducted in Western Kenya (Ayuo et al., 2008) and three weeks in Nairobi. The difference could be due to Mombasa County has fewer diagnostic centers compared to Western Kenya and Nairobi. On the other hand, our study population was all bacteriologically confirmed PTB cases while the study population was only the newly diagnosed adult PTB cases for western Kenya and adults who were TB suspects in Nairobi. The median time was also longer than that reported in other countries with high TB burden like Ethiopia (Asefa et al., 2014; Bogale et al., 2017; Gebeyehu et al., 2014; Kahsay et al., 2017), Uganda (Mistry et al., 2016) and Tanzania (Tarimo, 2012) and the difference was mainly in the definition of delay, the cut off time for delay in diagnosis and the population included in the studies where our study only factored the bacteriologically confirmed PTB cases only.

The duration from diagnosis to treatment of PTB patients in Mombasa County ranged from zero to nine weeks with a third of the patients having treatment initiated after two days against the recommended timelines of immediate or not later than two days enrollment on treatment after diagnosis (WHO, 2018b). First, patients living in areas where there are no diagnostic facilities have a greater chance of delay in the initiation

of their treatment certainly due to problems of access that involve distance and time. The possible reason for this prolonged duration in Mombasa was that due to referral of samples to the gene xpert sites, the patients had to return home and wait for feedback of their results. The gene xpert has an installed short message alert system which sends the results to the healthcare worker (HCW) referring the sample and thereafter the patient is notified of the results by the HCW through the provided mobile telephone number. This process leads to delay especially if the patient is not available on mobile phone or they are far away from the facility making it expensive to travel and time spent and as such some of the patients fail to report at the appropriate time to start their treatment. A study in India showed the duration between TB diagnosis and treatment initiation was up to four months although the cut off for delay was one week which was different from our study(Paul et al., 2012).

Despite the fact that TB diagnosis and treatment services are offered free in public health facilities in Kenya, our study showed that most patients first sought care from a private health provider and a chemist/pharmacist as compared to the public health sector. This might be because people have the freedom and right to choose where to seek health services and also explains the diverse health seeking behaviors of the people. Some people may visit the chemists/pharmacies for over the counter treatment since they do not know the severity of the symptoms or they want a quick service to save on time. The long ques in the public health facilities may also discourage patients from seeking services despite being free. However the laboratory diagnosis for most of the patients was made in a public health centres due to the availability of Xpert machines and affordability of the test which is free in the public sector. Public private partnership in TB control is a key component for TB control and

prevention in Kenya. About half of the patients with TB symptoms access the private sector as initial point of care (Enos et al., 2018; WHO, 2015a).

Despite TB being more prevalent among HIV positive people, TB-HIV co-infection rate was lower among the PTB cases in the county compared to what was reported routinely in Kenya (31%) among TB cases (National Tuberculosis, Leprosy and Lung Disease (NTLD-P), 2018). This low co-infection rate could be as a result successful implementation of TB and HIV collaborative activities, test and treat strategy and increased anti-retroviral therapy coverage among HIV positive patients (MOH-NASCOP, 2016; WHO-Tuberculosis, 2016). In addition, MTB detection is known to be less sensitive in HIV positive patients due to low bacteria load (Gopalan et al., 2016; Padmapriyadarsini et al., 2011) and therefore the possibility of excluding cases missed by the use of Gene Xpert MTB/RIF test cannot rule out the.

Delays in diagnosis

Delays in diagnosis was contributed to by both the health system factors and patients' factors especially in health seeking behaviors among the patients**.** It was found out that patients who had more than two visits to the health providers were found to have five times higher odds of delays in diagnosis compared to those who had two or less visits. This could be because they were either seen by different health workers in the same facility or different health workers in different health facilities which shows an important barrier to early diagnosis and treatment of TB, where each consecutive visit to a different health care worker may be like a first time visit if the hospital or patient records are not properly scrutinized. Also weak referral networks among health providers, patients' preferences and due to the fact only few facilities have diagnostic equipment. In general, however, the majority of the patients had visited a health care

provider two or fewer times before diagnosis of TB was made, and this could suggest that the awareness and knowledge of TB is high among health workers in a high HIV-TB burden country like Kenya. Our findings compares to a study done in Uganda which showed the proportion of patients who sought care before being diagnosed had fewer visits before diagnosis (Buregyeya et al., 2014).

There was higher likelihood of delay in diagnosis if the patient lived more than one kilometer from the nearest health facility. Longer distance of travel to health facility takes more time and increases cost of transport. Such costs, in addition to long waiting time in the health facilities have been reported as barriers to accessing services in health facilities, even if the services, like TB diagnosis and treatment services are offered free of charge the public health facilities (Ayuo et al., 2008; Cai et al., 2015; Finnie et al., 2011; MOH-NTLDP, 2018; Sendagire et al., 2010a; Tadesse et al., 2013). However, a study done in Zimbabwe showed distance to a DOT facility was not associated with patient delay and in fact those taking a longer time to reach a DOT facility were less likely to experience patient delays (Takarinda et al., 2015).

