FACTORS ASSOCIATED WITH *MYCOBACTERIUM LEPREA* OCCURRENCE AMONG PEOPLE WITH LEPROSY IN KWALE COUNTY, KENYA

BY

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MOI UNIVERSITY

DECLARATION

Candidate Declaration

I declare that this is my original work and has never been submitted to Moi University or any other institution in whole, part, or any other form for academic qualification or another purpose.

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Declaration by Supervisors

This thesis has been submitted to Moi University with our approval as Supervisors.

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DEDICATION

I dedicate this work to Effie Faith and CDC to whom I gathered the ingenuity to achieve the best in the academic and financial support during my study period.

Abstract

Background: Leprosy, an infection caused by *Mycobacterium Leprea*, remains an important problem globally. In 2020, approximately 22.9 per million population cases were reported to WHO. India contributed 60% of these cases. In Africa, the prevalence of leprosy is 0.21 per 10,000 population. Although there is no effective vaccine to prevent leprosy, about 85% of the world's population have natural immunity. Kenya has maintained the global target of leprosy elimination at the national level. However, the country reported a 6-fold increase in leprosy cases over 10 years (2011-2021), with Kwale County contributing 20.3%.

Objectives: To determine Social-demographic, clinical, behavioral, socioeconomic, and environmental factors associated with leprosy disease in Kwale County.

Methods: A case-control study design was conducted in Kwale among people with leprosy. A case was defined as any person presenting with hypopigmented skin lesions, loss of sensation, and manifestation of leprosy bacilli with or without positive skin, including a person recently discharged from treatment .A control was any person living in Kwale from the same village as the case, of the same age group, and sex, with no report of leprosy within the kinship. The study listed 65 cases extracted from the leprosy registers and traced them to their respective villages where consent was sought. The cases and controls were interviewed using a questionnaire. Univariate analysis for continuous and categorical variables.Variables with a p-value of<0.2 in the bivariate analysis were subjected to unconditional multivariate binary logistic regression. Stepwise backward elimination was used to develop the final model. Variables with a p-value of <0.05 in the multivariate model were regarded as independently associated with increased *Mycobacterium Leprea* occurrence.

Results: A total of 65 cases and 195 controls were enrolled. The mean age among the cases and controls was 55 years (SD±16 years) and 54 years (SD±15 years) respectively. Age group ≥50 years contributed 44 (68.2%) and 0-14 years contributed 1(1.5%). The proportion of males among the cases was 39 (60.0%) and controls 108 (55.6%). The majority of the cases 59 (90.8%) were Multibacillary type of leprosy, and 38 (58.5%) presented with disability grade II. The median delay in case detection was 45 months (IQR 12-69 months). A low frequency of changing bed linen (cOR=2.69, 95% CI 1.02-3.9); and food scarcity (cOR=2.55, 95% CI 1.25–5.24) were 2 times likely to increase *Mycobacterium Leprea* occurrence. In multivariate analysis, household crowding (≥5 members) increased *Mycobacterium Leprea* occurrence risk by 6 times (aOR=6.99, 95% CI 2.71–18.06). Family contact (aOR=4.33, 95% CI 2.18–8.58), Social contact (aOR=2.24, 95% CI 1.16–4.32), and absence of BCG scar (aOR=2.24, 95% CI 1.11–4.53) were independently linked to *Mycobacterium Leprea* occurrence.

Conclusion: Crowded households of ≥ 5 members, family, and social contacts, and absence of BCG scar were associated with leprosy.

Recommendations: Kwale County to enhance household contact tracing surveillance beside household members and involve distant relatives, workmates, and social friends.MOH to enhance and expand uptake of BCG vaccination coverage among all eligible populations

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Operational Definitions

Case: Any person who is presenting with a hypopigmented skin patch with loss of sensation, one or more enlarged nerves, and the presence of leprosy bacilli with or without positive skin smear for *Mycobacterium Leprea*, including patients recently released from treatment (24 months)

Contact: People who share a kitchen, and social space while residing in the same home, workplace, school, and friends.

