TUBERCULOSIS AND HIV INFECTIONS IN MINING FIELDS: A CASE OF OSIRI-MATANDA GOLD MINES IN NYATIKE SUB-COUNTY, MIGORI COUNTY, KENYA

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Tuberculosis and HIV Infections in Mining Fields: A Case of Osiri-Matanda Gold Mines in Nyatike Sub-County, Migori County, Kenya

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DECLARATION

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

Signature……..…….……...Date……..…….

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

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JKUAT, Kenya

DEDICATION

I dedicate this work to my wife Agnetta, and to children, Roy, Prince and Mark, who sacrificed their resources and comfort to enable me achieve this.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
APHL	Association of Public Health Laboratories
ART	Anti-Retroviral Therapy
CHEWS	Community Health Extension Workers
CHMT	County Health Management Team
DR-TB	Drug Resistant TB
EPTB	Extra Pulmonary TB
ERC	Ethics Review Committee
HIV	Human Immunodeficiency Virus
ICF	Intensive Case Finding
IPT	Isoniazid Preventive Therapy
IRB	Institutional Review Board
LED	Light Emitting Diode
LIMS	Laboratory Information Management System
MDR	Multi Drug Resistant
MTB	Mycobacterium tuberculosis
PLWH	Persons Living with HIV
PTB	Pulmonary Tuberculosis

RIF	Rifampicin
SOP	Standard Operating Procedure
TB	Tuberculosis
WHO	World Health Organization
XDR	Extensively Drug Resistant

DEFINITION OF OPERATIONAL TERMS

Aerosol Droplets these are light solid particles suspended in the air

Active Tuberculosis a current infection of TB in an individual presenting with any of the symptoms associated with TB

Drug Resistant TB (DR-TB) a type of *Mycobacterium tuberculosis* organism that does not respond to treatment with any of the first line and second line anti-TB regimen.

Extensively Drug Resistant TB (XDR TB) a type of DR-TB that does not respond to treatment with both isoniazid and rifampicin, any fluoroquinolone and at least one of the group A drugs

Fish Banda usually a building within the lake shore where fish are collected, sorted and weighed before being sold.

GeneXpert a semi-automated molecular testing device currently used for TB diagnosis

Index Patient a person who is the first to be diagnosed with TB in a household or set up where others may have equally been exposed

Luo a tribe of western Kenya and the upper Nile valley

Mono-resistant TB a type of resistance to any one first line anti-TB regimen, save for Rifampicin resistance which is normally treated as MDR

Mycobacterium Tuberculosis the bacilli that when inhaled by a susceptible human host, results to tuberculosis infection.

New Tuberculosis Infection a first time TB infection in an individual who had not been previously infected

Poly-resistant TB	a type of TB that does not respond to treatment with more than one first line TB drugs but not to both isoniazid and rifampicin i.e. not MDR-TB
Shanties	a crudely built structure used as housing
TB Relapse Patient	a patient who after successful completion of TB treatment, regains signs and symptoms consistent with active TB infection.
Presumed TB	a person whom by means of clinical presentation, is presumed to have TB infection.

ABSTRACT

Most interventions towards tuberculosis (TB) infections in Kenya occur within the health facilities, including TB screening, laboratory-based and radiological testing, and treatment initiation for anyone found to be infected. Little is however done towards those not visiting the health facilities, yet may harbor TB disease and continue its spread in the community. This cross-sectional study sought to find out if such infections exist among miners at Osiri-Matanda gold mines in Nyatike Sub-County, Migori County, and to determine TB drug resistance (DR-TB) as well as TB-HIV co-infection among them. A TB risk assessment tool was used to capture the demographic information of participants consenting to the study. HIV testing was done via a finger-prick blood sample. Sputum was collected and tested for TB infection by the Ziehl-Neelsen (ZN) staining method. GeneXpert testing was used to confirm the positive microscopy results and to determine rifampicin (RIF) resistance. The resulting data was analysed alongside key demographic characteristics captured such as age, sex, gender, weight, height and BMI. A total of 297 participants took part in the study of which 49.5% (147) were males and 50.5% (150) were females. The age range was 63 (15-78) and median age 40. A TB positivity of 15.5% (46/297) was obtained. Overall positivity was highest at age 35-44 (39%) and lowest in those above 64 years (<5%). Males accounted for 71.7% (33/46) of infections while females were 28.3% (13). HIV infections among TB positive participants was 37%, with the highest co-infection rate being in males at 76.5% (13) compared to 23.5% (4) in females. There was no RIF-resistant TB identified. Fever, cough, weight loss, chest pain, and night sweats ($p<0.0001$) were found to be determining factors for TB infections. Tuberculosis infection occurs undetected in this community with infections being higher in males than in females. The age group to focus on is ages 25-44 where there's a steady rise in TB infections. Considerable intervention towards TB and HIV eradication including active case finding must target populations living a collegiate lifestyles like miners, students and fisher folk.

CHAPTER ONE

INTRODUCTION

1.1 Background

Kenya is still considered among the countries with the highest tuberculosis (TB) disease burden even though it is one of the seven high TB-burdened countries that have achieved the ambitious target of 20% reduction in TB infections as set by WHO for the period between 2015 and 2020 (WHO, 2020). Of concern, however, is the emergence of drug-resistant TB (DR-TB) as well as the TB-HIV co-infection in these countries. This is partly attributed to a lack of active case detection and TB treatment initiation for everyone, alongside poor adherence to treatment guidelines and regimens. The nature of the population has been known to present challenges in the detection and management of TB infections. TB infection spreads from person to person via droplet aerosols facilitated by close contact with infected persons, especially in overcrowded areas with poor sanitation. A recent publication and World TB Day report in the Democratic Republic of Congo listed the South Kivu artisanal and industrial miners as one of the previously unrecognized communities with high levels of tuberculosis (Faccin et al., 2022). In Tanzania, tuberculosis infection was listed to be highest in two large mining areas of Geita and Kahama. A random active case finding in rural mining communities in Northwest Tanzania achieved 1,499 TB infections out of 144,707 screenings, with 154 TB-HIV co-infections (Abeid et al., 2022). Poor health-seeking behaviour has been cited as the main impediment to the fight against TB in mining communities and other rural set-ups (Chanda-Kapata et al., 2016; Huq et al., 2018; Rambiki et al., 2020).

The mining community is at particular risk of TB spread by the nature of the congregate lifestyle they adopt as well as the overcrowding within the mines and surrounding areas. In mining setups, the community is known to live in shanties for shelter and share virtually all available social amenities like toilets and water with very poorly constructed structures used for housing (Pelders et al., 2019). The shanties are not only vulnerable to TB but other calamities like fires as well (Odeny, 2020). The mining exercise itself is associated with the rigorous task of digging and moving

through underground tunnels, normally for long hours with very poor sanitation and oblivious of the cough etiquette recommended for TB control. Outside the mines, various other activities including small-scale businesses are carried out by spouses and relatives, sexual partners, or associates of the miners. All these activities take place in very confined locations as everyone struggles to be as close as possible to the mines hence they overrun the social amenities available (Pelders et al., 2019). Through this close contact, coupled with poor sanitation from where they live, which is normally the same place where child labour and other illicit activities like sex trade are carried out, and with a lack of proper health education, the mining community is exposed to potential outbreaks and spread of infections including TB and other communicable diseases like cholera (Walter, 2023).

Globally, TB is known to be a major opportunistic infection and a leading cause of death among persons living with HIV (PLWH) (Chepkondol et al., 2020). While it is advocated that patients get screened for TB at every hospital visit, the mining community is among the most at-risk groups who do not benefit from this intervention given the nature of their work and social life that presents laxity in seeking health services (WHO, 2013). Therefore should anyone in such populations be infected with TB, it is possible that as they go about their daily routines, several other community members as well as household members will most likely contract the disease from the infected person long before it can be diagnosed and treated (Sema et al., 2020). The complexity of the specific households and congregate lifestyles of these particular individuals will determine how many are at risk of TB from a particular index patient, and ensure the TB epidemic is maintained at that level; hence a sizeable number of infections are most likely possible within a short period given the contagious nature of the TB bacilli.

Community outreach services targeting TB infections have reported active TB infections that would otherwise have remained undiagnosed and untreated if such outreaches were not conducted (Abeid et al., 2022). Some have been diagnosed at very advanced stages of infections indicated by the wasting syndromes associated with such chronic infections. Tuberculosis-associated stigma has been reported in some mining setups and as such concerted efforts targeting to destigmatize both TB and HIV are

necessary to encourage screening and treatment (Maibvise et al., 2022). It is, therefore, necessary to evaluate if TB exists in the mining area of Osiri-Matanda and determine the risk of its continued spread by engaging in active screening, testing, and referrals for treatment of those found positive for tuberculosis infection.

1.2 Statement of the Problem

About half of those infected with TB are at the community level and are usually missed due to their inability to seek health services (Enos et al., 2018). Mining is a risk factor for TB especially due to the overcrowding in the mines, long hours of work in non-ventilated and overcrowded mining tunnels, poorly ventilated housing units, and close contact with households and other members of the population who might be infected. This is coupled with poor health-seeking behaviour in the mining population (WHO, 2013). All these attributes are easily identifiable in the populated Osiri-Matanda mines with the potential to facilitate the spread of TB. There have however been poor TB screening and referral activities within this population to evaluate the extent of TB infections and their potential to spread among the residents. There is also the danger of the development and spread of multi-drug resistant (MDR) tuberculosis in this population given that this has been reported to occur at 2.2 in a thousand populations (WHO, 2020).

1.3 Justification

Osiri-Matanda mines being a highly populated area with very poor sanitation and with several other activities going on including mining itself and associated businesses, there is a possibility that an infectious disease such as tuberculosis will easily spread among the population. If not checked, this would have a negative health effect on the population in general by maintaining the TB epidemics despite the national and global efforts to reduce it.

This study is therefore necessary to evaluate if any member of the mining population has TB infection by carrying out an active TB screening. Through this, other community services such as health education, identification of CHEWS and peer educators, as well as contact referrals and treatment would be established to support

the population moving forward. The data on demographics used alongside the laboratory results will give a clear picture of who is infected and further disaggregate it to age, sex, household numbers, and occupation. The analysis of these would help determine the risk of infection from any one positive case and help target TB intervention approaches to specific cohorts of the population whose risk shall have been determined.

It is expected that the outcome of this study will benefit Nyatike Sub County by offering an opportunity for the miners to know their TB status and get treatment where necessary. It will also be an opportunity to sensitise health workers on raising clinical suspicion when handling presumed TB patients and go beyond the hospital setup to identify most at-risk persons (MARPs) when it comes to TB infections. The outcome will also help reshape the county TB program, in general, to include frequent expanded and targeted active case-finding programs in overcrowded areas such as mines, fish *bandas*, and schools.

1.4 Null Hypothesis

There is no active TB infection among the mining population of Osiri-Matanda mines

1.5 Research Questions

1. What is the proportion of drug-susceptible and drug-resistant TB infections identified in the mining population of Osiri-Matanda mines?
2. What are the factors associated with TB among the miners at Osiri-Matanda gold mines?
3. What is the proportion of TB-HIV co-infections at Osiri-Matanda gold mines?

1.6 Objectives

1.7 Main Objective

To evaluate the proportion of active TB infections and HIV co-infection among the mine workers of Osiri-Matanda gold mines in Nyatike Sub-County, Migori County

1.8. Specific Objectives

1. To determine the proportion of the population with drug-susceptible and drug-resistant TB at Osiri-Matanda gold mines
2. To determine the factors associated with TB among the miners at Osiri-Matanda gold mines.
3. To evaluate the state of TB-HIV co-infection among the miners at Osiri-Matanda gold mines

CHAPTER TWO

LITERATURE REVIEW

2.1 Theoretical Framework

Tuberculosis disease prevalence refers to the number of people infected with TB in a population at a specific point in time. The risk of TB infection is varied and it concerns those factors that make someone vulnerable to TB infection than if the said factors were eliminated. There are people who by nature of their work, behavioural practices and social status are more prone to tuberculosis infections than everyone else. Scientifically, these people possess a varied degree of factors that make it easier to contract TB infection. The risk factors for tuberculosis disease are varied depending on the population of the study. Studies have identified the specific factors that facilitate TB infections and spread to include among others, contact with the infected person, alcohol and drug abuse as well as certain disease conditions such as diabetes and cancers (WHO, 2018; Khan et al., 2019). Other studies have published articles suggesting that the healthcare profession is a risk factor for TB (Kumar et al., 2019). Lately, researchers have discovered that the COVID-19 pandemic boosts TB infections and spread because of the refocusing of resources as the world works to overcome the pandemic. This has resulted in reduced case identification and clinic attendance with a resultant increase in TB deaths (Migliori et al., 2021). Since not much data is currently available on the TB-Covid-19 co-infection, the outcome of the previous tuberculosis-influenza co-infection has been inferred to the current pandemic. In this regard, it is also hypothesised that more fatalities are likely in such co-infections compared to when it's only TB infection (Yang et al., 2020).

Drug-resistant TB refers to tuberculosis-causing organisms resistant to the antibiotics normally used in its treatment. There are various forms of resistance exhibited to TB drugs by some strains of Mycobacterium tuberculosis. These include mono-resistance, whereby the strain of bacilli does not respond to treatment from one first-line anti-TB drug, usually Rifampicin or Isoniazid. Apart from resistance to either isoniazid or rifampicin, an individual can also be resistant to either pyrazinamide or Ethambutol and streptomycin. This is known as poly-resistance (Seung et al., 2015).

The Mycobacterium tuberculosis organism that does not respond to treatment with any of the first-line and second-line anti-TB regimens has been discovered and designated MDR-TB. There occurs also a variant that does not respond to treatment with both isoniazid and rifampicin, any fluoroquinolone, and at least one of the group A drugs, and this is called extensively drug-resistant TB (XDR-TB). Group A drugs include bedaquiline and linezolid (Mase et al., 2019)

Rifampicin resistance (RR) is a type of resistance to rifampicin only and is detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs (Prasad et al., 2018; WHO, 2018). It includes any resistance to rifampicin, in the form of mono-resistance, poly-resistance, MDR, or XDR (Mase et al., 2019; WHO, 2018).

2.2 Conceptual Framework

Tuberculosis infections spread from person to person in a population where an individual is already infected with the disease. There are key determinants to successful infection, some of which include poverty, overcrowding situations, poor ventilation as well as one's immunity status at the time of exposure. Any susceptible individual who contracts the disease is likely to maintain the infection cycle as long as they keep coming into contact with other susceptible individuals within the community. This spread is irrespective of whether the TB is drug-resistant or drug-susceptible type. Those with strong immunity are likely to remain uninfected even after getting in contact with the infected person. The **figure 2.1** below illustrates the conceptual framework for this hypothesis;

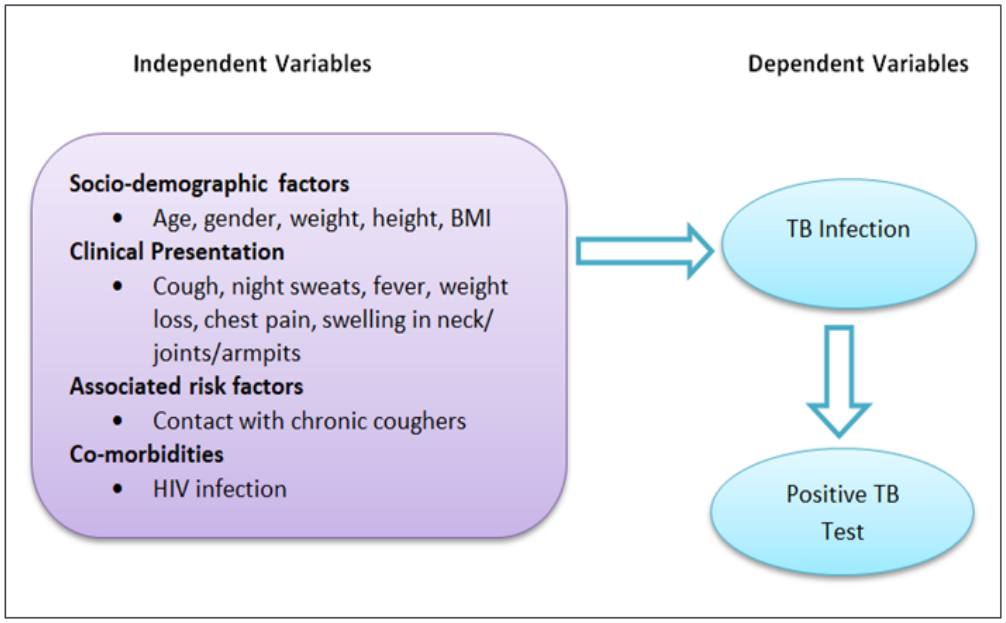

Figure 2.1: Tuberculosis (TB) Transmission Conceptual Framework

2.2.1 Mycobacterium Tuberculosis

Mycobacterium tuberculosis is an acid-fast bacterium, usually bacilli in morphology, which causes the disease tuberculosis in humans. Unlike most other bacteria, its cell wall is made of mycolic acids, which are oriented perpendicular to the plane of the membrane and act as a virulence factor for this organism (Brennan, 2003). This mycolic acid promotes infection and penetration of tissues of the body, primarily the lung where it is domiciled, and causes pulmonary TB (PTB). It can also spread to other parts of the body other than the lungs, and cause what is known as extra-pulmonary TB (EPTB).