Laboratory turnaround time was long and contributed to delay in diagnosis. Mombasa County had only nine GeneXpert machines which are placed in tertiary health facilities. This means that samples have to be collected from the patients in peripheral facilities and referred to these sites. This might have led to longer turnaround time due to the time taken to transport the samples and increased workload. Sample referral, laboratory networking, distance to diagnostic centers and the long time that this whole process can take further enhances delays in initiation of treatment among PTB patients. This leads to high rates of initial defaulting after PTB diagnosis among TB patients as some patients are not traced backed to start medications. A study in South Africa, 2014, showed increased delays due to operation reasons as a result of

GeneXpert testing at a centralized laboratory which limited the test's clinical utility for diagnosing pulmonary TB (Cohen et al., 2014).

Having only fever as a symptom increased the odds of delays in diagnosis. Many infectious diseases present with fever and it is possible clinicians might not suspect TB the first time a patient presents to the health facility, in the absence of other symptoms of TB. Our findings are similar to those of a study done in Tanzania that reported people who presented with fever and additional symptoms of TB were more likely to seek health care services and clinicians were more likely to suspect TB and send the patients for testing. (Enos et al., 2018; Senkoro et al., 2015). These additional symptoms might present as the disease progresses and consequently, patients might present with advanced disease by the time TB diagnosis is made in the health facility.

Having relapse PTB decreased the odds of delay in diagnosis in our study. This could be because having had a previous episode of PTB may be associated with more knowledge and awareness of TB. Also having had a previous episode of TB may have exposed one to the public health system hence help them to navigate more easily or get quicker access in the current episode. This compares to a retrospective cohort study in Iran that showed delay in TB diagnosis was significantly higher new case (Khazaei et al., 2016).

Adults aged 15 to 24 years had lower odds of diagnosis delays maybe because at this age, one is dependent on their parents, mostly school going and is decisions could be made easily since someone is watching over them. Parents and teachers will ensure the students do not miss school due to illness and may take prompt actions to ensure the person is helped and remains well to attend classes. Socio-demographic factors including unemployment have been shown to be independently associated with delays

in diagnosis (Buregyeya *et al*., 2014; Cai *et al*., 2015; Mohamed *et al*., 2009; WHO-EMRO, 2006). However these findings contrast with another study in Iran that showed being employed would lead to delays in diagnosis (Ebrahimi Kalan *et al*., 2018).

Although smoking did not remain an independent factor at multivariate level for diagnosis delays, Patients who had history of smoking with more than three smoking pack years had longer delays in diagnosis at bivariate level. Smoking causes prolonged cough which is most often mistaken by both patients and health care providers and dismissed as a 'smoker's cough' leading to delays in TB diagnosis. This compares to a finding in Brazil that showed smokers had delays in diagnosis (Maciel *et al*., 2010). Smokers neglect coughing for some time as the main symptom of pulmonary tuberculosis due to cigarette induced cough (Verhagen *et al*., 2010).

Delays in treatment initiation

Majority of the patients with bacteriologically confirmed TB in our study were males. I found that being a male had two times higher odds of delaying treatment than females. This difference was not clear for Mombasa County as I did not explore the various gender differences in taking treatment. However, male patients could fail to return for treatment due to their busy schedule as they were mostly working in industries and men have been shown to have poor decision making as regards healthcare seeking (Njau et al., 2012). Being a male has been identified as a risk factor for late diagnosis and treatment of both TB and HIV (Buregyeya et al., 2014) and similarly in a cross section study in a high burden hospital in South Africa, men were found to have longer delays in treatment initiation than women (Meintjes et al., 2008) which compares with our study in that Mombasa county has high HIV and TB burden. In contrast, several studies have shown that there is no gender related

difference between TB diagnosis and treatment initiation, but where gender was found significant, the females were reported to have longer delays than the males (Horton et al., 2016; Karim et al., 2007; Mfinanga et al., 2008; Sendagire et al., 2010b; Xu et al., 2013; Yang et al., 2014).

Use of motorcycle to reach the health facility contributed significantly to patient delay in starting treatment especially more so if one had already been in the facility and had to go back for the results at a later date. Accessibility therefore becomes difficult for such patients to seek health-care due to cost and distance to travel and time taken to the facility. Even if the TB diagnosis and treatment services are offered free in all the public health facilities, indirect costs incurred while seeking care may have led to delays especially among the unemployed (MOH-NTLDP, 2018). A study done in Western Kenya found that distance of more than 10 km to facility was associated to patient delay (Ayuo *et al*., 2008).

5.1 Limitations

Relying on patients' recall on diagnosis and treatment initiation periods could potentially introduce a recall bias which could distort the accuracy of the data. To counter this, the interviewers were trained on how to conduct the study using a standardized questionnaire and complemented this with verification of patients records contained in facility TB4 register and the patients' appointment cards. Our study findings cannot be generalized to all forms of TB since this only included bacteriologically confirmed PTB patients which means the delays would possibly be longer if smear negative and extra-pulmonary TB patients were included .