Control: Residents who are from the same village as the cases and are in the same age group and sex, with no *signs* of disease, or history of leprosy treatment.

Delay in case detection: The period that elapses between the onset of the first symptoms and the diagnosis in a health facility.

Disability grade II: People suffering from visible deformities as a result of leprosy neuropathy.

Disability: Difficulty in functioning of the body in one or more aspects of life, as experienced by a person with a medical disorder.

Family contact: Contact with a person suffering from leprosy in the same house and use of the same kitchen (nuclear family members living in the same house).

Formal education: Participant who has completed a school system recognized by Kenya's Ministry of Education and can attempt or read in English or Kiswahili words

Grade 0; no anesthesia or impairment;

Grade 0; no single evidence of visual loss; no problem associated with leprosy

Grade 1; loss of sensation in the hand or foot, anesthesia is present

Grade 2; visible impairment

Health system delay: The time between the first consultation with a health care provider and the diagnosis, and enrolment in treatment.

Household: a household with multiple occupants sharing a kitchen and referring to one person as the family head

Multibacillary (MB): A case of leprosy with greater than five skin lesions, with nerve involvement, or with bacilli in a slit-skin smear, irrespective of the number of skin lesions.

Non-formal education: Participants who have never attended a Kenyan educational institution and are unable to read and write in English or Kiswahili words.

Patient delay: The time between when a person notices the first sign and when the person sees the first healthcare provider.

Paucibacillary (PB): A case of leprosy with 1 to 5 skin lesions, without the demonstrated presence of bacilli in a skin smear.

Social contact: Contact with someone with leprosy but not from the same house and sharing a kitchen (extend family members, relatives including workplace, school, friends, and distant relative

Abbreviation and Acronyms

ACF: Active case finding

AFB: Acid fast bacilli

BCG: Bacillus Calmette Guerin

CDC: Center for Disease Control and Prevention

CHPs: Community Health Promoters

CTLC: County TB and leprosy coordinator

G I: Grade 1 disability

G II: Grade 2 disability

HCW: Health Care Workers

M&E: Monitoring and Evaluation

MB: Multibacillary

MDT: Multidrug Therapy

ML: *Mycobacterium Leprea*

MOH: Ministry of Health

NGO: Non-Governmental Organization

NSP: National Strategic Plan

DNTLP: Division of National Tuberculosis, Leprosy Programme

NTD: Neglected Tropical Disease

PB: Paucibacillary

PEP: Post-Exposure Prophylaxis

RIF: Rifampicin

SCTLC: Sub-County TB and Leprosy Coordinator

SDR: Single Dose of Rifampicin

SDR-PEP: A Single Dose of Rifampicin as Post-exposure prophylaxis

TB: Tuberculosis

WHO: World Health Organization

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CHAPTER ONE

1.0 Introduction

1.1 Background

Leprosy is a neglected chronic bacterial infectious disease. Its etiological agent is *Mycobacterium Leprea*, a bacillus that causes anesthetic skin lesions, enlarged peripheral nerves, and acid-fast bacilli in skin smears as clinical sign. Globally, 10-12 million leprosy cases have been reported (Chen & Shui, 2022). In the past 20 years, over 17 million cases were treated, with India and Brazil reporting the highest (60%) proportion of new leprosy cases (WHO, 2021a). An estimated 2-3 million people have disabilities from leprosy, often due to late diagnosis and treatment, leading to muscle malfunction and disfigurement of the hands and feet (Chen & Shui, 2022). In 2019, the African continent had the second-highest proportion of new leprosy cases among the WHO regions, where Nigeria accounted for 40% of all leprosy cases notified (WHO, 2020).