2.2.2 Transmission and Pathogenesis

The bacillus is transmitted through cough droplets that are passed from one person to another (Mandal et al., 2023). These aerosol droplets are generated through coughing, laughing, talking, sneezing, singing, and spitting from someone who has TB and is more pronounced in those with smear-positive TB than in smear-negative cases (WHO, 2018).

TB infections occur as a result of exposure to infectious cases of TB. This is determined by several factors including the existence of smear-positive cases in the population, socio-economic activities that facilitate crowding like in marketplaces and mines, poverty, population density in general as well as lack of access to treatment, cigarette smoking, alcohol abuse and other co-morbidities such as diabetes. Being male has also been listed as a risk factor for tuberculosis infection (Muttamba et al., 2019). Upon exposure to the TB bacilli, several factors determine if one will get infected or not. These include the quantity of the bacilli inhaled, smear positivity, how close one is to the index patient, and the amount of time taken near the patient as well as many other environmental factors, some of which are known to act as sterilizing agents for TB. The figure below (Fig. 2.2) shows the pathway for determining infectiousness of TB based on the traditional skin test outcome among the overall exposed group.

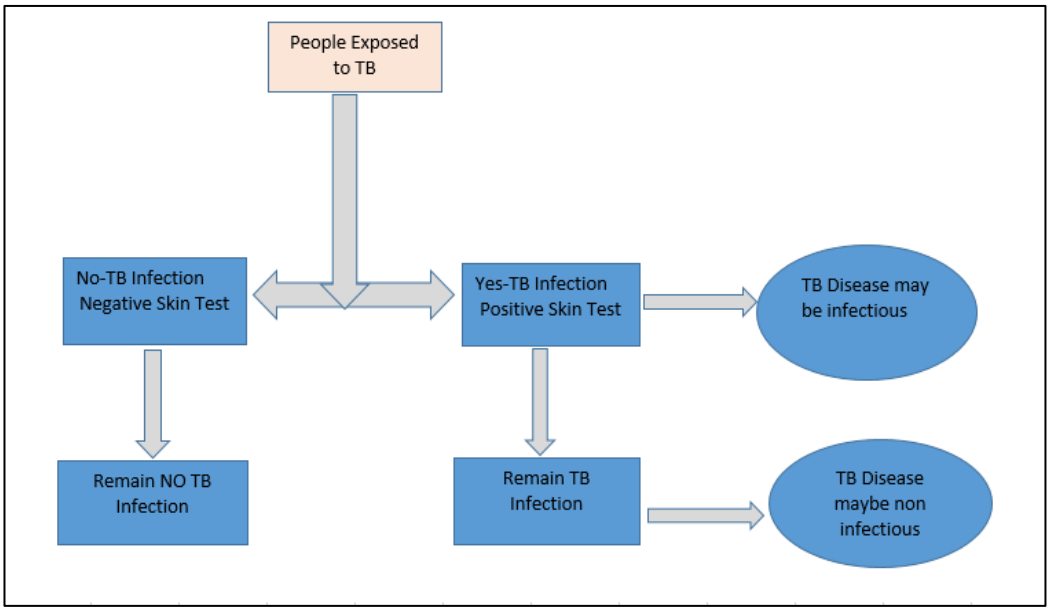

Figure 2.2: Flow Diagram (Determining Infectiousness of TB)

2.2.3 Prevalence

Apart from HIV/AIDS, TB plays an integral part in yearly mortality among those infected. While fatalities from other infectious agents largely occur due to co-morbidities, fatalities from TB as a single infectious agent still rank highest globally

(WHO, 2020). About 1.4 million people are estimated to have died in 2019 due to TB disease from a total of 10 million infections with about 208,000 of the deaths reported from those co-infected with HIV (WHO, 2020). This is a slight decrease in TB-related deaths that was reported in 2018, where, from an estimated 10 million infections, about 1.45 million deaths were reported (WHO, 2019). TB infections in adult men are slightly higher than in females, accounting for 56% and 57% of the total TB infections in 2018 and 2019 respectively (WHO, 2019; WHO, 2020). In 2017, 64% of the infections were among males while 36% were females (WHO, 2018). The TB-HIV co-infection constituted 9% of all TB case reports in 2017, with about 72% of these occurring in Africa (Masenga et al., 2017). Globally, India has the greatest number of TB-HIV co-infection with 27% reported in 2017, while China comes second at 9%, Indonesia at 8%, Philippines at 6%, and Pakistan at 5%. In Africa, Nigeria and South Africa are among the leading countries in terms of TB-HIV case reports at 4% and 3% respectively of the world prevalence (WHO, 2018). Another co-morbidity that is associated with TB and presents considerable challenges in management is diabetes mellitus (Noubiap, 2019). It is therefore advised that the magnitude of the association of risk be determined at local and country levels before a conclusion can be made on integrated programming for the diabetes mellitus-tuberculosis services (Workneh et al., 2017)

Occupation is a key factor in the spread of TB in the workplace and the spread is varied but more pronounced in occupations that involve close contact with the general or risk population (Semilan et al., 2021). The droplets would easily spread in enclosed setups than they would in open places where they are easily carried away by the wind. This spread is more pronounced in smear-positive TB patients than smear-negative TB patients (Warria et al., 2020).

South Africa has reported a TB burden of up to 7% among the miners (Ndlovu et al., 2018). This puts the country top of the world in terms of TB incidence among the mining communities (WHO, 2013). Mining has also been listed as a key determinant of TB infections in Sub-Saharan Africa This is not only associated with sanitation challenges in these mines and the failure to seek treatment for any ill health but also

the dust that originates from the mines themselves. Reduction of this dust is known to equally reduce the number of TB infections (Stuckler et al., 2011).

Despite the morbidity and mortality recorded, the worldwide TB incidence is reported to be reducing gradually over time, with at least 2% per year. The most notable decline was recorded between 2013 and 2017 (WHO, 2018). The WHO European region recorded the highest decline between these times at 5% per year followed by the WHO African region at 4% per year (WHO, 2018). The southern Africa region and the Russian Federation reported an impressive decline compared to other regions. This period coincides with the peak in HIV epidemics that resulted in more intense case finding for both HIV and TB infections and the establishment and expansion of prevention and control measures, which seem to have borne fruits (WHO, 2017; WHO, 2018). This reduction was however reversed by the Covid-19 pandemic that shifted the global focus and funding from the year 2020. This affected the number of new diagnoses by about -18% between 2019 (7.1 million) and 2020 (5.8 million). The recovery is promising but slow, with about 6.4 million reported in 2021 (WHO, 2022). This reduction in case identification translates to more TB deaths and community transmissions. About 1.6 million deaths were reported in 2021 from 1.4 million in 2019 (WHO, 2022)

The World Health Organization established an ambitious program known as the Global End TB strategy, with the overall aim of reducing the case fatality ratio (CFR) to 10% in order to achieve the first milestone in fighting TB infections (WHO, 2015). There is however a considerable variation in CFR per country, with the WHO African Region recording as high as 20% while some regions record as low as 5%. This variation is attributable to poverty levels that hinder the establishment of proper diagnostic and treatment programs. The **figure 2.3** below shows the estimated global TB prevalence as of 2019 (WHO, 2020).

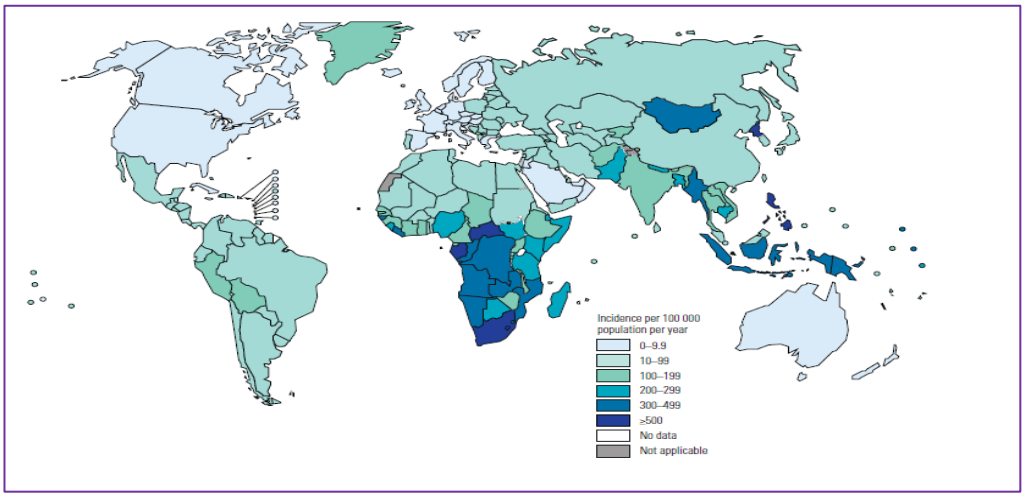

Figure 2.3: Estimated Global TB Incidence Rates

Source: (WHO, 2020)

As in other parts of the world, TB is still a major public health problem in Kenya, putting it among the 30 high-burden countries. A vast majority of TB infections in Kenya are missed due to poor health-seeking behaviour in some sections of its population (Enos et al., 2018). This means only those who turn up at the health facilities are screened, identified, and put on treatment. In 2017, 85,188 TB case reports were done, 84% being pulmonary TB cases, with 67% being bacteriologically confirmed. Only 4% of the TB patients identified were of unknown HIV status at the time of TB identification. 22,992 (29%) patients were known HIV-positive patients at the time of TB diagnosis, with 95% already on Anti-Retroviral Therapy (ART) (WHO, 2018). In 2019, the National Tuberculosis, Leprosy and Lung Disease Program (NTLD) estimated about 147,000 people have suffered from TB disease in Kenya. Out of these, only 86,385 were correctly diagnosed and treated (NTLD, 2019). This translates to a marginal decline in cases reported in 2018, being 156,000 with a case notification rate of 62% (96,478) (NTLD, 2018). In both cases, men remain the most affected with 65% and 64% cases in 2019 and 2018 respectively (NTLD, 2018; NTLD, 2019). The figure below (**Fig. 2.4)** represents the national TB incidence between 2000 and 2018 (NTLD, 2018).

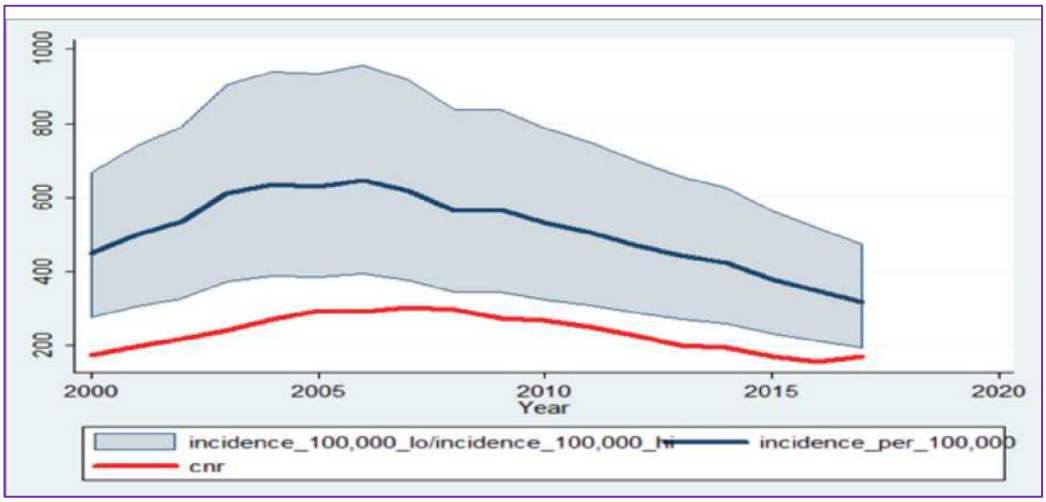

Figure 2.4: Kenya Tuberculosis Incidence (2000-2018)

Source: (NTLD, 2019)

Like the rest of the world, the COVID-19 pandemic seems to have eroded the earlier gains in the fight against TB. It is reported that some 90,841 TB infections were diagnosed in 2022 compared to 77,854 in 2021. However, this is just about 68% of the total estimated TB cases, meaning 32% remain undiagnosed and unaccounted for, with about 756 drug-resistant cases, largely in rural areas (NTLD, 2021)

The prevalence of TB per county is dependent on accurate reporting by the counties to the national platform. Migori County consistently remained among the top ten counties that contributed more than half of the national TB cases between 2012 and 2016 (**figure 2.5**) (NTLD, 2017).

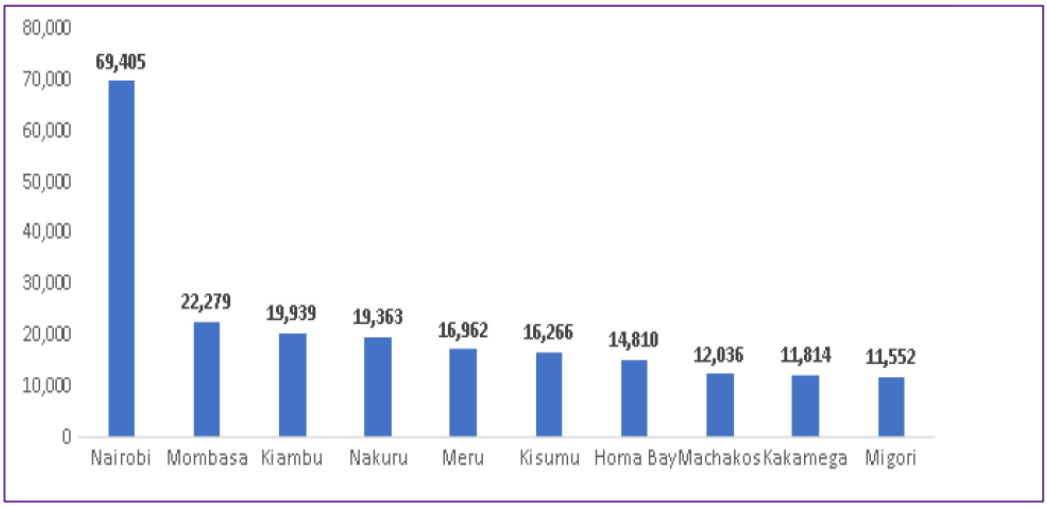

Figure 2.5: Top-10 Counties that Contributed Half of TB Infections in Kenya (2012-2016)

Source: (NTLD, 2017)

Similarly, the county was among the top ten counties that contributed up to 62% of annual TB deaths over the same period of 2012-216 (NTLD, 2017). The following **figure 2.6** indicates a disaggregation of TB-related deaths for priority counties in Kenya between 2012 and 2016.