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The median days from onset of symptoms to diagnosis of PTB was 10 weeks and the duration from diagnosis to treatment ranged from zero to nine weeks. Over half of the patients experienced diagnosis delays and one third of the patients experienced treatment initiation delays. More patients first visited a private clinic or pharmacy for health services but majority of the TB cases were diagnosed in a public health facility. Males were three times more than the females and majority of TB cases were HIV negative. Factors that increased delays in TB diagnosis were increased turnaround time due to Gene Xpert MTB/RIF referrals, distance to the nearest health facility and having fever as a symptom. Being male and use of motorcycle for transport were associated with delay in treatment initiation.

6.2 Recommendations

The study highlights the need to strengthen partnerships with the stand alone private providers including chemists and clinics to ensure early screening and referral of presumptive TB cases. This can be achieved through engagement and capacity building to create awareness of the guidelines and available infrastructure in the public sector, establishing sample networking mechanisms and supporting them with the necessary commodities for TB prevention and control.

The County health departent should enhance active case finding activities within the community and continuous sensitization of health workers for early TB diagnosis in the health facilities.

The county should strengthen sample referral networking for GeneXpert MTB/RIF testing and the national TB program should ensure more facilities are equipped with the Xpert MTB/RIF machines in the counties to reduce the TAT for the results. While health services are already decentralized in Kenya, further decentralizing of laboratory diagnosis in lower level facilities and improved referral procedures may help to reduce delay.

We recommend a future study in Mombasa County to determine the barriers to TB services related to gender for the TB program to formulate specific interventions for this population. It is important to confirm if there could be missed opportunities among HIV infected population by adopting other tests including a chest X-ray for the HIV positive clients who turn negative on the gene xpert MTB/RIF test to confirm with certainty the low prevalence of TB/HIV co-infection in Mombasa County. These findings will enable the NTLDP to put in place intervention strategies as well as develop useful tools for TB control and prevention among these key populations.

REFERENCES

Akrim, M., Bennani, K., Essolbi, A. , Sghiar, M. , Likos, A., Benmamoun, A., Menzhi Ol., Maaroufi1, A. (2014). New smear-positive pulmonary tuberculosis patients in Morocco: a cross-sectional study. *EMHJ-Eastern Mediterranean Health Journal, 20 (11), 707-716.*

Asefa, A., & Teshome, W. (2014). Total delay in treatment among smear positive pulmonary tuberculosis patients in five primary health centers, southern Ethiopia: a cross sectional study. *PloS One*, *9*(7), e102884.

Ayuo, P. O., Diero, L. O., Owino-Ong'or, W. D., & Mwangi, A. W. (2008). Causes of delay in diagnosis of pulmonary tuberculosis in patients attending a referral hospital in Western Kenya. *East African Medical Journal*, *85*(6), 263–268.

Bogale, S., Diro, E., Shiferaw, A. M., & Yenit, M. K. (2017). Factors associated with the length of delay with tuberculosis diagnosis and treatment among adult tuberculosis patients attending at public health facilities in Gondar town, Northwest, Ethiopia. *BMC Infectious Diseases*, *17*(1), 145.

Buregyeya, E., Criel, B., Nuwaha, F., & Colebunders, R. (2014). Delays in diagnosis and treatment of pulmonary tuberculosis in Wakiso and Mukono districts, Uganda. *BMC Public Health*, *14*(1), 586.

Cai, J., Wang, X., Ma, A., Wang, Q., Han, X., & Li, Y. (2015). Factors associated with patient and provider delays for tuberculosis diagnosis and treatment in Asia: A systematic review and meta-analysis. *PLoS ONE*, *10*(3)

Cazabon, D., Alsdurf, H., Satyanarayana, S., Nathavitharana, R., Subbaraman, R., Daftary, A., & Pai, M. (2017). Quality of tuberculosis care in high burden countries: the urgent need to address gaps in the care cascade. *International Journal of Infectious Diseases : IJID : Official Publication of the International Society for Infectious Diseases*, *56*, 111.

Cochran, W. G. (1963). *Sampling techniques.* 413.

Cohen, G. M., Drain, P. K., Noubary, F., Cloete, C., & Bassett, I. V. (2014). Diagnostic delays and clinical decision making with centralized Xpert MTB/RIF testing in Durban, South Africa. *Journal of Acquired Immune Deficiency Syndromes (1999)*, *67*(3), e88-93.

Deponti, G. N., Silva, D. R., Coelho, A. C., Muller, A. M., & Dalcin, P. de T. R. (2013). Delayed diagnosis and associated factors among new pulmonary tuberculosis patients diagnosed at the emergency department of a tertiary care hospital in Porto Alegre, South Brazil: a prospective patient recruitment study. *BMC Infectious Diseases*, *13*(1), 538.