Since 1989, Kenya has maintained a global leprosy eradication goal at the national level, adhering to the WHO reduction target of less than one case per 10,000 people (Nyamogoba et al., 2019), However, uneven re-emergence in specific regions poses a significant concern**.** Over 80% of Kenyan counties reported at least one active leprosy case from 2011-2021 (NTLDP, 2021). Many cases go unnoticed and undocumented. Spatial disparities in leprosy cases notification are unexplained. Counties near large water bodies in the western and coastal regions reported high proportions of leprosy cases over one decade period (NTLDP, 2021; Nyamogoba et al., 2019)**.**In 2019, approximately 7.5% of patients diagnosed in the country were children under 15 years against the global target of less than 3% (NTLDP, 2020)(WHO, 2020), an indication of

the active community transmission, fragile surveillance systems, and evidence of endemicity of the disease (Wangara et al., 2019). In 2021, 16.2%% of newly diagnosed patients had disability grade II against the global average of 6.7%, and the National target of 5% (NTLDP, 2021; WHO, 2020b). Chiefly attributed to either individual or healthcare system delays, requiring collaborative efforts to train healthcare workers to identify and evaluate leprosy cases early (Dharmawan et al., 2021). In 2019 and 2021, Kwale County reported 41% and 30% of Kenya's leprosy cases, respectively, contributing 20.3% (1162 cases) over a decade. In this regard, the study determines risk factors associated with leprosy disease development in Kwale County.

Multibacillary type of leprosy patients are the primary source of *Mycobacterium Leprea* occurrence in other people, with droplets from coughing and sneezing thought to be the primary transmission mode (Nery et al., 2019), Although there is no effective vaccine to prevent leprosy, approximately 85% of the world population have a natural immunity to the disease,15% may contract the disease when exposed to leprosy bacilli (Ofosu & Bonsu, 2011).

Understanding the factors that contribute to the occurrence of leprosy is essential to planning preventive and control measures for its eradication (WHO, 2018). Leprosy transmission still needs to be better understood (Ramona et al., 2021). Some investigators maintain that inhaling pathogenic bacteria-containing droplets (*Mycobacterium Leprea*) spreads leprosy (Nobre et al., 2017), Some argue that leprosy can be spread through close skin contact, animal and environmental reservoirs (Wheat et al., 2014). Most infected people are asymptomatic, but some develop signs and symptoms of infection and may develop abnormalities (Urgesa et al., 2022). The leprosy condition generally affects the skin and nerves in the extremities of the human body like the hands and feet, but the Multibacillary type is often more severe, affecting

the eyes and other tissues (Tiwari & Richardus, 2016). Skin lesions that range from hypopigmented patches to several nodules with major thickening of the skin become so much more frequent as the disease condition continues to progress (WHO, 2020).

People who live in close bodily proximity with Multibacillary type leprosy patients and are not on medication are most at risk of contracting leprosy (WHO, 2020). The typical length of time of incubation is five to seven years, but it can last up to 20 years (Ofosu & Bonsu, 2011). The reactions that cause nerve function loss constitute a significant contribution to chronic disability (Dos Santos et al., 2020), and the economic hardship associated with leprosy patients has worsened the life expectancy of severely disabled people, owing primarily to low poverty levels (Bekala et al., 2021).

Globally, understanding the progression of leprosy disease is incomplete due to the long incubation period, which is approximately three to seven years for Pauci bacillary disease and seven to seventeen years or longer for multi-bacillary disease (WHO, 2018). The long incubation period proves challenging to study the causal relationship between what happened at the time of infection and the first sign of the disease symptoms (Oktaria et al, 2018). The transmission of leprosy is not properly understood (Oliveira et al., 2019). Some scholars believe that leprosy can be spread through inhalation of particles that contain the bacteria (WHO, 2020), Some insist that the disease can easily be spread through skin-to-skin contact, environmental factors, and human-animal interaction (Ribeiro et al., 2023).

Age has been identified as a likely risk factor for developing leprosy disease (De Sousa Oliveira et al., 2019), other scholars have suggested that there is a linkage between the likelihood of developing leprosy and the age category of the index contact with leprosy individual who is not on any prophylaxis (Dos Santos et al., 2020). Once infected, a

vulnerable person has an incubation time frame of three to seventeen years or more before signs and symptoms of the disease appear (WHO, 2020). The male gender is more affected compared to females, with symptoms appearing in men after a decade or more of age (De Sousa Oliveira et al., 2019).