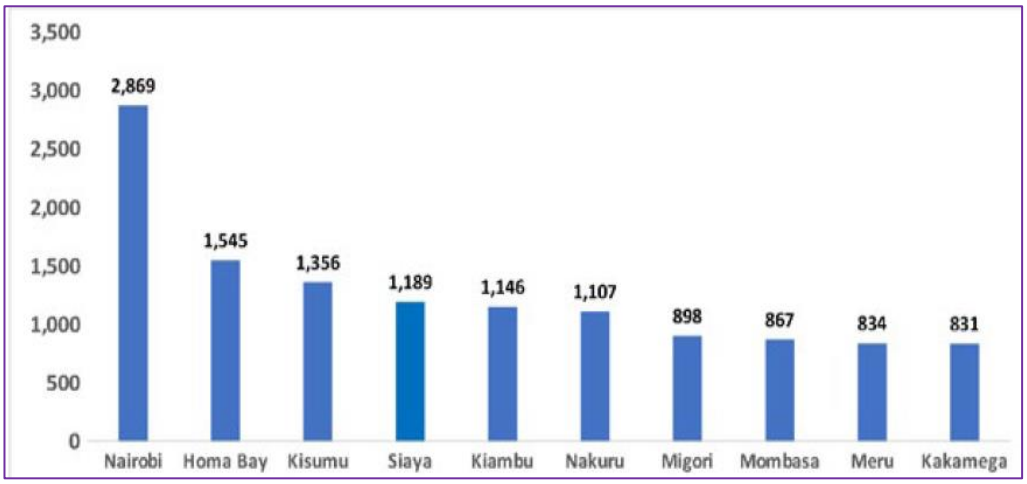

Figure 2.6: Top-10 Counties that Contributed Half of TB Deaths (2012-2016)

Source: (NTLD, 2017)

2.2.4 Drug Resistance Trends

The epidemic trends exhibited by TB are varied and diverse. In 2017 for example, there were fewer than 10 new cases for every 100,000 persons in most high-income countries, 150-400 in the majority of the countries considered among the top 30 in terms of TB infections, and more than 500 in several countries including Mozambique, the Philippines and South Africa. Across the world in 2017, 558 000 new cases (483 000-639 000) of rifampicin-resistant TB (RR-TB) were reported, half of which came from just three countries: India (24%), China (13%) and the Russian Federation (10%).

Among RR-TB cases, an estimated 82% had MDR-TB (WHO, 2018). MDR-TB and RR-TB were detected in about 3.5% and 18% of new patients and relapse patients respectively, with the most noteworthy proportions, about half, in nations of the previous Soviet Union (WHO, 2018). Kenya is still a priority country in both drug-sensitive and drug-resistant tuberculosis (DR-TB). In 2019, 2170 are estimated to have suffered DR-TB in Kenya, with a poor notification rate of only 32% (692) (NTLD, 2019).

2.2.5 Mechanisms of TB Drug Resistance

Like other drug-resistant organisms, TB drug resistance is associated with target mutations of specific drug targets. In all cases of MDR and XDR-TB, point mutations have been detected at *katG S315 T* as well as a combination of *katG N138H* and *ahpC t-76a* targets. Rifampicin mono resistance is associated with mutations at *the rpoB*hot-spot region (S450 L mutation). Apart from the mutational modifications of drug targets, the multi-drug efflux system also plays a role in the TB drug resistance mechanism, the pump genes being embedded in the organism at the chromosomal level. The genes that are overexpressed in drug-resistant cases include *Rv1250, Rv876, Rv3239, Rv2459, Rv2456, Rv2846 and* Rv*2938.* (Ghajavand et al., 2019; Vaziri et al., 2019).

2.2.6 End TB Strategy

The World Health Organization developed a policy document titled End TB Strategy (WHO, 2015) that outlines three pillars geared toward the prevention, diagnosis, and treatment of TB. This document summarises the components as follows;

Pillar 1 of the End TB Strategy; Integrated, Patient-centred Care and Prevention

This pillar targets early identification of TB through various testing strategies that include laboratory testing as well as clinical screening of presumed TB patients. It also includes the universal Drug Sensitivity Test (DST) that supports the identification of suspected resistant TB cases. The screening under this pillar goes as far as to include contacts of high-risk groups and treatment of all identified cases depending on their rifampicin resistance test outcomes as well as any other co-morbidity identified in the process. All those who are at risk of TB but are negative at this stage are offered preventive treatment known as Isoniazid Preventive Therapy (IPT) (WHO, 2015*).*

Pillar 2 of the End TB Strategy; Bold Policies and Supportive Systems

The second pillar seeks to enhance political commitment and resource mobilization and allocation towards TB prevention. It also focuses on mobilizing communities and civil society organizations to fight TB and encourages public-private partnerships in the provision of universal health care. (WHO, 2015; WHO, 2018).

Pillar 3 of the End TB Strategy; Intensified Research and Innovation

The third pillar of the end TB strategy encourages innovations toward TB prevention, care and treatment, and specifically focuses on the discovery and use of new diagnostic, therapeutic, and follow-up tools (WHO, 2015).

2.3 TB Diagnosis in Kenya

There are various ways through which Laboratory TB diagnosis can be achieved. Key among these include GeneXpert testing, smear microscopy (ZN staining, Auramine O staining), and Sputum culture. The most current method is the assay of a

lipoarabinomannan (LAM), a glycolipid on the cell wall of the Mycobacterium tuberculosis that normally finds its way into urine via the kidney in active TB infections. The lab diagnosis comes after a clinical diagnosis, normally done by the clinician at the encounter with the client using the TB Intensive Case Finding (ICF) form. This is a set of structured questions that seek to establish if the client has had any of the universal signs consistent with TB disease, key among them being cough of any duration, fever, unexplained weight loss, and night sweats. Any 'YES' response in this tool is an indication of possible TB infection and is used as a basis for seeking further testing of the patient to rule out TB. (**See Appendix VII for the ICF form**).

2.3.1 Sample Collection for TB Diagnosis

Sputum is the main sample for diagnosis of pulmonary TB. Patients are normally instructed on sputum collection and if followed, a proper diagnosis should be the result from whichever sample produced. A spot sputum sample would normally contain saliva except for chronic coughers and the patients should be advised on how to collect this sample for maximum yield. Studies have found salivary samples more appropriate for pulmonary TB diagnosis compared to blood in cases where only the two are feasible (Yoshizawa et al., 2013). Aspirates from various extrapulmonary body sites suspected to be infected with TB including lymph nodes can also be used for diagnosis of extra-pulmonary tuberculosis. Urine is also used currently in the case of TB-LAM.

2.3.2 GeneXpert Test

GeneXpert, also known as Xpert® MTB/RIF assay or simply GeneXpert testing is a nucleic acid amplification technique currently employed in TB diagnosis. Unlike smear microscopy, GeneXpert has the advantage of detecting both the presence of *Mycobacterium tuberculosis* bacilli as well as Rifampicin resistance (RR). Hence this provides a quick diagnosis to enable treatment initiation, which is paramount in TB control and prevention (WHO, 2014).

GeneXpert testing is done in the background of a comprehensive algorithm that describes steps followed throughout the process of TB diagnosis. In Kenya, GeneXpert was initially recommended for TB diagnosis in all HIV-positive patients who present

with signs associated with TB, children under 15 years with TB symptoms, and all smear-negative TB symptomatic patients. It is also applied for testing all previously treated patients including possible TB relapse cases, treatment failure, patients who are returning to TB treatment after loss to follow-up (LTFU), DR-TB contacts, healthcare workers who exhibit TB symptoms, patients who develop active TB while on Isoniazid Preventive Therapy (IPT), refugees, prisoners and those whose sputum sample smears remains positive after two months of treatment. However, due to surging numbers of rifampicin-resistant cases, GeneXpert is now the preferred first test for TB (NTLD, 2021). Follow-up microscopy testing is done for all patients on treatment regardless of the method for initial diagnosis.

2.3.3 Smear Microscopy

Smears are made from sputum samples collected on the spot as well as early morning. The smears are stained either by Ziel-Neelsen (Z-N) stains for bright-field microscopy, or Auramine O stain for Fluorescence microscopy (FM), alongside known positive and negative slides as controls. Although the Z-N technique is widely used, fluorescence microscopy is slowly gaining preference because of the precision, increased sensitivity, and clarity by which the bacilli appear under a fluorescent light light-emitting diode (LED) microscope. The **figure 2.7** illustrates the optical difference between bright-field microscopy for Z-N stained smears and the Auramine O stained Fluorescent microscopy.

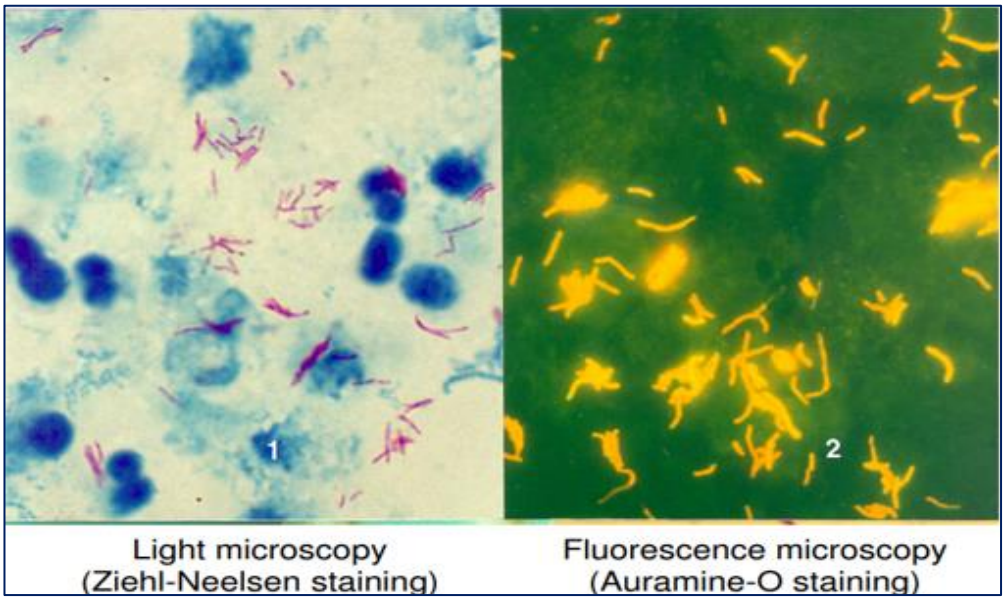

Figure 2.7: Optical Difference between Bright-Field and Fluorescence Microscopy

2.3.4 Determine™ TB LAM Antigen Test

This test uses an Abbott lateral flow test kit to diagnose TB in urine samples. This has been recommended and used on those who are immune-compromised to enhance early diagnosis and treatment (Mathabire et al., 2019). This, however, is confirmed with GeneXpert since LAM antigen is present in other mycobacteria as well. The **figure 2.8** is the Abbott Determine™ lateral flow assay kit used for the TB-LAM antigen test.

2.3.5 Mycobacterium Tuberculosis Culture

A sputum culture can be done to diagnose TB. It can also include inoculation of other specimen such as urine, blood, tissue aspirates, or cerebrospinal fluid (CSF) on a suitable enriched media followed by incubation at a suitable temperature. The colonial morphology and ability to grow in certain media distinguishes the tubercle bacilli from other bacteria. The media for TB cultivation include Lowenstein-Jensen (LJ) media, American Trudeau Society (ATS), and Middlebrook 7H10 media among others. The most current development in TB culture technique is the introduction of Mycobacteria Growth Indicator Tube (MGIT), a form of broth media that combines the primary culture components with the drug sensitivity testing (DST) option in one inoculation

and incubation. This has the advantage of reducing the time taken to achieve full growth and sensitivity testing to about 7-14 days compared to the traditional culture method that would be incubated for up to 21 days before DST could commence.

Tubercle bacilli is a fastidious organism and very difficult and expensive to grow. Hence culture is not a routine method applied in its diagnosis and is only preferred in drug sensitivity testing for resistant strains detected by GeneXpert test.

Figure 2.8: Abbott Determine^{TM} TB LAM Ag Test Kit

2.4 Prevention and treatment of TB Infection

Despite its seemingly high morbidity and mortality, TB remains preventable and treatable, save for the challenges posed by its drug-resistant variants. Strict adherence to cough etiquette is key for personal TB prevention, as so is avoidance of overcrowding areas where the infection can easily be transmitted from one person to another.

2.4.1 Isoniazid Preventive Therapy (IPT)

Isoniazid is an effective TB prevention regimen especially for persons living with HIV (Semu et al., 2017). A six-month course of isoniazid daily prevents the development of active TB in HIV-infected persons with the benefit lasting up to two years. Several tests, including laboratory-based and clinical, must first be done to completely rule out any active TB before administering IPT to any patient. If not done, there's the potential of patients developing DR-TB due to unintended Isoniazid mono-therapy.

2.4.2 Treatment and Patient Care

The WHO made key recommendations on TB treatment, which is periodically revised and updated by a team of experts to align it to the current trends of TB disease susceptibility. Such updates are shared with member countries to guide in the choice of regimes for each confirmed TB (WHO, 2017). The WHO member countries use these to develop their country-specific guidelines for TB treatment. Kenya assimilates this in its guidelines, with the revisions communicated by official circulars as captured in its strategic plan (NTLD, 2019). Currently, for all drug-susceptible TB (DS-TB), WHO recommends a six-month treatment course consisting of 4 first-line drugs such as Isoniazid (H), Rifampicin (R), Pyrazinamide (Z) and Ethambutol (E) for two months, followed by Isoniazid and Rifampicin (HR) for 4 months. These drugs are taken daily. The combination for this regimen is designated 2HRZE/4HR (WHO, 2021). However, for TB-HIV co-infection, antiretroviral therapy (ART) is administered to these patients regardless of their CD4 count. There has been a lot of success in managing TB-HIV co-infection provided the patient adheres to the treatment regimen (Tiberi et al., 2017). Treatment for TB is initiated first, followed by ART within 2-8 weeks depending on the level of immunosuppression

There is a complexity of TB infection that generally does not respond to normal TB treatment regimen. This is referred to as multi-drug resistant TB (MDR-TB). This requires a combination of four drugs whose effectiveness would be felt in 6 months and three drugs thereafter for the duration of the treatment. Generally, treatment of MDR-TB would last 18-24 months. Previously, injection of Kanamycin and Capreomycin was preferred as part of the regimen. However, that changed, and of late

oral regimens are used instead (Mase et al., 2019). This can further be complicated when the patient is resistant to rifampicin, and maybe isoniazid too, and also resistant to any of the fluoroquinolone and any one group A drugs. In this case the TB is referred to as extensively drug-resistant TB (XDR-TB) (Chakaya et al., 2021; WHO, 2022).

Generally, TB infections remain treatable in most cases, and the complexity depends on the type of TB. About 50% deaths are incurred from untreated TB disease, and about 85% cure rate is possible from people correctly using the regimens described above. The concept of Universal Health Coverage (UHC) is necessary to bridge the gap of poverty and ensure each individual can access these treatments regardless of their settings (WHO, 2022).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

The study was carried out in Osiri-Matanda gold mines in Nyatike sub-county, Migori County. Migori is a county in the former Nyanza Province of south-western Kenya, lying at Latitude 0O 39' 59.99"N, and Longitude 34O49' 59.99"E. The county covers an area of 2,597 square kilometers. It borders Homa Bay to the North, the Republic of Tanzania to the South and South West, Kisii to the North East, Narok to the East and North East, and Lake Victoria to the West. The figure below (**Fig. 3.1)** shows the map of Migori County and the location of some of the mining sites.