Eltayeb, D. (2016). Factors associated with patient and health system delay in diagnosis and commencement of treatment for pulmonary tuberculosis in the Middle East and North Africa *(MENA)*.

Enos, M., Sitienei, J., Mungai, B., Kamene, M., Wambugu, J., Kipruto, H., Ngari, F. (2018). Kenya tuberculosis prevalence survey 2016: Challenges and opportunities of ending TB in Kenya. *PloS One*, *13*(12), e0209098.

Finnie, R. K. C., Khoza, L. B., van den Borne, B., Mabunda, T., Abotchie, P., & Mullen, P. D. (2011). Factors associated with patient and health care system delay in diagnosis and treatment for TB in sub-Saharan African countries with high burdens of TB and HIV. *Tropical Medicine & International Health*, *16*(4), 394–411.

Gebeyehu, E., Azage, M., & Abeje, G. (2014). Factors Associated with Patient's Delay in Tuberculosis Treatment in Bahir Dar City Administration, Northwest Ethiopia. *BioMed Research International*, *2014*, 1–6.

Gebreegziabher, S. B., Bjune, G. A., & Yimer, S. A. (2016). Patients' and health system's delays in the diagnosis and treatment of new pulmonary tuberculosis patients in West Gojjam Zone, Northwest Ethiopia: a cross-sectional study. *BMC Infectious Diseases*, *16*(1), 673.

Godfrey, J., Rosie, M., E, S. L., Conradie., & Catherine, A. (2016). Tuberculosis control. *The Lancet*, *387*(10024), 1157–1158.

Gopalan, N., Chandrasekaran, P., Swaminathan, S., & Tripathy, S. (2016). Current trends and intricacies in the management of HIV-associated pulmonary tuberculosis. *AIDS Research and Therapy*, *13*, 34.

Horton, K. C., MacPherson, P., Houben, R. M. G. J., White, R. G., & Corbett, E. L. (2016). Sex Differences in Tuberculosis Burden and Notifications in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. *PLOS Medicine*, *13*(9), e1002119.

Kahsay, A., Gedefaw, M., Asres, M., & Weldu, Y. (2017). Patients' Delay in Seeking Health Care for Tuberculosis Diagnosis in East Gojjam Zone, Northwest Ethiopia. *The American Journal of Tropical Medicine and Hygiene*, *96*(5), 1071–1075.

Karim, F., Islam, M. A., Chowdhury, A., Johansson, E., & Diwan, V. K. (2007). Gender differences in delays in diagnosis and treatment of tuberculosis. *Health Policy and Planning*, *22*(5), 329–334.

Khazaei, S., Mansournia, M. A., Nematollahi, S., Ayubi, E., Zahiri, A., Mohamadian-Hafshejani, A., khazaei, S. (2016). Determinants of delay in tuberculosis diagnosis in Hamadan province, 2006−2014. *Egyptian Journal of Chest Diseases and Tuberculosis*, *65*(4), 811–815.

KNBS. (2009). The 2009 Kenya Population and Housing Census.

Meintjes, G., Schoeman, H., Morroni, C., Wilson, D., & Maartens, G. (2008). Patient and provider delay in tuberculosis suspects from communities with a high HIV prevalence in South Africa: A cross-sectional study. *BMC Infectious Diseases*, *8*(1), 72.

Mfinanga, S. G., Mutayoba, B. K., Kahwa, A., Kimaro, G., Mtandu, R., Ngadaya, E., … Kitua, A. Y. (2008). The magnitude and factors associated with delays in management of smear positive tuberculosis in Dar es Salaam, Tanzania. *BMC Health Services Research*, *8*(1), 158.

Mistry, N., Rangan, S., Dholakia, Y., Lobo, E., Shah, S., & Patil, A. (2016). Durations and Delays in Care Seeking, Diagnosis and Treatment Initiation in Uncomplicated Pulmonary Tuberculosis Patients in Mumbai, India. *PLOS ONE*, *11*(3), e0152287.

MOH-NASCOP. (2016). Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya.

MOH-NTLD-P. (2018). Kenya Natinal Tuberculosis, Leprosy and lung disease annual report, 2017.

MOH-NTLDP. (2018). Tuberculosis patients cost survey in Kenya, 2017.

MOH-NTLDP mid-term review. (2018). Report of an independent Mid-Term Review of the Implementation of the Kenya National Tuberculosis , Leprosy and Lung Disease Programme Strategic Plan 2015-2018.

Mombasa County Government. (2013). Mombasa County Government First County Integrated development Plan 2013-2017.

National HIV and STI Control Program. (2016). Kenya HIV estimates 2015.

National Tuberculosis, Leprosy and Lung Disease (NTLD-P), M. O. H. (2018). Annual TB report, 2017.

Njau, I. W., Karanja, S. M., Wanzala, P., & Omolo, J. O. (2012). Factors associated with late presentation of suspected tuberculosis cases to tuberculosis management facilities: The case in Dagoretti district, Nairobi, Kenya. *Pan African Medical Journal*, *12*(1).