Children are more at risk of being affected in communities where *Mycobacterium Leprea* occurrence is endemic (Lima et al., 2020). Existing literature, on the contacts of Multibacillary individuals indicates that the likelihood for children to develop leprosy disease was higher compared to adults (De Andrade et al., 2019), The *Mycobacterium Leprea* occurrence chiefly affects the skin and peripheral nerves, but the more serious Multibacillary form mainly affects the eyes and other organs, potentially due to the long incubation timeframe and delayed detection of leprosy patients (Dos Santos et al., 2020). Previous studies have revealed a higher load of *Mycobacterium Leprea* occurrence in men than in women (Dharmawan et al., 2021), even with early detection for male and elderly populations in *Mycobacterium Leprea* occurrence (Teixeira et al., 2020). Multibacillary type of leprosy tends to occur in people with compromised cell-mediated immune responses and other vulnerable groups for Multibacillary types of leprosy (Muthuvel et al., 2017).

General knowledge among the rural communities on *Mycobacterium Leprea* occurrence is limited (Marega et al., 2022), in addition, the available literature on the transmission mechanism is inconclusive and numerous transmission modes are possible (Urgesa et al., 2022). Previous studies have suggested potential evidence suggesting that households experiencing food scarcity may contribute to malnutrition (Oktaria et al., 2018), subsequently resulting in an increased incidence of active *Mycobacterium Leprea* (Oktaria et al., 2022). A similar study by Wagenaar et al, in 2015, reported comparable findings, highlighting that households with limited income often have

insufficient resources to allocate to food (Wagenaar et al., 2015), leading to reduced intake of nutrient-rich foods and consequently increasing the likelihood of *Mycobacterium Leprea* occurrence and delays in seeking Health care service promptly (Wheat et al, 2014). Leprosy is understood to be a disease of poverty (Nobre et al., 2017), but the specific socioeconomic factors linked to *Mycobacterium Leprea* occurren*ce* are not well documented (Nery et al., 2019), Understanding the specific socioeconomic risk factors like low education attainment and low income for leprosy transmission is crucial (Marega et al., 2022; Ploemacher et al., 2020)

The World Health Organization views the substantial occurrence of new leprosy cases linked to grade II disability as an impactful indicator in the community in countries where the proportion of disability grade II above the global average of 5% is reported (WHO, 2021b). Programmatic challenges in the health system and patients' access to healthcare services might be the major contributors (WHO, 2021a), In addition, the WHO has categorized grade II disability as a more reliable measure of disease burden compared to leprosy prevalence (WHO, 2020a), emphasizing close monitoring on the proportion of patients diagnosed with varied degree of disability in endemic countries. This suggests that active transmission of leprosy disease is occurring in the communities, with advanced forms of the leprosy disease as reported in China where physical impairment at the time of diagnosis has been linked to a poor prognosis for deformities (Chen & Shui, 2022). The prolonged delay in case detection suggests the possibility of nerve damage and irreversible impairment.

Existing research findings from Brazil reveal that the Bacillus Calmette Guerin vaccine may have effects on improving outcomes for susceptible individuals such as children and the elderly in leprosy endemic regions (De Sousa Oliveira et al., 2019), despite the nonspecific nature of the BCG vaccine for *Mycobacterium Leprea*, studies further

document that approximately 50% effectiveness of the vaccine in protecting against *Mycobacterium Leprea occurrence* (Lima et al., 2020). Globally, Countries like Brazil, Colombia, Peru, and Australia, have demonstrated the administration of the second booster dose of the BCG vaccine to index contact of leprosy with the National Prophylactic Measure (Ribeiro et al., 2023), even though this is not recommended by the World Health Organization.