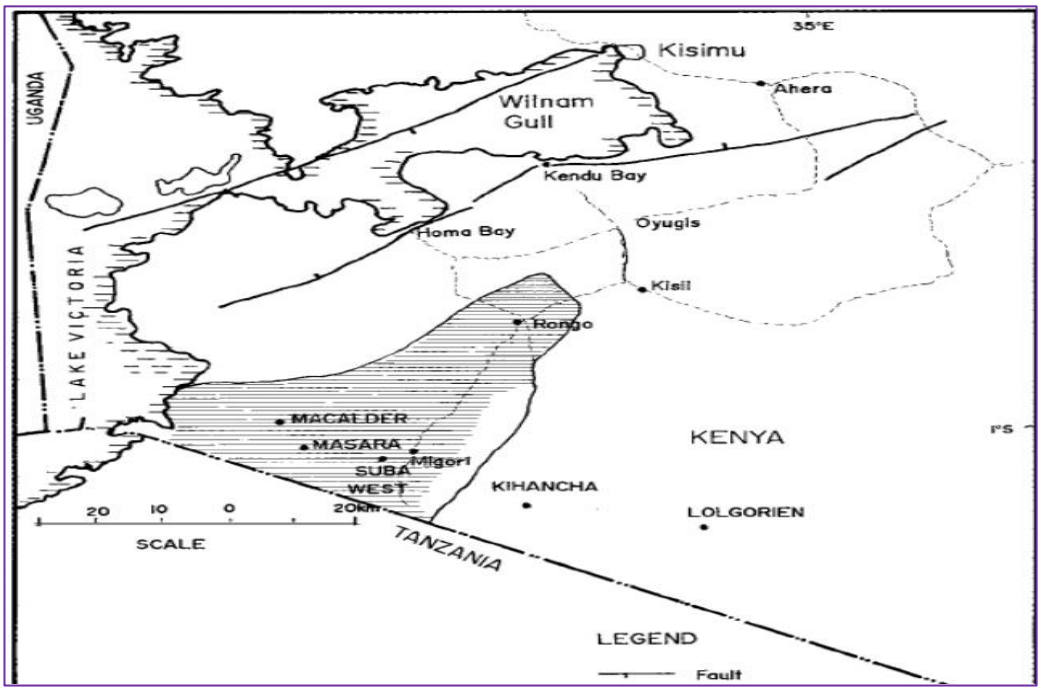

Figure 3.1: A Map Showing the Location of Migori and some of its Mining Sites

The county has a population density of 355 per square kilometer and the poverty level is estimated at 43% as of the year 2013. Its capital is Migori, which is its largest town. The county has eight sub-counties; Kuria East, Kuria West, Suna East, Suna West, Awendo, Rongo, Uriri, and Nyatike.

Osiri-Matanda is a fairly small market center located in Nyatike Sub County, Macalder division, about 30 kilometers from Migori town. The center is cosmopolitan, consisting of people from various regions of Kenya and beyond. Majority of the inhabitants are from Nyanza, Western, and Rift Valley regions. They are mainly in the area because of the gold mining activities and associated businesses. The main economic activity is the gold mine itself, but small business enterprises exist including fish trading, open-air food and cloth market, and various retail shops. Part of this population also does farming, mainly subsistence maize crop farming as well as small-scale tobacco farming. The gold-related activities involve several people going down the gold tunnels to dig for the mineral. Others, mainly women, wait outside the mining wells to extract the gold using mercury. Not much has been documented about Osiri-Matanda and the gold mines in terms of tuberculosis and other diseases. However, because of the risk of gold mining activity, a lot of information has been made available concerning frequent accidents and the effects of chemicals used in gold processing in the area. The mines are basically artisanal but the yields are processed and sold to specific businessmen. The crude nature of mining in this over 70-year-old gold mine has occasioned several accidental collapses of the mines and has resulted in casualties in each instance. These are normally reported in local daily newspapers (Odeny, 2020)

Apart from the accidents, severe effects of mercury used in gold extraction have been reported in some of the workers. Mercury is known to damage the nervous, digestive, and immune systems and poison the lungs, kidneys, skin, and eyes (Paduraru et al., 2022). Unfortunately, levels of more than one part per million were reported in some of some mine workers by the International Pollutants Elimination Network (IPEN) and exceeded the recommended levels. The government of Kenya is putting up legal mechanisms required in its plan to out-law the use of mercury in the mining sub-sector because of the documented effects including birth defects (Muchira et al., 2020).

Migori County has about 226 health facilities, with 7 sub-county hospitals and one county referral hospital. Macalder sub-county hospital is the closest of these to the Osiri-Matanda mines. It lies within Macalder Sub County, with the health facility laboratory serving as the sub-county's only referral facility for GeneXpert sample

testing from across 45 health facilities. Due to its proximity to the Osiri-Matanda mines, it is expected that the Macalder sub-county hospital would be the main health resource center for the mine workers in this area.

3.2 Study Design

A cross-sectional prospective study design was used to evaluate the TB infection and disease burden in the population. Smear microscopy gave results for MTB infection, while GeneXpert testing gave results for rifampicin resistance. All rifampicin-resistant samples were further to be analysed for multi-drug resistance (MDR) to facilitate proper patient management.

3.3 Study Population

The study was carried out among persons of 15 years and above and mature minors who were living in the Osiri-Matanda mining area at the time of the study. The participants were sampled and enrolled in the study based on the inclusion criteria described. Those eligible and consented to the study equally had their sputum samples taken and transported to the Macalder sub-county hospital laboratory for TB analysis.

3.4 Inclusion Criteria

The study included;

1. All clients living or working within the study area at the time of the study and giving consent to be enrolled in the study.
2. All participants from 15 years old and above.
3. All clients on TB treatment at the time of the study were also included in the study and formed part of the final prevalence data. However, they were not eligible for sample collection since they already tested positive and were on the government-approved treatment plan with timelines for follow-up testing.

3.5 Exclusion Criteria

The study excluded;

1. Those between 15-17 years who were not mature minors and not accompanied by parents for assent

However, all those who were excluded equally gained from TB and general health information that was given by the healthcare workers.

3.6 Sample Size Determination

Adequate sample size was determined using the modified Cochran's formula for small populations (Cochran, 1977)

Where;

n is the sample size,
no is the random sample to be picked from the population
N is the population size

Assuming a prevalence (p) of 0.5%, margin of error (e) of 0.05, and confidence level of 95% (z-1.96). Then taking q =1-p, and the formula;

$$= (1.96)2(0.5)\ (0.5)/\ (0.05)2$$

$$=385$$

Therefore,

no =385, and the population (N) estimated to be 2000, the sample size (n) was determined as follows;

$$\mathbf{n} = 385/\ \{1+(385-1)/2000\}$$
$$\mathbf{n} = 322.85$$
$$\mathbf{n} = 323$$

Therefore, from this population, estimated to be about 2000, a total of 323 participants were to take part in the study.

3.7 Selection Procedure for Eligible Participants

Consent forms and a questionnaire (TB Risk Assessment form) were administered to clients who chose to take part in the study. All participants who were 18 years and above were given information about the study and when they chose to participate, they gave their signatures as consent for the same and the consenting staff signed the form too. The mature minors between 15-17 years were also allowed to give their consent. However, parental assent was needed for any participant between 15 and 17 years and those who were not accompanied by the parents for assent were not included in the study.

3.8 Sampling Technique

Sputum samples were taken from participants who consented to participate within the period of the study. The consenting clients were screened and those eligible had their samples taken for laboratory analysis. All participants who met the inclusion criteria were eligible for sputum sample collection except those who declined as well as those already on treatment. Sample labelling was done as per the normal serialization used within the lab for AFB microscopy and GeneXpert samples. Other participants-identifying details were picked from the lab requisition forms filled out by the clinician.

3.9 Sample Collection and Transportation

Each eligible participant was given a brief instruction detailing the procedure for sputum sample collection, the quantities required, and the timelines for delivering this. Each participant was given a sputum mug and a falcon tube for sample collection. The participant was asked to sit under shade and relax shortly before removing the sputum. Then inhale deeply a few times and cough from deep within the lungs. They then lean forward and inhale and exhale slowly two times while holding their breath for about 5 seconds each time, and a third time cough out forcefully to bring up sputum. This was

repeated severally in order to collect samples sufficient enough for the tests. The clients collected the samples during the very day to ensure the sample collection procedure was adhered to. The samples were received by a designated officer who then documented the details required and serialised the samples, then put them in designated cool boxes with ice packs and transported them to the laboratory for analysis. The receiving officer on the bench was a trained lab technologist familiar with the Ministry of Health (MOH) TB testing processes including microscopy and GeneXpert testing. Additionally, the officer underwent orientation on the specific requirements for this study.

3.10 Laboratory Techniques

3.10.1 Pre-analytical Procedures

Upon reception at the Macalder Hospital laboratory, gloves were used by the receiving officer, and samples were inspected for quality. Noted was the volume of samples, whether blood-stained, and whether muco-purulent or salivary sample. Smears were made from the samples in sputum mugs, dried, and heat-fixed ready for staining. And because time did not allow for making all the smears the same day, the remaining samples were stored overnight in the fridge at 2-8^{O}C, together with the GeneXpert samples yet to be analysed, and the smears made again the following day.

3.10.2 Smear Microscopy and Drug Resistance Testing

Sputum smear microscopy was done in the Macalder sub-county hospital laboratory on all the samples received in universal sputum mugs as well as the control slides. For all smear-positive samples (MTB positive), GeneXpert testing was done on the samples collected in falcon tubes for the same participants. Both tests were done as per the existing laboratory SOP available in the laboratory SOP file. (AFB Microscopy SOP; Cepheid Xpert ® MTB/RIF Assay, 2013). Results were documented and communicated back to the clients based on the method they chose in the questionnaire. For microscopy, the results were recorded as either AFB negative (0), or if positive, as an exact number, 1+, 2+, or 3+. For GeneXpert, any of the three results was expected. Those negative for MTB would be documented as 'MTB Not Detected', and in that

case, discordant with the initial microscopy results, and another sample would be sought as a tie-breaker. Those positive for MTB and sensitive to Rifampicin (MTB Pos/No RIF-R) were documented and contacted to seek treatment, where they were initiated on a 6-month non-DR-TB treatment regimen given to TB patients. Those who would have tested MTB positive and RIF resistant (MTB Pos/RIF-R) were to be contacted and followed up for another sample collection to facilitate further drug resistance analysis and management as per the MOH TB management guideline for suspected DR-TB. However, as seen later in the results, there was no RIF resistance detected, hence no sample was recollected for further MDR TB analysis. Drug resistance testing is normally done using the Mycobacteria Growth Indicator Tube (MGIT). An indeterminate result, normally a consequence of machine error or sample contamination, is usually corrected when a fresh sample is collected for a test re-run (Mwanza et al., 2018). This study also got no indeterminate result.

3.10.3 Rapid HIV Test

All participants who consented to the study were offered HIV testing and tested using the current national HIV Testing Service (HTS) algorithm developed by the National AIDS and STI Control Programme (NASCOP). In this algorithm, Alere DetermineTM HIV 1/2, a screening kit, was used to test finger-prick blood samples of all participants and those who were none-reactive were documented as negative. Those whose samples were reactive were confirmed using the First Response HIV 1-2.O Card test, a confirmatory test kit (NASCOP, 2015). There was no discordance detected between the screening and confirmatory test results, hence those who tested positive with the screening kit were truly confirmed by the confirmatory test kit. The figure below (**fig. 3.2)** is a flow diagram for the rapid HIV testing algorithm in Kenya.

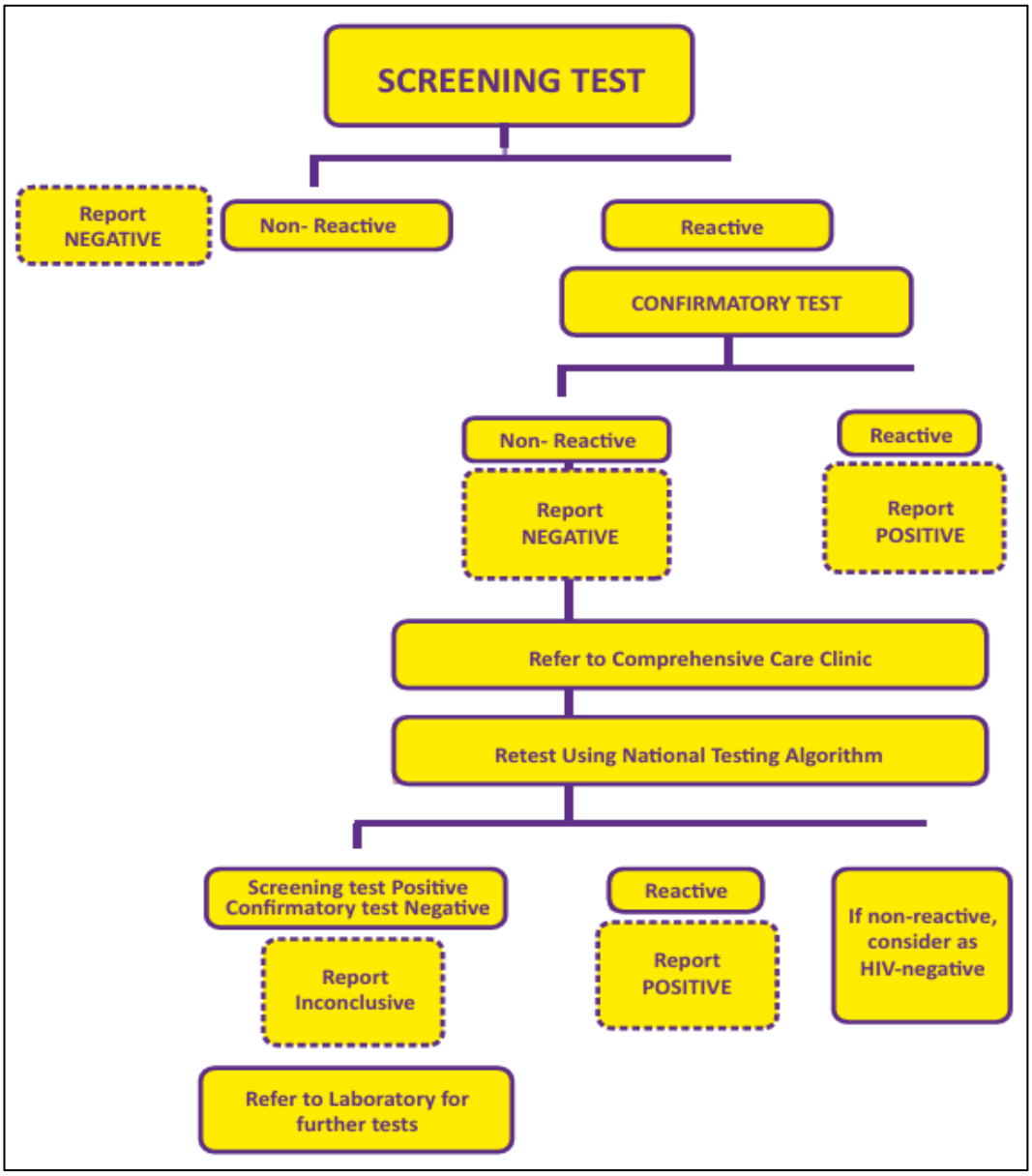

Figure 3.2: HIV Rapid Testing Algorithm

Source: (Adopted from Kenya National HTS Guidelines, 2015)

In order to better understand the procedures for this study, the figure 3.3 below summarises the analytical plan used for the study.