Padmapriyadarsini, C., Narendran, G., & Swaminathan, S. (2011). Diagnosis & treatment of tuberculosis in HIV co-infected patients. *The Indian Journal of Medical Research*, *134*(6), 850–865.

Paul, D., Busireddy, A., Nagaraja, S. B., Satyanarayana, S., Dewan, P. K., Nair, S. A., … Oeltmann, J. E. (2012). Factors associated with delays in treatment initiation after tuberculosis diagnosis in two districts of India. *PloS One*, *7*(7), e39040.

Ryu, Y. J. (2015). Diagnosis of Pulmonary Tuberculosis: Recent Advances and Diagnostic Algorithms.

Sendagire, I., Schim Van der Loeff, M., Mubiru, M., Konde-Lule, J., & Cobelens, F. (2010a). Long delays and missed opportunities in diagnosing smear-positive pulmonary tuberculosis in Kampala, Uganda: a cross-sectional study. *PloS One*, *5*(12), e14459.

Sendagire, I., Schim Van der Loeff, M., Mubiru, M., Konde-Lule, J., & Cobelens, F. (2010b). Long delays and missed opportunities in diagnosing smear-positive pulmonary tuberculosis in Kampala, Uganda: a cross-sectional study. *PloS One*, *5*(12), e14459.

Senkoro, M., Hinderaker, S. G., Mfinanga, S. G., Range, N., Kamara, D. V., Egwaga, S., & van Leth, F. (2015). Health care-seeking behaviour among people with cough in Tanzania: findings from a tuberculosis prevalence survey. *The International Journal of Tuberculosis and Lung Disease*, *19*(6), 640–646.

Sreeramareddy, C. T., Panduru, K. V, Menten, J., & Van den Ende, J. (2009). Time delays in diagnosis of pulmonary tuberculosis: a systematic review of literature. *BMC Infectious Diseases*, *9*(1), 91.

Storla, D. G., Yimer, S., & Bjune, G. A. (2008). A systematic review of delay in the diagnosis and treatment of tuberculosis. *BMC Public Health*, *8*, 15.

Tadesse, T., Demissie, M., Berhane, Y., Kebede, Y., & Abebe, M. (2013). Long distance travelling and financial burdens discourage tuberculosis DOTs treatment initiation and compliance in Ethiopia: a qualitative study. *BMC Public Health*, *13*, 424.

Takarinda, K. C., Harries, A. D., Nyathi, B., Ngwenya, M., Mutasa-Apollo, T., & Sandy, C. (2015). Tuberculosis treatment delays and associated factors within the Zimbabwe national tuberculosis programme. *BMC Public Health*, *15*, 29.

Tarimo, G. B. (2012). Delay in seeking care among tuberculosis patients attending tuberculosis clinics in Rungwe district, Tanzania.

Tollefson, D., Ngari, F., Mwakala, M., Gethi, D., Kipruto, H., Cain, K., & Bloss, E. (2016). Under-reporting of sputum smear-positive tuberculosis cases in Kenya. *The International Journal of Tuberculosis and Lung Disease : The Official Journal of the International Union against Tuberculosis and Lung Disease*, *20*(10), 1334–1341.

Tudor, C., Van Der Walt, M. L., Margot, B., Dorman, S. E., Pan, W. K., Yenokyan, G., & Farley, J. E. (2016). Occupational Risk Factors for Tuberculosis among Healthcare Workers in KwaZulu-Natal, South Africa. *Clinical Infectious Diseases*, *62*(S3), S255–S261.

Ukwaja, K. N., Alobu, I., Nweke, C. O., & Onyenwe, E. C. (2013). Healthcare-seeking behavior, treatment delays and its determinants among pulmonary tuberculosis patients in rural Nigeria: a cross-sectional study. *BMC Health Services Research*, *13*(1), 25.

Verhagen, L. M., Kapinga, R., & van Rosmalen-Nooijens, K. (2010). Factors underlying diagnostic delay in tuberculosis patients in a rural area in Tanzania: a qualitative approach. *Infection*, *38*, 433–446.

WHO-Regional Office for the Eastern Mediterranean. (2006). *Diagnostic and treatment delay in tuberculosis*.

WHO-Tuberculosis. (2016). *Global tuberculosis report.*

WHO. (2013a). Definitions and reporting framework for tuberculosis - 2013 revision. World Health Organization, Geneva, Switzerland.

WHO. (2013b). Global Tuberculosis Report 2013. In *World Health Organization*.

WHO. (2015a). Public-private mix for TB care and control. *World Health Organization*, 66.

WHO. (2015b). *THE END TB STRATEGY. WHO/HTM/TB*.

WHO. (2016). Who Global Tuberculosis Report. In *World Health Organisation (WHO) Report*.

WHO. (2018a). *Global tuberculosis report*.