The findings from one of the studies in Brazil indicated that individuals not receiving any vaccine were 8.4 times more likely to develop leprosy (Lima et al., 2020). A similar study further revealed that a second BCG vaccination increases protection, resulting in a 95% decrease in relative risk (Lima et al., 2020).In addition, the varied outcomes about different male and female genders were observed in vaccination rates, with more females vaccinated (De Sousa Oliveira et al., 2019; Lima et al., 2020), suggesting a general trend of greater health awareness among women compared to men. Despite advances in understanding the molecular biology of *Mycobacterium Leprea* as reported in studies conducted in India and Mozambique, specific vaccines against leprosy are in the early stages of development and clinical evaluations (Barbosa et al., 2022; Marega et al., 2022).

Existing literature, suggests that cultural factors, such as the kinship nature of leprosy or its linkage with witchcraft in developing countries, the fear of social isolation, and the loss of identity, are all recognized as predictors associated with prolonged detection and notification of leprosy cases (Véras et al., 2021). Long et al,2021 from Brazil, attributed the challenges to probably the delay in patient detection times and are primarily rooted in individual patient or community-related concerns (Long et al., 2021). However, challenges posed by healthcare practitioners and health system-related factors, such as inadequate training on leprosy and its clinical signs and symptoms, as

well as difficulties in accessing health services, may also contribute to prolonged delays in case detection (Bekala et al., 2021). Previous studies have suggested that *Mycobacterium leprae* transmission may be influenced by behavioral and socio-cultural practices, such as bed linen change frequency, shared linen usage, and frequency of bathing in open water bodies (Emerson et al., 2020; Wagenaar et al., 2015).In rural communities setting, the person in charge of household duties (typically the mother) may decide not to frequently change the bedclothes if water is scarce, or irregular bedclothes may be a behavioral trait linked to a perception of poor hygiene (Emerson et al., 2020; Kerr-Pontes et al., 2006).

Household and environmental factors such as household crowding, house type, floors and walls, close contact with domestic animals, working on agricultural farms, and settling in forested areas, among others, are proxies for *Mycobacterium Leprea* exposure in human incidence (Shetty et al., 2018). The origin of leprosy within armadillos is still subject to debate, with the chances of laboratory spillover being given consideration (De Andrade et al., 2019).In Brazil, Positive samples confirmed that armadillos had leprosy before the laboratory results and further investigation on the geographic risk factors needs to be explored (Oliveira et al, 2019). Findings from the study conducted in Ethiopia suggest that household contacts, especially those in households with existing Multibacillary leprosy patients and older contacts, may have an increased risk of *Mycobacterium Leprea* occurrence (Urgesa et al., 2022).

Bacillus Calmette Guerin vaccination and treatment of the leprosy case reduce the risk of contacts contracting leprosy disease (Dos Santos et al., 2020; Teixeira et al., 2020) the detailed investigation of immune response changes induced by these measures, explaining the resulting protective effect (Long et al., 2021), is still necessary. Given the complex challenges in eradicating leprosy (Wangara et al., 2019), urgent measures

are needed to uncover the hidden aspects of leprosy and reduce morbidity and physical disabilities associated with the disease (Aceng et al., 2019).Thus, the prevention and control measures should include strategies for diagnosing, treating, and adhering to medication for Multibacillary types of patients (Anantharam et al., 2021). However, screening of people in communities usually focuses on identifying skin lesions with loss of sensation, although this may be absent in 30% of patients (Chen & Shui, 2022), especially those with advanced forms of leprosy. Carrying targeted outreaches and in-reaches in endemic communities as a strategy for early diagnosis could significantly reduce active transmission of *Mycobacterium Leprea* occurrence in the community (Lin et al., 2020).

1.2 Problem Statement

Despite the low number of reported cases, leprosy still causes significant morbidity and disability among those infected, with the vast majority (95%) being Multibacillary (MB) type of patients (NTLDP, 2021). Patients with a Multibacillary type of leprosy have worse symptoms and a prolonged illness progression in rural communities as individuals remain undiagnosed for long periods and is a thriving significant risk factor for leprosy transmission (Chen & Shui, 2022; Urgesa et al., 2022)

Kenya had reached the post-elimination stage of leprosy control by 1989, particularly after meeting the WHO elimination target of no more than one case per 10,000 people (WHO, 2021). However, statistics gathered by the Ministry of Health indicate that the country has seen a 6-fold increase in leprosy cases (26-163) over 10 years (NTLDP, 2021).