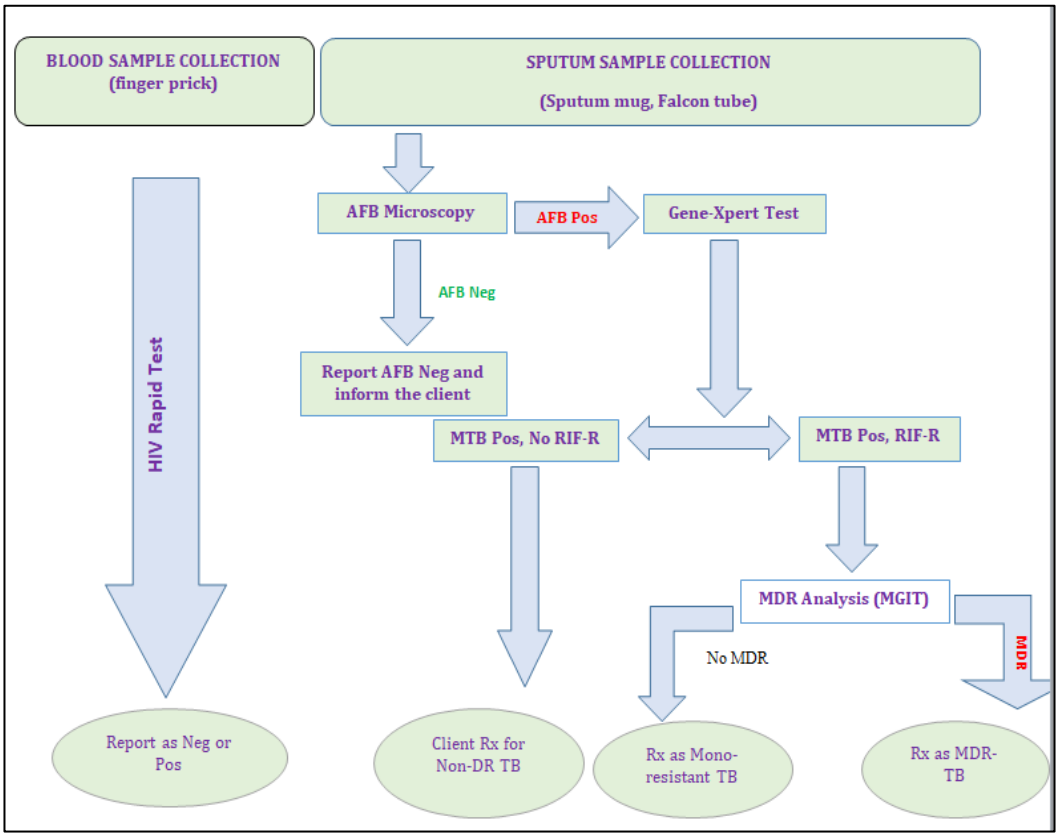

Figure 3.3: Study Analytical Plan

3.11 Data Collection Procedures

3.11.1 Ethical Consideration

Ethical approval for the study was obtained from the Masinde Muliro University of Science and Technology Institutional Ethics Review Committee (MMUST/IERC/172/2021). The study licensure was granted by the National Commission for Science, Technology and Innovation (NACOSTI). Before the commencement of data collection, study authorization was granted by the Board of Postgraduate Studies of JKUAT and the Migori County Health Management Team (CHMT). Research assistants were recruited and trained on the data collection methods and tools that ensure fairness to all participants without discrimination.

Tuberculosis disease is known to be stigmatising and as such several people testing positive for the disease suffer psychological harm. Outreach activity and the

consenting process was used to give clear information about TB including how it spreads and where various support services can be accessed in case one turns positive. The existing TB infrastructure at the health facility includes psychosocial and treatment counseling, both of which are geared towards reducing stigma while supporting the patients to cope with long-term treatment. The data collected was stored confidentially in electronic form as Excel sheets in a password-locked folder on a personal computer. These are all personal information from participants including testing outcomes. All testing results were only delivered via the method of choice preferred by the participants as per their responses to the study questionnaire.

Finally, except for the token given to the study clinician, laboratory technologists and the interviewer for their time in this study, there was no other provision for compensation to any of the study participants, and this was made clear to all during the consenting process.

3.11.2 Instruments for Data Collection

A TB Risk Assessment and Sampling Tool (**appendix VIII**) was used to capture the data for each participant. Except for the vital variables needed for analysis, patient identifying details such as name in this tool were kept confidential and were never used for data reporting.

3.11.3 Validity of Research Instruments

The research instruments were presented and discussed with three experts in the area of public health and biological sciences for review and scrutiny and their suggestions were included in the revised draft.

3.11.4 Data Collection and Analysis

Sensitive data on TB status and drug resistance outcomes was anticipated from this study. These were analysed in accordance with the objectives. Quantitative data were analysed using both descriptive and inferential statistics. Qualitative data was transcribed into categories and themes as they emerged.

3.11.5 Data Presentation

The final data from this study was presented in distribution frequency tables, percentages, pie charts, histograms and graphs.

3.11.6 Potential Limitations and Biases

Interviewer bias occurs due to the perception and presentation of the interview questions by the interviewer. This study dealt with this bias by relying on only one interviewer for the duration of the study, thus ensuring the same questions were directed in the same fashion to all participants. Recall bias is also a possibility especially when seeking information on previous TB exposure and treatment as it was expected that not all previous TB patients would correctly identify it was TB they were treated for. Correct and detailed TB information was relayed to the participants including signs and symptoms, treatment course and duration, and the type of drugs used by the patients to enable them to conclude if their previous treatment was TB or otherwise. Also anticipated was transfer bias especially by potential loss to follow up when seeking additional samples for MDR testing. However, the questionnaire had rigorous contact information including physical contact that would help in tracing any potential loss to follow-up, hence eliminating this bias. There is also an existing defaulter management program currently implemented by the HIV care and treatment partner in the county.

A potential limitation due to non-response error as a result of the busy schedule of those getting to the mining tunnels was also anticipated. Any low response rate would mean the results would only apply to the participants and not to the general population. To have balanced coverage in the participant enrolment, mobilization drives were conducted preceding an integrated outreach activity and these were used these to sensitise the potential participants on the importance of their participation.

CHAPTER FOUR

RESULTS

4.1 Results

4.1.1 Demographic Characteristics of Participants

A total of 297 participants participated in the study, males 49.5% (147), while females 50.5% (150). 92.2% (274) of these were eligible for TB testing by microscopy. 48.2 %(132) of those eligible were males while 51.8% (142) were females. Major reasons for test ineligibility were those currently on TB treatment (7.7%). None was below 15 years. The youngest participant was 15 years, the oldest 78 years, and the mean age for participation was 40.4 Ages 35-44 contributed 27.7% (97) of the total participants, and 25.3% (75) were eligible for the study. The lowest participation was recorded in the age 55-64, being 9.4% (28) of total participants, with eligibility of 7.1% (21). **Table 4.1** summarises the demographic characteristics of the participants including TB testing eligibility.

Table 4.1: Demographic Characteristics of the Participants

		Ineligible						Eligible		Total
		Reason I		Reason II		Reason III				
		n[2]	%[*3]	n[2]	%[*3]	n[2]	%[*3]	n[4]	%[*3]	
Sex	Male	0	0%	0	0%	15	5.05%	132	44%	147
	Female	0	0%	0	0%	8	2.69%	142	48%	150
Total		0	0%	0	0%	23	7.74%	274	92.3%	297
Age (Years)	15-24	0	0%	0	0%	4	1.3%	41	13.8%	45
	25-34	0	0%	0	0%	7	2.4%	61	20.5%	68
	35-44	0	0%	0	0%	7	2.4%	75	25.3%	82
	45-54	0	0%	0	0%	4	1.3%	48	16.2%	52
	55-64	0	0%	0	0%	1	0.3%	21	7.1%	22
	65+	0	0%	0	0%	0	0.0%	28	9.4%	28
Total		0	0%	0	0%	23	7.7%	274	92.3%	297

The youngest participant was 15 years, the oldest 78 years, and the mean age for participation was 40.4 years. Ages 35-44 contributed 27.7% (97) of the total participants and 25.3% (75) were eligible for the study. The lowest participation was recorded in the age 55-64, being 9.4% (28) of total participants, with eligibility of 7.1% (21). **Figure 4.1** shows the age distribution among the testing-eligible participants.

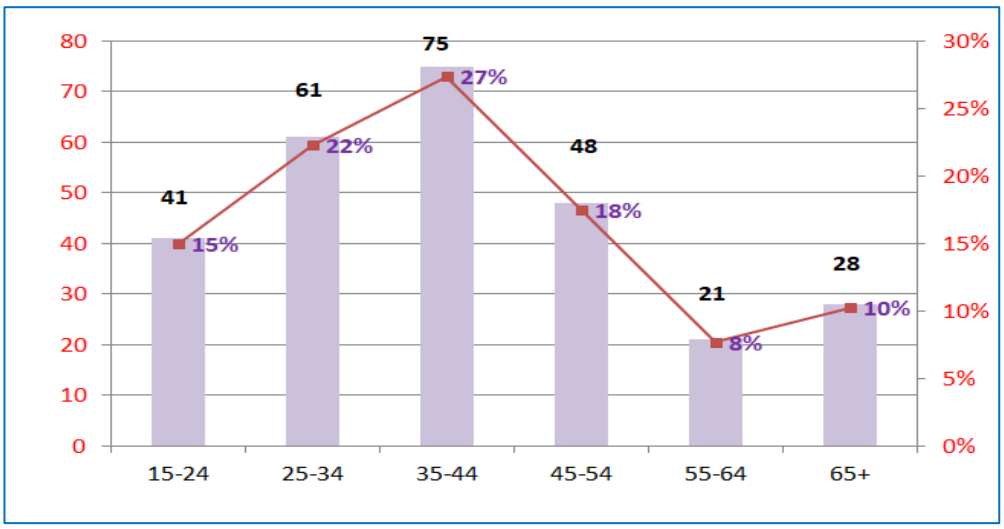

Figure 4.1: Age Distribution among Eligible Participants

4.1.2 TB Microscopy and GeneXpert Test Outcomes

Out of 274 samples tested by ZN microscopy, 23 were positive for TB hence eligible for GeneXpert testing. Eighteen (18) of these were males (78.3%) while 5 (21.7%) were females. The positive and negative control slides also tested positive and negative as applicable. All the 23 eligible participants tested positive for GeneXpert, with no Rifampicin resistance (RIF-R), hence concordant with the microscopy results. Table **4.2** is a summary of lab testing outcomes for microscopy and GeneXpert.

Table 4.2: Summary of Lab Microscopy and GeneXpert Test Outcomes

		MALES							FEMALES						
	Lab Results	**15-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65+**	**Total**	**15-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65+**	**Total**
Microscopy	3+	0	0	3	0	1	0	4	0	1	0	0	0	1	2
	2+	0	2	1	1	1	0	5	0	0	0	0	0	0	0
	1+	1	1	3	0	0	1	6	0	0	1	0	0	0	1
	Exact Number	1	0	2	0	0	0	3	0	0	1	1	0	0	2
	Negative (0)	16	28	27	19	10	14	114	23	29	37	27	9	12	137
	Total	**18**	**31**	**36**	**20**	**12**	**15**	**132**	**23**	**30**	**39**	**28**	**9**	**13**	**142**
Gene-Xpert	MTB Pos/RIF-R	0	0	0	0	0	0	0	0	0	0	0	0	0	
	MTB Pos/No RIF-R	2	3	9	1	2	1	18	0	1	2	1	0	1	5
	MTB Not Detected	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Indeterminate	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Total	**2**	**3**	**9**	**1**	**2**	**1**	**18**	**0**	**1**	**2**	**1**	**0**	**1**	**5**

4.1.3 Socio-Demographic Characteristics of Participants with Confirmed TB Infections

Mann-Whitney U was used to analyse the data for the socio-demographic characteristics including gender, weight and height. Chi-square evaluated age and BMI. Both height and age were found to be insignificant factors for TB in this population (p=0.182, p= 0.421 respectively). However, gender (p=0.001), weight (p=<0.0001) and BMI ((p=<0.0001) were significant in TB infections. The median age, weight, height and BMI for those found negative (n=251) and the IQR were 40.0: IQR21.0; 68.0: IQR 13; 1.78: IQR 0.1; and 21.4: IQR 4.2 respectively. Among those positive (n=46), there was 39.0: IQR 16.3; 63.0: IQR 6.0; 1.80: IQR 0.1; and 18.8: IQR 4.0 respectively **Table 4.3** summarises the socio-demographic factors analysed in this data.

Table 4.3: Socio-Demographic Characteristics

Characteristic	TB-, n=251	TB+, n=46	p
Age, yrs.	40.0 (21.0)	39.0 (16.3)	0.421
Gender, M/F	114/137	33/13	0.001*
Weight, Kg	68.0 (13.0)	63.0 (6.0)	<0.0001*
Height, m	1.78 (0.1)	1.80 (0.1)	0.181*
BMI, Kg/m^2	21.4 (4.2)	18.8 (4.0)	<0.0001

4.1.4 Analysis of TB Positivity

4.1.4.1 Age Distribution in TB Positivity

Overall TB positivity in this population was 15.5%, that is, 46 TB infections out of a total population of 297. 50% of the infections were newly identified while the other 50% self-reported that they were already on treatment at the time of the study. Minimum age of infection was 17 years, maximum 76 years, median age 39, and mean age 38.3 years. None of the infections identified was RIF resistant (DR-TB). TB infections peaked at ages 35-44 although there's a steady rise from ages 15-24. 63% of all TB infections were between the ages of 25-44. The figure below **(fig. 4.2)** shows the age distribution of TB infections in the population.

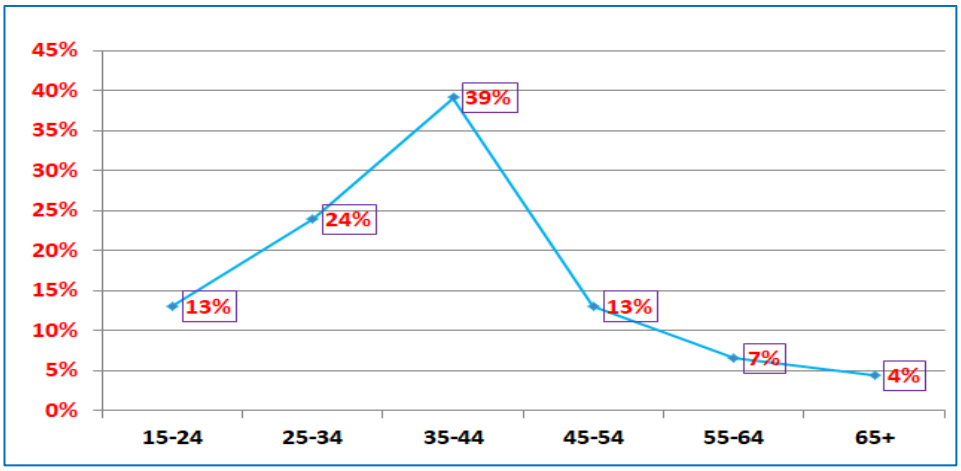

Figure 4.2: Age Distribution of TB Infections

4.1.4.2 TB Infections among Male Participants

Males contributed 71.7% (33/46) of all TB cases in this population. This was distributed across all age groups, with the peak being age 35-44, contributing 45% (15/33) of all positive cases. Age 25-34 contributed 21% (7/33) of all positive cases. 66% of all male positivity came from the ages 25-44. Ages 15-44 gave a combined TB positivity of 81% in males. The least contributor to male positivity came from those of ages ≥65 at 3% (1/33). The **figure 4.3** shows the TB case distribution among male participants.

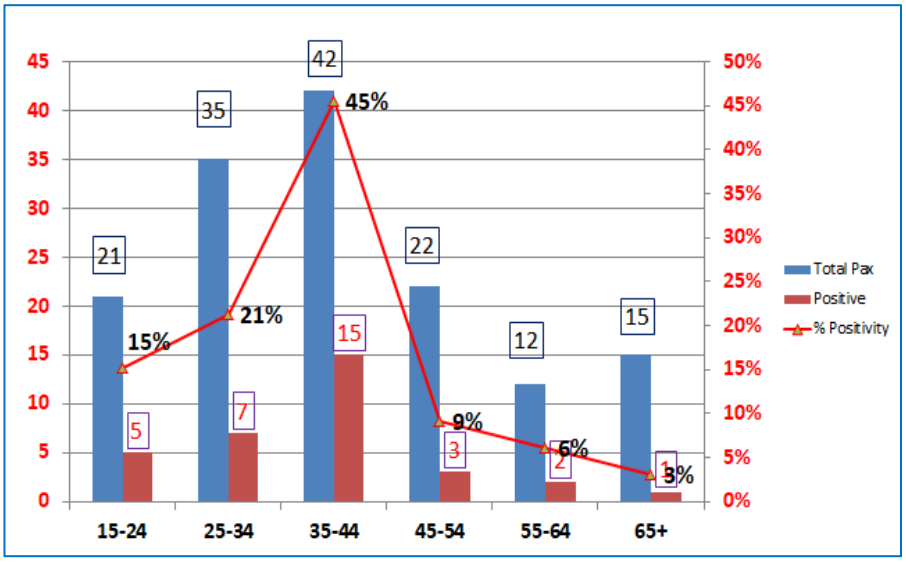

Figure 4.3: TB Infections among Males

4.1.4.3 TB Infections among Female Participants

Females contributed 28.3% (13) of all TB cases identified. Age 25-34 contributed 30.8% (4) of TB among the female population. And like in males, the cases were distributed in all the age groups. The figure below (**fig. 4.4)** shows the TB case distribution among female participants.