WHO. (2018b). Tuberculosis Key facts.

Xu, X., Liu, J.-H., Cao, S.-Y., Zhao, Y., Dong, X.-X., Liang, Y., & Lu, Z.-X. (2013). Delays in care seeking, diagnosis and treatment among pulmonary tuberculosis patients in Shenzhen, China. *The International Journal of Tuberculosis and Lung Disease*, *17*(5), 615–620.

Yang, W.-T., Gounder, C. R., Akande, T., De Neve, J.-W., McIntire, K. N., Chandrasekhar, A., Gupta, A. (2014). Barriers and Delays in Tuberculosis Diagnosis and Treatment Services: Does Gender Matter? *Tuberculosis Research and Treatment*, *2014*, 1–15.

Yonge, S., Otieno, M., & Omedo, R. (2016). Risk Factors in Transmission of Tuberculosis Infection in Mombasa, Kenya*: An Epidemiological Descriptive Study*.

APPENDICES

Appendix 1: Consent Form – English

Title of Study: Delays in diagnosis and treatment initiation among tuberculosis patients Mombasa County.

Introduction:

My name is _____ from Ministry of Health. I am here to gather information from you, which will help us assess whether you had delays in diagnosis and treatment initiation in relation to your current diagnosis of tuberculosis.

Purpose of Study:

The main purpose is to determine the magnitude of tuberculosis diagnosis and treatment delays in the country by interviewing all new TB patients that will participate in the study. In addition, the study will describe the factors associated with the delays which will be very useful for the management of TB in the country.

Request: I request you to take part in a research study. The research study aims to determine factors associated with delay in TB diagnosis in Kenya. Delayed diagnosis and hence treatment leads to more cross infections. An understanding of factors associated with delay in diagnosis of TB may enable the national tuberculosis program in the ministry of health to design ways of getting more timely diagnosis and hence control TB spread. The study session is expected to last about 30 minutes. During this time, you will be asked some questions about the current and past illness and other practices and experiences. The study will not interfere with your current treatment.

Benefits: There will be no direct benefit to you for your participation. But your contribution will help us to better understand the magnitude and risk factors related to

delays in diagnosing and initiating treatment for tuberculosis in this country. This will go a long way in improving the management of TB.

Risks: The study will not pose any risks to you. There will be no costs to you for taking part in this study.

Confidentiality: Efforts to maintain confidentiality will be taken so that risks of disclosing the information you have given us will be fully minimized. All data collected will be handled confidentially and no names will be included in the report. The data will be stored in computers with passwords and hard copies will be kept in lockable cabinets that have authorized access to the investigators only.

Consent: Your participation is voluntary. If you wish to withdraw from this study at any time you shall not be penalized.

Questions: If during the course of this study you have any questions concerning the nature of this research you should contact Dr. Polly Kiende: Telephone Number: 0720316297

If in case you have a question concerning your rights of participation, you should contact; The Moi University Ethical Review Committee, secretary; Telephone Number:

I _____ have read/been read and understood the purpose of the study and my role. I hereby give consent for my participation as explained to me.

Study participant's/guardian/parent name: _____

Sign: _____ Date _____

Name of Investigator: _____ Sign: _____ Date: _____

Appendix 2: Consent form (Swahili)

Anwani ya Uchunguzi: Kuchelewa kwa kugunduliwa na kuanzishwa matibabu ya ugonjwa wa kifua kikuu Kaunti ya Mombasa.

Utangulizi

Jina langu ni _____ kutoka kwa Wizara ya Afya. Niko hapa kuchukuwa taarifa kutoka kwako ambayo itatusaidia kutafuta iwapo kuna kuchelewa kwa kuutambua na kuanzishwa matibabu ya ugonjwa wa kifua kikuu.

Kusudi la Uchunguzi: Kusudi la uchunguzi huu ni kupeleleza kiwango cha Kuchelewa kwa kuutambua na kuanzishwa matibabu ya ugonjwa wa kifua kikuu kwa kuwachunguza kwa undani watu waliopatikana kuwa na kifua kikuu katika Mombasa Kaunti. Taarifa hii itakuwa ya muhimu kwa usimamizi wa kifua kikuu nchini Kenya.

Ombi: Ninakuomba ushiriki kakatika utafiti huu. Utafiti huu unalengakutambua kana kwamba kuna kuchelewa kuutambua na pia kuwaanzisha matibabu wanaopatikana na ugonjwa wa kifua kikuu. Mombasa. Wanaougua ugonjwa huu wanaendelea kuambukiza wenzao iwapo hawajatambulika na kuwekwa kwa matibabu.Kuelewa maswala yanayosababisha kuchelewa kuutambua ugonjwa wa kifua kikuu itatusaidia tuweze kuepukana na hizo sababu. Mahojiano haya yanatarajiwa kuchukua muda wa dakika thelathini. Utaulizwa maswali kuhusiana na ugonjwa ulionao sasa, jinsi ulianza kuugua na matibabu yote ambayo umepata tangu uanze kuugua. Utafiti huu hautaadhiri matibabu yako ya sasa.