In addition,16.2% of all notified cases in 2021 were diagnosed with disability Grade II against the national target of <10% and the global average of 5.3% (NTLDP, 2021;

WHO, 2021b) . In 2019 and 2015, children below 15 years of age accounted for 7.5% and 15% of the total new cases detected in the country (NTLDP, 2021; Wangara et al., 2019) compared with the global and national target of less than 3% (WHO, 2020a), suggesting active leprosy transmission in the community and delays in patient detection.

The significant spatial epidemiological variations of most new leprosy cases detected in Kenya over 10 years have been documented in Kwale County (20.3%) (NTLDP, 2021), an indication of the need to determine the factors associated with *Mycobacterium Leprea* occurrence in the study area

1.3 Justification

Over the last decade, Kwale County reported higher leprosy case proportions compared to other regions. Research findings aim to inform the community and stakeholders on predictors of *Mycobacterium leprae* occurrence in Kwale County.

This study was conducted to reduce the knowledge gap about the factors associated with *Mycobacterium Leprea* occurrence by determining the social-demographic, behavioral, socio-economic, clinical, and environmental characteristics.

The findings from the study strengthen the county Health Management system to develop targeted strategies on how to combat and eradicate leprosy disease.

Identifying the predictors associated with *Mycobacterium Leprea* occurren*ce* in the County will help enhance a robust surveillance system for community-facility active case finding of leprosy cases.

Enhanced awareness of the specific risk factors for the disease incidence was essential to developing better strategies for early case detection in the study setting. The study

findings are to inform the County to initiate targeted household contact screening through community health promoters.

The study findings aim to bridge the epidemiological gap in leprosy transmission, aiding in the development of advocacy and community engagement strategies. Risk communication and community engagement networks can use these findings to alter social behaviors and reduce stigma, aiding leprosy control in the study setting.The study's findings can aid the county health management team, Ministry of Health, community members, and training institutions in identifying leprosy predictors, and in developing national and county guidelines for management, treatment, care, and control of the disease.

1.4 Research Questions

What factors are associated with *Mycobacterium Leprea* occurrence among people with leprosy in Kwale County?

1.5 Broad Objective

To determine the associated factors with *Mycobacterium Leprea* occurrence among people with leprosy disease

1.6 Specific Objectives

1. Identify social-demographic factors associated with *Mycobacterium Leprea* occurrence in Kwale County.
2. To determine the clinical factors associated with *Mycobacterium Leprea* occurrence in Kwale County.
3. To determine behavioral and socio-economic factors associated *with Mycobacterium Leprea* occurrence in Kwale County.
4. Determine the household and environmental factors associated with *Mycobacterium Leprea* occurrence in Kwale County.

CHAPTER TWO

2.0 Literature Review

2.1 Introduction

Leprosy is a chronic disease of the nervous system as well as the eyes, skin, and upper respiratory tract (Nobre et al., 2017). Even though a non-lethal and ultimately curable *Mycobacterial Leprea* usually causes leprosy. Delayed diagnosis and inadequate treatment may lead to economic hardship, stigma, and disabilities (Anantharam et al., 2021; Nery et al., 2019) A greater fraction of patients suffer damage to the nerve, necessitating ongoing care to prevent secondary damage (Dos Santos et al., 2020). The long incubation period for disease progression facilitates potential transmission and re-infection (An et al., 2017).

People of all ages and genders, particularly those in economically disadvantaged settings, are susceptible to *Mycobacterium Leprea* occurrence (Lin et al., 2020). Leprosy disease is a neglected tropical condition that primarily affects vulnerable and marginalized populations (Ploemacher et al., 2020). The drivers of the leprosy disease are still being studied (Long et al., 2021). It is an old disease that remains a global public health challenge in most of the countries in Sub-Saharan Africa like Kenya (Tiwari & Richardus, 2016).