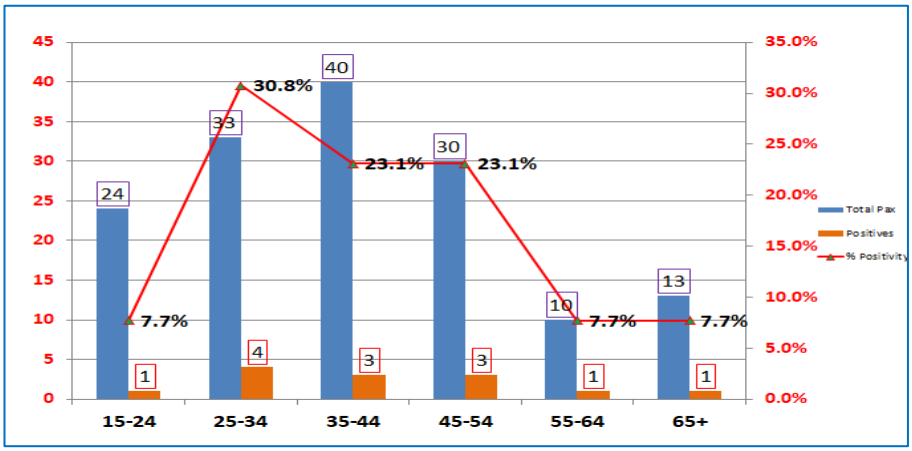

Figure 4.4: TB Infections among Females

4.1.5 HIV Testing and TB-HIV Co-infection

A total of 55 (18.5%) participants tested positive for HIV, of which 30 were males while 25 were females. Among the confirmed TB infections, 17 of them equally had HIV infection, giving a TB-HIV co-infection rate of 37% (n=46). In comparison, more males (30) were infected with HIV at 20.4% (n=147) compared to females (25) at 16.7% (n=150). The co-infection is equally higher in males (13) giving 76.5% (n=17)) compared to females with 4, giving 23.5% (n=17). No TB-HIV co-infection was present in those 65 years and older. **Table 4.4** is a summary of the HIV test results among those positive and those negative for TB.

Table 4.4: Summary of HIV and TB-HIV Co-infection

	MALES							FEMALES						
Lab Results	**15-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65+**	**Total**	**15-24**	**25-34**	**35-44**	**45-54**	**55-64**	**65+**	**Total**
HIV Negative	14	27	33	19	10	14	117	13	27	34	29	10	12	125
HIV Positive	7	8	9	3	2	1	30	11	6	6	1	0	1	25
HIV inconclusive	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TB-HIV co-infection	1	2	6	2	2	0	13	0	2	1	1	0	0	4

4.1.6 Clinical Presentation, Comorbidities and Associated Risk Factors

Analysis was done for clinical presentation, comorbidities and risk factors associated with TB. All were significant ($p \leq 0.05$), except for contact with chronic coughers ($p = 0.385$), hence not considered a serious factor in determining TB infections in this population. **Table 4.5** summarises the key findings in the analysis of clinical presentation, comorbidities, and TB-associated risk factors

Table 4.5: Summary of Clinical Presentation, Comorbidities and TB Associated Risk Factors

Clinical presentation	Yes/no	Tb-, n=251	Tb+, n=46	P
Contact with chronic coughers	Yes	8	3	0.385
	No	243	43	
Fever >2 weeks	Yes	6	8	<0.0001
	No	245	38	
Weight loss	Yes	5	10	<0.0001
	No	246	36	
Chest pain	Yes	20	13	<0.0001
	No	231	33	
Night sweats	Yes	10	13	<0.0001
	No	241	33	
Swelling in the neck, armpits, joints	Yes	2	3	
	No	249	43	0.028
HIV (Positive/Negative)	Yes	38	17	
	No	213	29	0.001

CHAPTER FIVE

DISCUSSION, CONCLUSIONS & RECOMMENDATIONS

5.1 Discussion

The study sought to evaluate the positivity rate of both drug-resistant and non-drug-resistant (DR and Non-DR) tuberculosis in the population, identify the factors consistent with TB as well as determine the co-relates of TB in the population of miners including HIV. A TB positivity of 15.5% was obtained among the mining community in this study. Of the 46 reported TB disease cases in this study, it's worth noting that 50% were living in the community oblivious of their TB status, hence the possibility of the continued spread of TB in the population. This is consistent with the Kenya Tuberculosis Prevalence Survey (Enos et al., 2018) which found that about 40% of TB infections remain undetected and untreated back in the community. Other studies have reported higher TB prevalence among the mining populations compared to the general populations (Rambiki et al., 2020; Faccin et al., 2022; Abeid et al., 2022) This means a good proportion of TB infections are symptom-naïve and could be missed if the measure of testing eligibility has to rely on symptoms alone . The same prevalence survey found that TB is highly prevalent among males at 809 per 100,000 populations. In our case, the prevalence of male infection is 71.7% (33/46), more than twice the prevalence among females. It is estimated that one TB-infected individual can infect up to 5-15 other people in a year (WHO, 2021). With this in mind, our study suggests that up to 345 other persons could get TB infections from the 23 new infections alone if no intervention is given. This means up to five thousand people risk infections from this community, assuming all the 345 new infections equally infect 15 other persons in one year.

In terms of age distribution of TB disease, ages 35-44 years remain the most significant age in terms of TB infections, accounting for 39% of the infections. The graph however has a steep gradient between ages 15 years to age 35. It is possible that the miners who majority (70.4%) had attained at least a primary level of education, and 20.2% secondary, had lived long enough within the mining community to contract or pass on the infections at 35 years of age. The school-going ages have slightly lower infection

rates compared to ages 35-44. The longer they stay within the mining areas, the higher the exposure and the higher the possibility of infection transmission (Nimje et al., 2020)

In this study, no case (0%) of MDR-TB was detected. A prevalence survey in Kenya (Enos et al., 2018) got a prevalence of 1.5%. Similar DR-TB prevalence studies preceding this study in other countries equally yielded very low levels of the same. In Ethiopia, a 1.1% prevalence was detected (Seyoum et al., 2014), with the same proportions reported in India (Sharma et al., 2011; Kidenya et al., 2014). Studies in Tanzania have had a prevalence ranging from 0.4% to 2.1% over a period of 15 years from early 2000, with almost the same proportion reported for the East Africa region at 0.4–4.4% (Kidenya et al., 2014). In early 2009-2010, Mozambique reported MDR TB prevalence as high as 7.7% (Nunes et al., 2005) while Swaziland reported 7.7% in one study (Sanchez et al., 2012). Recently, it was reported that there has been a steady decline in the number of DR-TB between the years 2015 and 2020 but this downward trend stabilised since 2020, most likely due to the effect of Covid-19 on global disease epidemiology (WHO, 2022). In summary, while it is expected that some section of the population may have MDR-TB, there is a variation of this in different studies, which could be a result of the differences in study populations, sample size, and sampling technique for the studies as well as the effectiveness of the DOT strategy in TB infections. Kenya, though considered among the countries with the highest tuberculosis (TB) disease burden, is one of the seven countries that have achieved the ambitious target of 20% reduction in TB infections as set by WHO for the period between 2015 and 2020 (WHO, 2020). The DOT strategy that focuses on drug adherence could have contributed to null cases of DR-TB as this purely depends on poor adherence among those infected.

Tuberculosis and HIV co-infection have presented considerable challenges in managing (Tornheim et al., 2018). The World Health Organization thus developed a policy guideline to support integration of TB and HIV services programming (WHO, 2012). A study in India found HIV to be an insignificant factor in TB infection and transmission (1%) compared to other possible co-morbidities such as undernutrition (24%), and diabetes (15%) among others (Rakesh et al., 2020). Another study in

Ethiopia gave the TB-HIV co-infection rate at 18.1% (Abebe et al., 2020). World Health Organization TB report in 2018 suggested that 29% of TB cases are equally HIV co-infected at the time of diagnosis (WHO, 2018). In the Kenyan TB Prevalence mentioned earlier, 83% of TB cases were HIV-negative, meaning the co-infection rate was about 17% (Enos et al., 2018). In 2021, DHIS2 reported 24.05% and 37.5% co-infections respectively for Kenya and Migori County. In our study, 37% of those with TB disease were also HIV co-infected. The mining community is a filtered population, and most at risk for both HIV and TB, and it is expected, as our study suggests, that the co-infection rate will be slightly higher than the national and global prevalence. However, this figure could be higher than reported if not for the vibrant HIV control program in the region that puts emphasis on TB prevention among the HIV-positive patients enrolled in care and seems to be making headways in its efforts.

The Kenya prevalence survey found that 74% of those who had TB reported at least one of the symptoms including contact with chronic coughers, weight loss, fever, chest pain, night sweats, and swelling on the joints, neck, and armpit (Enos et al., 2018). In our study, all except contact with chronic coughers, were found to be associated factors consistent with TB disease in the mining population ($p<0.05$). Contact with chronic coughers seems to be weakly significant in TB infections in this mining community, contrary to previous studies including one in South Africa that suggested that the inhalation of silica dust in gold mines is a risk factor for pulmonary TB (Stuckler et al., 2011). Further studies are suggested over this paradox. However, in trying to explain this, one hypothesis is that while some studies focus on cough in the general population without cough triggers except maybe TB infection, coughing among miners is a common phenomenon given the amount of dust inhaled therein and the cough droplets may only harbor and transmit TB if a TB case is involved. In cases where tubercle bacilli particles are not in the silica dust within the mines, any chronic cough will just remain so, chronic cough, and won't transmit TB infection.

Finally, on the socio-demographic factors and their contribution to TB infections, height and age were strongly significant ($p<0.05$). However, gender, weight and BMI were all significant, with p-values of 0.001 or less. A study in Ibadan, Nigeria found that health-seeking behavior is very poor among lower-level cadres as well as those

with lower levels of education compared to civil servants. Proximity, affordability, prompt attention, and readily available drugs all contribute to up to 61% of some of the decisions to seek healthcare (Latunji et al., 2018). In Ethiopia, a low level of health-seeking was found in 85% of participants of a study, with males contributing up to twofold lower health-seeking behaviour than females (Asfaw et al., 2018). All these factors could be the reason why more males are likely to be infected with TB than females in our study.

Weight and BMI have a direct bearing on individual weight and nutritional status. Undernutrition and diabetes were both found to contribute about 40% of all TB co-morbidities in India (Rakesh et al., 2020). This is consistent with our study findings on the socio-demographic factors of TB in Osiri-Matanda gold miners.

5.2 Conclusions

1. From the outcome of this study, it can conclude that drug-susceptible TB is present in this population. However, drug-resistant TB cannot be ruled out and an expanded study would serve to give a clearer picture of this.
2. It can also be concluded that TB doesn't have to present with the normal signs documented as some individuals tested positive but whose signs and symptoms were not consistent with TB.
3. The data from this study suggest that TB-HIV co-infection prevalence is higher than the national prevalence. While the HIV care program has achieved a lot in curbing TB infections within the hospitals among those on HIV care and treatment programs, much still needs to be done for the community that does not necessarily visit the health facilities. One such group is the miners who, because of their busy schedules have little time for hospital visits except when they are too sick to go about their daily chores.

5.3 Recommendations

1. Active case-finding interventions involving the mining community as well as other risk groups are recommended, and at regular intervals. Resources should be channelled to high-burdened areas and especially populations with

collegiate lifestyles such as mines, fishing areas, prisons and schools. This should be for everyone, with emphasis on the males, especially ages 25-44 years. An expanded study, with a much larger population and multi-site in nature, would serve to further give more TB status in different mining populations.

2. To prevent missed opportunities, it is recommended that screening and other interventions targeting TB should not only rely on the common signs previously documented. Tuberculosis testing, for example should be carried out on any sputum sample produced regardless of how weak in quality it is.
3. Further collaboration and synergy between the TB and HIV programs is recommended for control of the dual epidemic of the co-infection.

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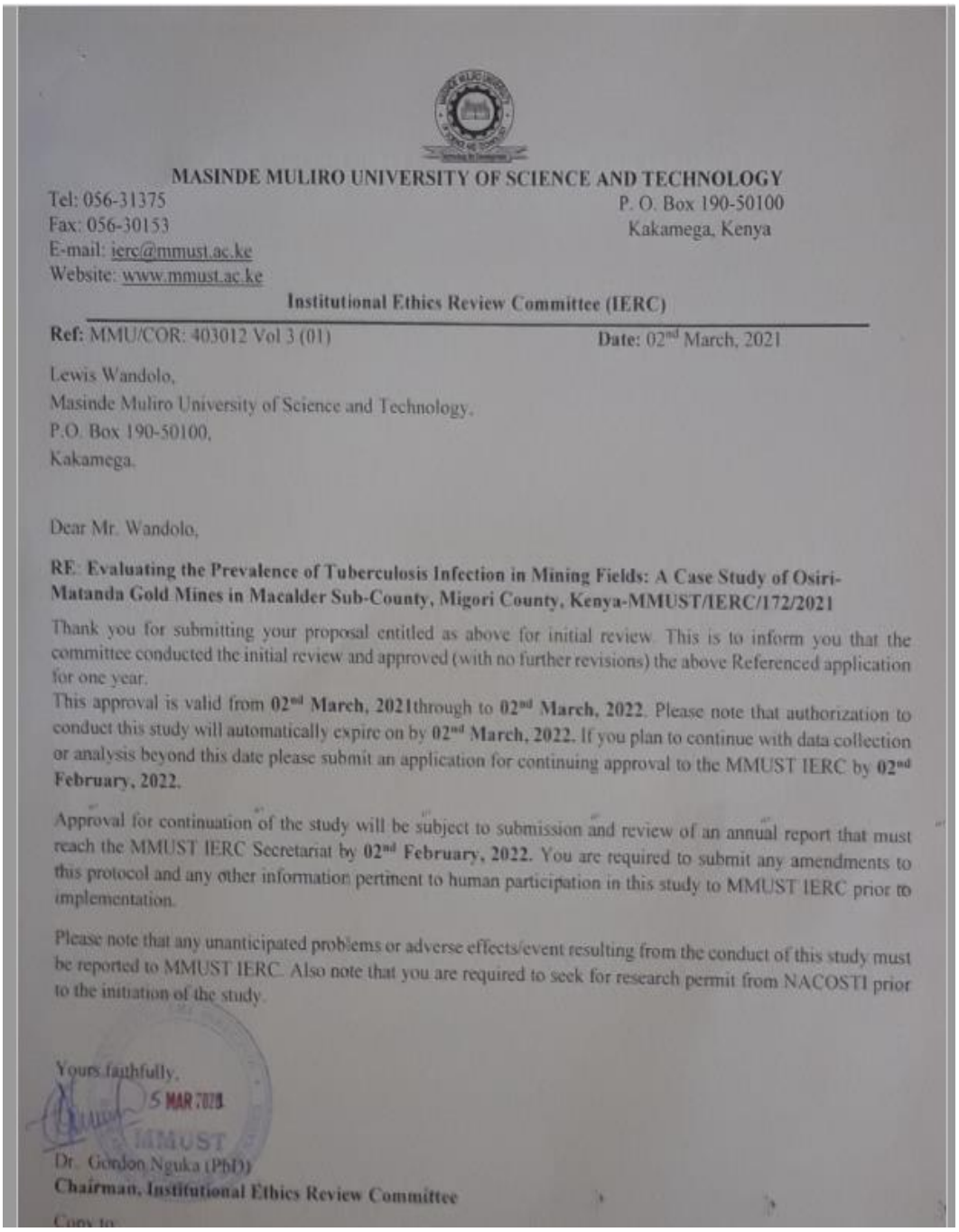
APPENDICES

Appendix I: Institutional Ethics Review Committee Approval



MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY

Tel: 056-31375
Fax: 056-30153
E-mail: ierc@mmust.ac.ke
Website: www.mmust.ac.ke

P. O. Box 190-50100
Kakamega, Kenya

Institutional Ethics Review Committee (IERC)

Ref: MMU/COR: 403012 Vol 3 (01) **Date:** 02nd March, 2021

Lewis Wandolo,
Masinde Muliro University of Science and Technology,
P.O. Box 190-50100,
Kakamega.