Manufaa: Manufaa ya moja kwa moja kwa kushiriki kwako hayapo, Lakini uchangio wako utatusaidia kuelewa Zaidi kiwangocha uchelewaji wakuutambua nakuanzisha matibabu ya Kifua Kikuu nchini. Hii itapelekea kuboresha utabibu wa Kifua Kikuu.

Madhara: Utafiti huu hauna hatari zozote kwa afya yako wala hautagharamiwa Kuhusika katika utafiti huu.

Kuhifadhi Siri: Majibu utakayotupatia yatachukuliwa kwa siri. Hautatambulika kwa taarifa yoyote ama nakala ama kwa makundi yoyote. Hifadhi zako zinazohusiana na kushiriki kwako kwenye uchunguzi huu zitahifadhiwa kwenye Afisi Kuu inayohusiana na uchunguzi huu kwa uchunguzi zaidi. Kufikiwa kwa hifadhi hizo zitakuwatukwawachunguziwakuu.

Kushiriki:Kushiriki kwako ni kwa hiari. Unaweza kujiondoa kwa uchunguzi huu kwa wakati wowote bila adhabu yoyote.

Mada: Iwapo kwa wakati wa uchunguzi huu utakuwa na maswali yoyote kuhusiana na hali ya utafiti huu wapaswa kuwasiliana na Daktari,Polly Kiende; Nambari ya simu: 0720316297

Iwapo kwa sababu yoyote uko na swali kuhusiana na haki ya kushiriki, wasiliana na Katibu Mkuu, Kamati Kuu ya Uchunguzi wa Masuala ya Siri, chuo kikuu cha Moi, Eldoret, kwa nambari ya simu …….

Mimi_____ nimesoma/nimesomewa na kuelewa kabisa taarifa iliyo hapo juu na yanayohitajika kutoka kwangu. Ninatoa idhini yakushiriki kwangu kama nilivyoelezwa.

Jina la mshiriki wa uchunguzi/Mzazi _____

Sahihi _____

Tarehe _____

Jina la mchunguzi: _____

Sahihi _____

Tarehe _____

Appendix 3: Questionnaire

Diagnostic and treatment delays and their determinants

Questionnaire No---------- Clients sub-county TB No…….

Clients Initials…….

Name of interviewer ----------

Date of the interview (dd/mm/yy): ……

TB register number:

1. Type of the facility (tick one)
    - Dispensary
    - Health Centre
    - Sub county hospital
    - County Hospital
2. Facility ownership **(tick one)**
    - FBO
    - GOK
    - PRIVATE
    - NGO
3. Unique ID: ----------
4. Type of patient (New or relapse)
5. Date of onset of symptoms (DD/MM/YY)----------
6. Date first seen in a health facility (DD/MM/YY)----------
7. Date of diagnosis (DD/MM/YY)----------
8. Date started on treatment (DD/MM/YY)----------
9. Place of residence: (tick one)
    - Urban
    - Suburban
    - Rural
    - Homeless/displaced
10. Age(years): ----------
11. Sex (male or female)----------

12. Educational level: (select all that applies)
    - Tertiary (University, College etc or higher)
    - Primary
    - Secondary
    - None
13. Occupation: (select one)
    - Formal employment
    - Casual
    - Informal business
    - Formal business
    - Farmer
    - Housewife
    - Unemployed
    - Student
14. Marital Status: (colour red for the answer)
    a. Married
    b. Single
    c. Divorced/separated
    d. Widowed
15. Number of household members----------
16. Number of rooms in the house----------
17. History of smoking: (select one)
    a. Never
    b. Current smoker
    c. Quit smoking
18. If smoker specify amount of daily consumption (number of cigarettes/day): ----
19. Duration of smoking: years--------; months----------
20. Other chronic diseases (select one)
    - HIV/AIDS:(colour red for the option)
      - Negative
      - positive
      - Unknown
    - Diabetes,

- COPD,
- Asthma
- Hypertension
- Other (specify): --------

21. Previous exposure to TB: (Yes or No)……..
22. If yes from who: (select one)
    - From family member
    - Friend
    - Another patient
    - Others (specify)

History of current illness

21. When did the start feeling sick (in months or weeks)……month……..weeks
22. Which symptoms did you experience which led you to seek treatment for your current illness? (tick all options that apply)
    - Cough
    - Productive cough
    - Blood stained sputum
    - Night sweats
    - Weight loss
    - Chest pains
    - Fever
    - Don't know
    - Other (specify)
23. How long did you experience the symptoms before seeking help/how long did you take to seek health care before visiting a health centre? (select one)
    - Weeks
    - Months
    - Year
24. Where did you first seek treatment or advice for these symptoms and what was the cost of one consultation (legal)