Dear Mr. Wandolo,

RE: Evaluating the Prevalence of Tuberculosis Infection in Mining Fields: A Case Study of Osiri-Matanda Gold Mines in Macalder Sub-County, Migori County, Kenya-MMUST/IERC/172/2021

Thank you for submitting your proposal entitled as above for initial review. This is to inform you that the committee conducted the initial review and approved (with no further revisions) the above Referenced application for one year.

This approval is valid from **02nd March, 2021**through to **02nd March, 2022**. Please note that authorization to conduct this study will automatically expire on by **02nd March, 2022.** If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the MMUST IERC by **02nd February, 2022.**

Approval for continuation of the study will be subject to submission and review of an annual report that must reach the MMUST IERC Secretariat by **02nd February, 2022.** You are required to submit any amendments to this protocol and any other information pertinent to human participation in this study to MMUST IERC prior to implementation.

Please note that any unanticipated problems or adverse effects/event resulting from the conduct of this study must be reported to MMUST IERC. Also note that you are required to seek for research permit from NACOSTI prior to the initiation of the study.

Yours faithfully,

5 MAR 2021

MMUST

Dr. Gordon Nguka (PhD)
Chairman, Institutional Ethics Review Committee

Copy to:

Appendix II: NACOSTI Research Licence

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 974382

Date of Issue: 26/March/2021

RESEARCH LICENSE

This is to Certify that Mr.. LEVIS OCHIENG' WANDOLO of Jomo Kenyatta University of Agriculture and Technology, has been licensed to conduct research in Migori on the topic: Evaluating the Prevalence of Tuberculosis Infection in Mining Fields: A Case Study of Osiri-Matanda Gold Mines in Macalder Sub-County, Migori County, Kenya for the period ending : 26/March/2022.

License No: NACOSTI/P/21/9433

974382

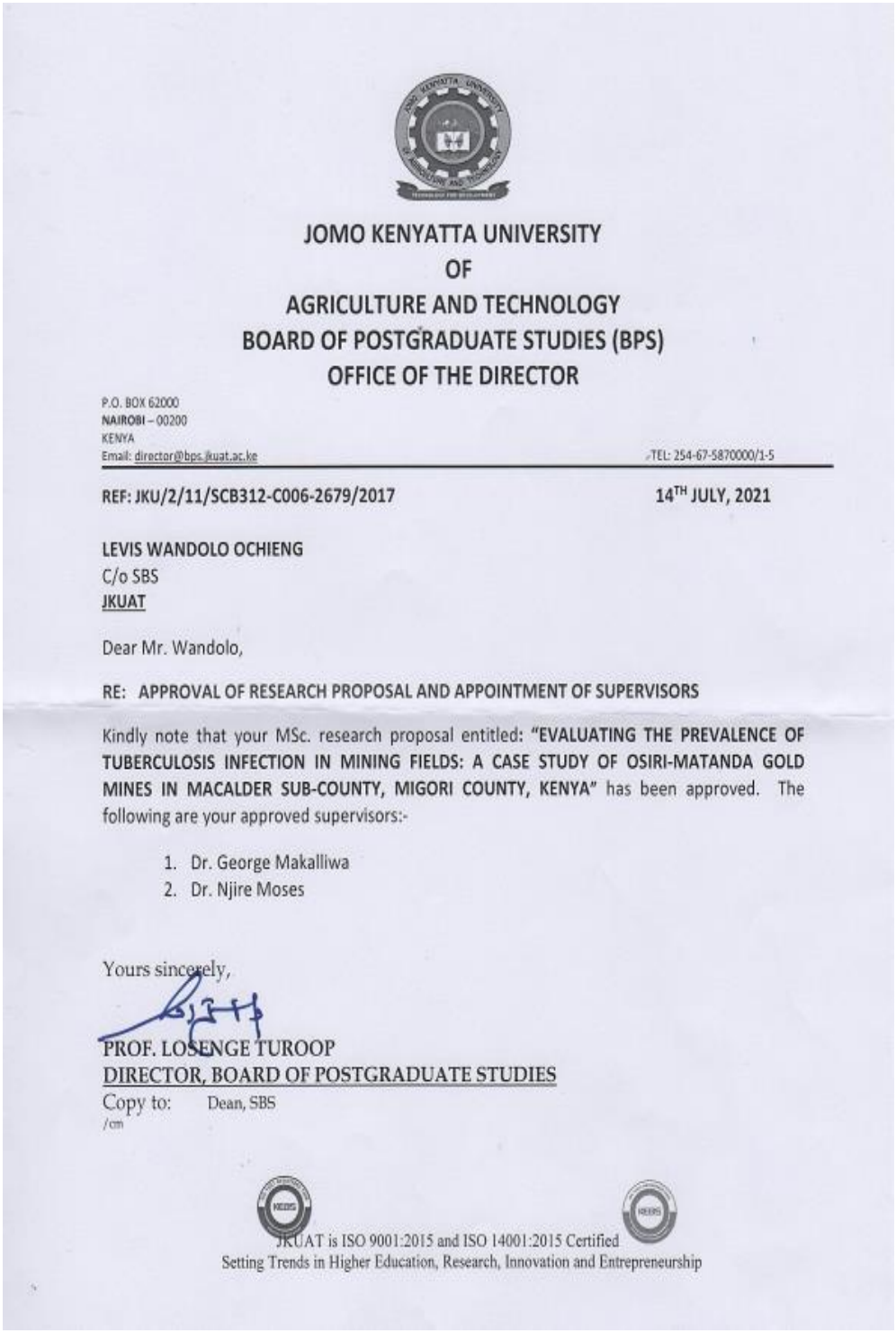
Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix III: Research Approval (Graduate School, JKUAT))



JOMO KENYATTA UNIVERSITY
OF
AGRICULTURE AND TECHNOLOGY
BOARD OF POSTGRADUATE STUDIES (BPS)
OFFICE OF THE DIRECTOR

P.O. BOX 62000
NAIROBI – 00200
KENYA
Email: director@bps.jkuat.ac.ke TEL: 254-67-5870000/1-5

REF: JKU/2/11/SCB312-C006-2679/2017 14TH JULY, 2021

LEVIS WANDOLO OCHIENG
C/o SBS
JKUAT

Dear Mr. Wandolo,

RE: APPROVAL OF RESEARCH PROPOSAL AND APPOINTMENT OF SUPERVISORS

Kindly note that your MSc. research proposal entitled: **"EVALUATING THE PREVALENCE OF TUBERCULOSIS INFECTION IN MINING FIELDS: A CASE STUDY OF OSIRI-MATANDA GOLD MINES IN MACALDER SUB-COUNTY, MIGORI COUNTY, KENYA"** has been approved. The following are your approved supervisors:-

1. Dr. George Makalliwa
2. Dr. Njire Moses

Yours sincerely,

PROF. LOSENGE TUROOP
DIRECTOR, BOARD OF POSTGRADUATE STUDIES
Copy to: Dean, SBS
/cm

JKUAT is ISO 9001:2015 and ISO 14001:2015 Certified
Setting Trends in Higher Education, Research, Innovation and Entrepreneurship

Appendix IV: Migori County Health Management Team Approval

MIGORI COUNTY

DEPARTMENT OF HEALTH SERVICES

COUNTY DIRECTOR OF HEALTH
MIGORI COUNTY
P O BOX 203-40400
SUNA - MIGORI

MIG/COH/TRAIN/VOL II

Date: 19th July, 2021

TO WHOM IT MAY CONCERN

RE: RESEARCH AUTHORIZATION; MR. LEVIS O. WANDOLO ID NO. 21893913

The above subject matter refers.

The above named student Reg No: **NACOSTI/P/21/9433** from Jomo Kenyatta University of Agriculture and Technology, Kisii Campus has been authorized to carry out research on **"Evaluating the Prevalence of Tuberculosis in Mining Fields; A case Study of Osiri-Matanda Gold Mines in Macalder Sub County, Migori County"** for the period ending 26th March 2022.

Any assistance accorded to him will be highly appreciated.

Dr. Dan Ochiel
County Director of Medical Services
MIGORI

Cc: Chief Officer of Medical Services
Migori

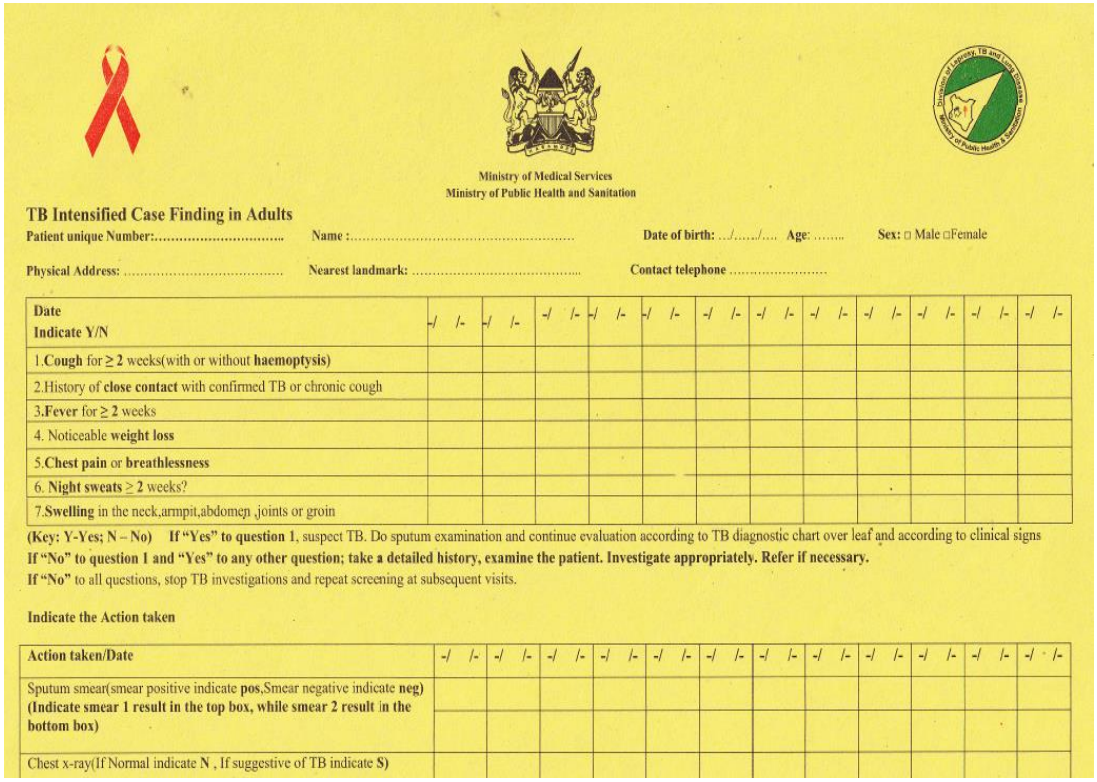
Appendix V: Work Plan (2023-2024)

Activity	**June 2023**	**July 2023**	**Aug 2023**	**Sept 2023**	**Oct 2023**	**Nov 2023**	**Dec 2023**	**Jan 2024**	**Feb 2024**	**Mar 2024**	**April 2024**	**May 2024**	**June 2024**	**July 2024**
Manuscript preparation and publishing														
Intent to submit thesis														
Submission of thesis														
Thesis defense														

Appendix VI: Budget

	Item description	Unit Cost (KSHS)	Total Cost (KSHS)
1.	**Proposal Writing, Presentation and Approval**	500.00	
	• 3 ream of foolscaps	15.00	1500.00
	• 12 biro pens	1,200.00	180.00
	• 1 flash disk	5,000.00	1,200.00
	• Safaricom modem	1,500.00	5,000.00
	• Airtime for internet browsing	400.00	4,500.00
	• Printing 3 draft copies	300.00	1,200.00
	• Printing 1 final copy	5,000.00	300.00
	• 1 Photocopy of proposal		5,000.00
	• Binding 2 copies		
	• Ethical approval		
		Sub-total	**17,530.00**
2.	**Data Collection**		
	• Printing and photocopy of consent form	25,000.00	25,000.00
	• Photocopies of data collection tools	25,000.00	25,000.00
	• Transport	15,000.00	15,000.00
		Sub-total	**65,000.00**
3.	**Data Analysis**		
	• Editing and coding	5,000.00	5,000.00
	• Analysis	6,000.00	6,000.00
		Sub-total	**11,000.00**
4.	**Report preparation**		
	• Typing and printing 2 copies of draft	1,000.00	2,000.00
	• Binding 2 copies	200.00	400.00
5.	**Publication**	20,000.00	20,000.00
6.	**Thesis development and printing**		10,500.00
	• Typing, printing and binding 7 copies	1,500.00	
		Sub-total	**32,900.00**
	Total Expenditure		**95,930.00**
	Add 10% contingencies		**9,593.00**
	GRAND TOTAL		**126,430.00**

Appendix VII: TB Intensive Case Finding (ICF) Form



Ministry of Medical Services
Ministry of Public Health and Sanitation

TB Intensified Case Finding in Adults

Patient unique Number:..... **Name :**..... **Date of birth:** .../...../.... **Age:**..... **Sex:** □ Male □Female

Physical Address: ..... **Nearest landmark:** ..... **Contact telephone** .....

Date **Indicate Y/N**	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-
1.**Cough** for ≥ **2** weeks(with or without **haemoptysis**)													
2.History of **close contact** with confirmed TB or chronic cough													
3.**Fever** for ≥ **2** weeks													
4. Noticeable **weight loss**													
5.**Chest pain** or **breathlessness**													
6. **Night sweats** ≥ **2** weeks?													
7.**Swelling** in the neck,armpit,abdomen ,joints or groin													

(Key: Y-Yes; N – No) If "Yes" to question 1, suspect TB. Do sputum examination and continue evaluation according to TB diagnostic chart over leaf and according to clinical signs
If "No" to question 1 and "Yes" to any other question; take a detailed history, examine the patient. Investigate appropriately. Refer if necessary.
If "No" to all questions, stop TB investigations and repeat screening at subsequent visits.

Indicate the Action taken

Action taken/Date	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-	-/ /-
Sputum smear(smear positive indicate **pos**,Smear negative indicate **neg**) **(Indicate smear 1 result in the top box, while smear 2 result in the bottom box)**													
Chest x-ray(If Normal indicate **N** , If suggestive of TB indicate **S**)													

Appendix VIII: TB Risk Assessment and Sampling Tool

TB RISK ASSESSMENT AND SAMPLING FORM

Participant number.....Age.....

Sex.....Height.....Weight.....BMI.....

Marital status.....occupation.....Education.....

1. Are you currently on TB treatment? Yes /No
2. How many people do you live with in your household?
3. TB Risk Assessment (*Only for those not currently on TB treatment*)

Indicator	YES/NO
Cough of any duration	
History of close contact with confirmed TB or chronic cough	
Fever of more than two weeks	
Any noticeable weight loss	
Chest pain or breathlessness	
Night sweats	
Swelling in the neck, armpits, joints or groin	

4. Would you wish to be contacted once your results are ready? YES/NO.
   If yes, give contact
   .....
   .....
   .....

   If NO, give reason
   .....
   .....
   .....

5. Would you accept to be initiated on TB treatment when your result show you have TB? YES/NO
If NO, give reason
.....

.....
.....
.....

6. If infected with TB, it is possible that you can transmit this to your household members. Would you wish any of your household members be contacted for testing and treatment in case you find out you are infected with TB? YES/NO.

If NO, give reason
.....
.....
.....
.....

For Laboratory Use

Date Sample Taken.....

Date sample tested.....

Test Result.....

Date Client Contacted.....

Appendix IX: Adult Consent Form (English)

STUDY PARTICIPANT VERBAL CONSENT FORM

Hello, my name is _____, I'm a study assistant and doing this interview on behalf of Levis Wandolo, who is a student of Jomo Kenyatta University of Science and Technology. You have been chosen at random to be in a study looking at tuberculosis infection and awareness. The study involves ***Evaluating the Prevalence of Tuberculosis Infection in Osiri-Matanda Gold Mines in Macalder Sub-County, Migori County, Kenya***. This study will take two months but your involvement is only needed during this interview, and if a sample has to be taken for lab test, we may contact you to deliver your results and support you access treatment if necessary. If you choose to be in the study, I will ask you a few questions about TB based on the TB Risk assessment form. Your responses in the risk assessment will guide us as to whether we will have your sample taken for laboratory test. You will be expected to give us two sputum samples in the containers which I will offer you if eligible.

There are no foreseeable risks or benefits to you for participating in this study. There is no cost or payment to you. If you have questions while taking part, please stop me and ask. We will do our best to keep your information confidential. We will use numerical identifiers, and the link to you will only be known by myself for the duration of the study and will only be used for contacting you when your test results are out and if we feel we need to support you get further treatment or information.

If you have questions about this research study you may contact ***Levis Wandolo*** at **0725451290**. If you feel as if you were not treated well during this study, or have questions concerning your rights as a research participant call The Secretary/Chairperson MMUST – IERC Tel:056-31375 , Email: **ierc@mmust.ac.ke.**

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. May I continue?

I certify that I have consented the participant number _____

Researcher's name: Levis O. Wandolo.

Signature:

_____

Date: _____

Appendix X: Adult Consent Form (Dholuo)

YIE MAR CHIWRUOK E NONRO

Ber, nyinga en _____, an jatich nonro kendo atiyo kae e loo Levis Wandolo, ma en japuonjre e mbalariany mar Jomo Kenyatta. Wakwayi mondo ichiwri e nonro ma wadwa timo kaluwore gi tuo mar kahera. Nonro ni nono tuo mar kahera e kind jogo modak kata matiyo ei kata machiegni gi hoho mar kunyo magang ma Osiri Matanda, ei Makalda kaye.. Nonro ni dhi kawo dweche ariyo, to in iwuon wabiro kawo seche ni mana sani ma wadwaro penji penjo moko kaluwre gi tuo mar kahera, kendo bange ka okaw okego mari ma opim e kar pim ma Makaldar, wabiro manyi mondo wamiyi duokoni kendo wakonyi iyud thieth kaponi pim oyudo ni in gi tuo mar kahera. Ka iyie mondo ichiwri e nonro ni, abiro penji penjo moko matin kuom tuo mar kahera ka watiyo gi andike moro ma ondiko gigo ma nono yot mar ngata yudo tuo ni. Duoko mari e andike nogo bende ema biro nyiso wa aka onego ichiw okego mondo water a kar pimo mondo oipm. Wabiro dwaro mondo ichiw okego e chupe ariyo ma wabiro miyi kaponi wayudo ni onego pimi.

One hinyruok moro amora e nonro ni, kendo chiwruok ni onge chude moro amora ma ibiro dwar kuomi kata ma ibiro miyi. Ka in gi penjo moro amora sama wadhi nyime gi penjo gi kata puodhi donjo e nonro ni, in thuolo inyalo chunga mondo ipenji. Wabiro temo ahinya mar keto wechego ma wawacho kodi kata ma wafwenyo kaka duoko ni mar pim kama ngato angata ma ok jokanyo e nonro ni ok nyal yudo. Wabiro tiyo gi namba moko ka warwako ji e nonro, kendo ngeyo wuon namba ka namba ibiro tim mana gi jatelo e nonro ni kendo wabiro mana tiyo gi magi kuom manyi ka duoko ni mar pim osewuok kendo kata ka waneno ka onego wakonyi iyud thief kaluwre kod duoko mari.

Ka in gi penjo moro amora kuom nonro ni to inyalo goyo simu ne **Levis *Wandolo* e namba simo mar 0725451290.** Bende ka ineno ka ja tich nonro ok otiyo ni makare kendo kata in gi penjo moko kaluwre gii ratiro magi kaka ja chiwre e nonro to inyalo goyo simo ne Jagoro kata jakom mar ofis ma ngiyo weche ratich jogo ma

chiwre e nonro e mbalariany mar Masinde Muliro, e namba 05631375, kata ndik negi baruwa mar email e **ierc@mmust.ac.ke.**

Chwruok ni e nonro ni onge chude moro amora, kendo onge gimoro amora ma wanyalo timo kata ma wanyalo tuoni yudo ka itamri chiwri e nonro ni. Kaluwore kod gigo ma asomoni kendo ma wasewacho, bende wanyalo dhi nyime?

Aketo lweta ni asomo andike mar chiwruok e nonro ni ne jachiwre namba_____

Nying jatich nonro: Levis O. Wandolo.

Sei:_____Tarik_____

Appendix XI: Parental Assent Form (English)

PARENTAL ASSENT FOR CHILDREN UNDER EIGHTEEN YEARS OF AGE WHO WISH TO TAKE PART IN THE STUDY

Title of Study: ***Evaluating the Prevalence of Tuberculosis Infection in Mining Fields: A Case Study of Osiri-Matanda Gold Mines in Macalder Sub-County, Migori County, Kenya***

Principal Investigator: Levis O. Wandolo, Jomo Kenyatta University of Agriculture and Technology

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission

in order for your child to participate in this study. We will give you a copy of this form for your records.

If the child is at an age that he/she can appreciate what is being done then he/she will also be required to agree to participate in the study after being fully informed.

WHAT IS THE PURPOSE OF THE STUDY?

The researchers listed above are interviewing individuals who are living or working within Osiri-Matanda mining area. Participants in this research study will be asked questions about tuberculosis disease. Participants will also have the choice to undergo a tuberculosis testing when they are eligible. There will be approximately 320 participants in this study randomly chosen. We are asking for your consent to consider your child to participate in this study.

WHAT WILL HAPPEN IF YOU DECIDE YOU WANT YOUR CHILD TO BE IN THIS RESEARCH STUDY?

If you agree for your child to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 7 minutes. The interview will be mainly on TB.

After the interview has finished and the participant is eligible and has consented for testing, two specimen containers will be given where they will be expected to collect sputum samples and deliver to the lab technologist for testing. You will be informed about the results once they are out.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact is so that we can deliver your test result or support you get treatment.

ARE THERE ANY RISKS, HARMS, DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

Your child may benefit by receiving free TB information and testing, and appropriate referral for treatment where one is found positive for TB. Also the information you provide will help us better understand your household and any TB risk so we best know how to support you

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participating in this study is absolutely free and you will not be asked for any payment to participate.

IS THERE REIMBURSEMENT FOR PARTICIPATING IN THIS STUDY?

You will not be reimbursed any cost you incur to participate in this study, save for the study benefits listed above.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

WHAT ARE YOUR OTHER CHOICES?

Your decision to have your child participate in this research is voluntary. You are free to decline or withdraw participation of your child in the study at any time without injustice or loss of benefits. Just inform the study staff and the participation of your child in the study will be stopped. You do not have to give reasons for withdrawing your child if you do not wish to do so. Withdrawal of your child from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities.

For more information, contact Levis O. Wandolo at 0725451290.

CONSENT FORM (STATEMENT OF CONSENT)

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child of 15 years and above in this study.

Parent/guardian statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw it any time.

I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child’s legal rights as a participant in this research study.

I voluntarily agree to my child’s participation in this research study: Yes No

I agree to my child undergoing TB testing: Yes No

I agree to provide contact information for follow up: **Yes** **No**

Parent/Guardian signature/Thumb stamp_____

Parent/Guardian printed name_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____**Date**: _____

Signature: _____

Role in the study: _____

Appendix XII: Parental Assent Form (Dholuo)

NDIKRUOR MAR JANYUOL KALUWRE GI CHIWRUOK E NONRO KUOM NYITHINDO MA HIGINI GI POK OROMO APAR GI ABORO

Wi Nonro: ***Ngiyo ngeny mar Tuo mar Kahera kuom Jogo matiyo kata modak e kuonde kunyo magang: Nonro mar Kar Magang mar Osiri-Matanda ei Macalder Sub-County, Migori County, Kenya***

Jatend Nonro: Levis O. Wandolo mar mbalariany mar Jomo Kenyatta

Weche Mokwongo:

Daher mar nyisi kuom nonro ma itimo gi ja nonro ma nyinge ondik malo kanyo no. Andike mar chiwruokni lero ni weche mangeny mag nonro ni mondo okonyi e yie kata tamruok nyathini mondo odonj e nonro ni. In gi thoulo mar penjo kaluwre gi gima omiyo watimo nonro ni, gik ma biro timre ka nyathini odonjo e nonro ni, gigo ma nyalo hinye kata ber ma onyalo yudo, ratiro mare bende kaka jachiwre e nonro, kendo gimoro amora ma ok oyangre kuom nonro kata kuom, andike ni. Ka waseduoko penjo ni ma iyie gi duoko wa to eka inyalo yiero mondo nyathini odonj e nonro ni kata ooyo. Gima watimo ni iluongo ni yiero mari kaluwre gi gigo ma ose lerni kuom nonro ni. Ka isewinjo tiend gigi kendo iyieni nyathini odonj e nonro ni, abiro kwayi mondo iketnwa lweti e otasni. Onego ingeni nonro mag weche mag thieth nigi misee adek ma iluwo, ma gin kaka; i) Donjo kata tamruok nyathini donjo e nonro en yiero mare, ii) Nyathini ka odonjo e nonro to en gi ratiro mar wuok saa asaya ma ok owacho gima omiyo oweyo nonro, iii) Tamruok mare dojo e nonro ok dhi ketho ratiche mar yudo weche mag thieth makare e kar thieth makaye kata makamoro amora

Wanyalo dhi nyime? EE/OOYO

Kuom nyithindo ma hikgi pok oromo apar gi aboro, walero ne jonyuolgi kata joritgi kaluwre gi nonro. Wabiro ngiyo wechegi kodi kendo in ema ibiro yiene nyathini mondo odonj e nonroni. Wabiro miyi otasni mondo ikan ma nyiso ni ne olerni kaluwre gi nonrno ni.

Ka nyathini nigi higini ma onyalo pogo gigo ma itimone to en bende wabiro dwaro mondo ochiw yie mare mar donjo e nonro ka osewinjo weche ma walero kuom nonro ni.

NONRO NI NGIYO ANGO?

Ja nonro ma ondik nyinge kaye ni timo nonro kuom jogo ma tiyo kata odak magang ma Osiri-Matanda. Jogo mochiwre e nonro ni ibiro penj penjo kuom tuo mar kahera. Bende gibiro bedo gi ratiro mar yudo pim mar tuo mar kahera. Jochiwre e nonro ni biro bedo jii moromo 320. Wakwayo mondo iyieni nyathini ochiwre e nonro ni.

GIGO MA BIRO TIMRE KA IYIERO MONDO NYATHINI OCHIWRE E NONRO NI?

Ka iyieni nyathini ochiwre e nonro ni, magi e gigo mabiro timrene;

Ibiro penji penjo gi jatich nonro machielo e kama opondo ma in gi thuolo mar duoko penjo. Penjo go biro kawo dakika abiriyo. Penjo go biro mana bedo moluwore gi tuo mar kahera.

Bang ka penjo go oserumo kendo jachiwre oyud ka oromo gi donjo e nonro kendo oyie mondo opime tuo mar kahera, ibiro miye chupe ariyo mag okego kendo ibiro dwar mondo ogol okego bas ochiw ne ja pimo mondo opim. Ibiro nyisi duoko ka osewuok. Wakwayo namba mar simu ma wanyalo yudi godo kaponi wadwari. Ka iyie miyowa namba mari mar simu, ibiro tii kode mana gi jogo ma tiyo e nonro ni kendo ok wabiro chiw namba no ni ngato angata mopogre gi jotich nonro. Gima omiyo wanyalo dwaro manyi en seche maduoko ni osewuok kendo seche ma wadwa konyi iyud thieth.

BENDE NITIERE GIGO MA NYALO HINYO NGATO KA OCHIWRE E NONRO NI?

Nonro mag weche mag thieth seche moo kelo ga hinyruok e weche mag obuongo, weche mag dak e anyuola kendo kata bende hinyruok mag del. Kinde tee jo nonro idwaro mondo otem orit ahinya gigo manyalo kelo hinyruok. Achiel kuom gigo ma wangiyo en weche ma nyalo miyo ngato ngee ni ichiwri e nnro machalo kama. Wabiro

kano kendo rito gigo ma wawacho kodi e yoo ma opandre ahinya. Wabiro tiyo gi namba e yore mag fwenyo nyathini e computer kendo kalatas moro amora ma watiyo godo bende wabiro kano e kabat ma igoyo kiful.

Samoro dwoko penjo bende nyalo bedo ma ok yom ni. Ka nitie penjo moro amora ma ok idwar dwok to oyieni inyalo kalo ma ok iduoko. In thuolo mar tamri duoko penjo moro amora ma openji ka ok iwinj ka in thuolo mar duoko.

BENDE NITIERE GIGO MA NGAT MA OCHIWRE E NONRO NI NYALO YUDO?

Nyathini nyalo yudo puonj kuom weche mag kahera kendo pimo, kachiel kod tudruok e yore mag thieth kaponi oyud ka en gi tuo mar kahera. Bende weche ma imiyowa biro konyo wa e ngeyo anyuola ni kod yot maru mar yudo tuo mar kahera bas to wangeyo kaka wakonyi.

BENDE NITIERE GINO MA ACHULO MAR DONJO E NONRO NI?

Chiwruok e nonro ni en nono kendo onge gino ma ibiro dwar mondo ichul kuom chiwruok e nonro.

BENDE NITIERE GINO MA IBIRO MIYA KA ADONJO E NONRO NI?

One gimoro amora ma ibiro chuli kuom donjo e nonro ni mopogre kod puonj kod pim kuom tuo mar kahera ma ne wasewacho chien kacha ka.

TO KAPONI AN KOD PENJO BANGE?

Ka in kod penjo moko kendo kuom chiwruok mar nyathini e nonro ni to inbiro goyo simo kata oro ote machuok ne jatich nonro e namba ma onchiw piny mar otasni.

IN GI YIERO MAGE MOPOGRE GI MA WASEWACHO GI?

Donjo mar nyathini e nonro ni en yiero makende ma iyiero. In thuolo mar tamri rwako kata golo nyathini e nonro saa asaya ma ihero ma onge ratiche mora amora ma ibiro mayi. Idwaro mana ni inyiso jatich nonro ni igole to bas igoloni godo. Ok ochuno I nyaka iwach gima omiyo igole ka ok idwa wacho gima omiyo. Bende gole ok biro keth ratiro mare mar yudo kony e weche mag thieth e kar thieth ma kaye kata moro amora.

Ka in gi wach moro amora mopogre gi sani to pod inyalo goyo simo ne
Levis O. Wandolo at 0725451290.

GIMA OMIYO IDWARO NI ICHIW YIE NI NGAT MACHIELO

Ngano ma ingiyo mondo odonj e nonro ni ok nyal chiwo yie ni kende nikech en nyathi ma pok oromo higni apar gi aboro. Idwaro mondo ichiw yie ne nyathini nikech hike pok ochopo apar gi aboro.

Yie mar janyuol kata jarit nyathi

Asesomo kata osesomna weche man e andike mar yie ni. Asebedo gi thuolo mar loso e weche mag noroni gi jatich nonro ni. Penjo na bende gise duoko ka gitiyo gi dhok ma awinjo maler. Hinyruok ma nyalo betie kod ber mar nonro ni bende ose ler na. Angeyo ni idhi miya otas mar yie ni adhi godo ka ase goyo sei. Angeyo ni donjo e nonro ni en yiero mara kendo an gi thuolo mar gole e nonro saa asaya ma ahero.

Angeyo bende ni jotich nonro dhi temo matek mondo gikan makare weche ma wawacho kod mago ma nyalo chiwo fwenyruok ni nyathina nitie e nonro ni.Kuom keto sei e otas mar yie ni, pok awito ratiro moro amora mar nyathina kaka jachiwre e nonro ni.

Achiwra mondo nyathina odonj e nonro ni: **Ee** **Ooyo**

Achirwa mondo nyathina otimne pim mar tuo mar kahera **Ee** **Ooyo**

Achiwra mar miyo jatich nonro yore ma inyalo yuda godo **Ee** **Ooyo**

Sei mar janyuol/jarit nyathi_____

Nying janyuol/jarit nyathi_____

Weche mag ja tim nonro

An, ma ogoyo sei piny kae ni, oselero tiend nonro ni ne jachiwre ma nyinga ondik malo kae ni, kendo ageno ni jachiwre osewinjo kendo chiwruok mare en yiero ma oyiero kende.

Nying jatich nonro: _____**Tarik**: _____

Sei: _____

Tija e nonro kaa: _____