First action	Date(dd/mm/yy)	Total expenses
Pharmacy/Chemist		
Clinic		
Self-medication		
laboratory		
Traditional healer/herbalist		
Dispensary		
Health centre		
Hospital		
Others (specify)		

25	Facility ownership	FBO GOK Private NGO
26	How many visits did you make to a treatment site before diagnosis was made?	Number of visits (text)
27	During the first visit was sputum taken?	Yes No
28	What were the results?	Positive Negative Do not know
29	Was x-ray ever done for you?	Yes No
30	In which visit was x-ray done	(NUMBER)

31. If private practice, specify the specialty of the Health Care Practitioner whom you first sought his consultation:
    a. Chest specialist
    b. Student/Trainee
    c. General Practitioner/Medical officer
    d. Others (specify)

32. Reasons of the first consultation of the health facility (mentioned in q.24) with the onset of symptoms (i.e. first in order in q.24) (check) (check boxes options) (select all the that applies)

    Accessible

    Confidence in getting cured

    Services available anytime

    Referred by previous health service

    Free services

    Advised by somebody

    Others (specify)

33. Reasons of non-consultation of other health facility (refer to q.24) with the onset of symptoms (in case he did not consult) (check boxes): (tickall the answers)

0	Too far
1	Too busy/long waiting time
2	Bad experience
3	Others (specify) –Attitude, cost, lack of services, referred by someone,

34. Satisfaction with Care (score: 0 best, 3 worst**)**

Service	score
Availability of services in PHC/TB Centres	
Prompt action from HCP in PHC	
PHC well equipped	
PHC giving free medicine	
There is enough PHC in the area	
Health facility workload	
Waiting time (0:<= 15mn, 1: 15-30 min: 2: >30 mn-1 hr 3: >1 hr)	

35 .Perceived Causes of Delay in Health Seeking Behavior (colour red for all the answer)

No delay
Fear of what would be found on diagnosis
Hoped their symptoms would go away on their own (denial and concealment)
Fear of social isolation
Economic constraints
Inadequate staff attitude
Poor quality of health services
Others (mention)

36. Date of first TB diagnosis (dd/mm/yy): ----------
37. No of health seeking encounters (Health Care Practitioners) before initial TB diagnosis: ----------
38. Health facility of the HCP who made the initial TB diagnosis (by code mentioned in q.24) ----------
39. The specialty of the HCP who made the initial TB diagnosis:
    a. Chest specialist
    b. Internist
    c. GP
    d. Others (specify)
40. Date of initiation of treatment (dd/mm/yy): ----------

Accessibility to the public health facility providing treatment

41. What means of transport do you use to get to this health facility
    - Walking
    - Bicycle
    - Motor cycle
    - Matatu (psv)
    - Boat (peddle or motor
    - Time to reach from home to the nearest public health facility: Less than 30 minutes
    - 30minutes-one hour
    - More than 1 hour

42. Distance (in Km) from home to the nearest health facility providing treatment: -
    ----

End. Thank the participant

Appendix 4: IREC approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2017/188
Approval Number: 0003014

10th May, 2018

Ms. Polly Kiende,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
10 MAY 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Ms. Kiende,

RE: FORMAL APPROVAL

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

"Factors Associated with Delays in Diagnosis and Treatment Initiation among Tuberculosis Patients, Mombasa County, Kenya, 2018".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3014*** on 10th May, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 9th May, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

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

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

Appendix 5: Mombasa County Permission Letter

COUNTY GOVERNMENT OF MOMBASA

DEPARTMENT OF HEALTH SERVICES

OFFICE OF THE COUNTY CHIEF OFFICER

Email : cehealthmis@gmail.com
When replying please quote

P O Box 90441 – 80100
Msanifu Kombo Street,
MOMBASA

Ref: CON/MSA/MED.1/05/028

19th July, 2018

Polly Kiende
Kenya Field Epidemiology and Laboratory Training
Program (MOH)
P. O. Box 225-00202
NAIROBI
Email: Polmahope.pk@gmail.com
+254720316297

RE: REQUEST TO UNDERTAKE RESEARCH WORK

Your request to carry out research on ***'Factors associated with delays in diagnosis and treatment initiation among TB patients in Mombasa County'*** refers.

This office has no objection to your request and is hereby approved. By a copy of this letter all Public Health Facility In charges (List of facilities attached) and Hospitals will accord you the necessary assistance for your assessment to be successful.

On completion of the study you are required to disseminate the findings to the County Management Team for the recommendations to be considered.

Note that a list of the said health facilities is attached.

GOVERNMENT OF MOMBASA
CHIEF OFFICER - HEALTH
19 JUL 2018
P. O. Box 90440 - 80100
MOMBASA
DEPARTMENT OF HEALTH SERVICES

DR KHADIJA SOOD SHIKELY, HSC
COUNTY CHIEF OFFICER, MEDICAL SERVICES
COUNTY GOVERMENT OF MOMBASA.

Copy: All Medical Superintendents
All Sub County Medical Officers of Health – Mombasa County