In 2019, Globally, India contributed 60% of the leprosy burden followed by Brazil, Indonesia, and(Chen & Shui, 2022; Long et al., 2021). In Africa, the prevalence of leprosy has dropped from 57,516 cases back in 2000 to only 33,690 in 2010 (WHO, 2020). The figures represent a 42% decrease (WHO, 2021). The disease's rate of prevalence fell by 98% shortly after the introduction of multi-drug therapy in 1981, from 21.1 per 10,000 people in 1983 to 0.2 per 10,000 people in 2015 (WHO, 2021), however, its uptake throughout Africa has been extremely low, causing the prevalence

of the disease to remain significantly low (Nery et al., 2019), most attributed to inadequate reporting and notification of cases

In 2020, the African Region of WHO reported 16,690 new leprosy cases, with a detection rate of approximately 14.9 per 1 million inhabitants, a significant decrease from the 20,207 cases reported in the previous year (Ribeiro et al., 2023; WHO, 2020).

In Mozambique, WHO, notified 2,065 new leprosy cases in 2020, with 43.3% being female and 10.3% children under 15 years old. Additionally, 81.4% had Multibacillary type of leprosy, and 19.3% had grade II disability, with 12.8% notified being children (Marega et al., 2022; WHO, 2020). The presence of disability due to peripheral nerve damage at the time of diagnosis is considered an indicator of delayed detection (Dharmawan et al., 2021). Early notification and prompt treatment of cases are important to prevent disabilities observed in patients (Muthuvel et al., 2017).

In Kenya, the disease has had a resurgence in some parts of the country in the coastal strip, and the western region of the for over a period of 10 years (Nyamogoba et al., 2019). Data reported by the Ministry of Health indicates that Over a 10-year period, the Coast and Western regions notified 64,4% and 14% of all leprosy cases reported in the country (NTLDP, 2021). This might be an indication of the re-emergence of active leprosy transmission in rural communities. In addition, it might suggest the likelihood of more leprosy cases being missed in the community due to inadequate surveillance structures at level one (Marega et al., 2022).

In 2021, 95% of those diagnosed had the Multibacillary type of leprosy (NTLDP, 2021), the advanced form and most infectious type of leprosy suggest active local transmission of the disease in the region (NTLDP, 2021).

In 2021, approximately 16.2% of leprosy cases were diagnosed with disabilities grade II, compared with the global average of 6.7% (Chen & Shui, 2022), which might be attributed to the patient, healthcare system delays, or both.

The study's goal is to identify factors that increase the likelihood of *Mycobacterium Leprea* occurrence among the people of Kwale County. A significant challenge in leprosy management, prevention, and control is the prolonged incubation period, spanning from two years to even more than two decades (Oktaria et al., 2022).

Multidrug therapy (MDT) has been the primary approach for leprosy control since introduced by the WHO in the 1980s (Shetty et al., 2018). However, its uptake in Sub-Saharan Africa is low. (WHO, 2021). The findings from other documented studies reported in Brazil and Columbia have shown the effectiveness of a single dose of rifampicin (SDR) as an intervention on post-exposure prophylaxis(PEP) when administered to contacts of leprosy patients(Ribeiro et al., 2023)(Schoenmakers et al., 2021).

In 2018, the World Health Organization (WHO) recommended implementing chemoprophylaxis with SDR-PEP in their guidelines (WHO, 2020a). Ongoing studies have indicated positive outcomes on the implementation and feasibility of rifampicin as leprosy post-exposure chemoprophylaxis (Schoenmakers et al., 2021).

Various barriers, including cultural or religious beliefs, social stigma, lack of education, fear of isolation, and weak surveillance structures in the healthcare system contribute to the delay in early case detection for both the individual and healthcare system structures (Anantharam et al., 2021). *Mycobacterium leprea, a* specific immune reactive component (antigens) can be demonstrated in the lesions (in skin scrapings, biopsy homogenates, and histopathology sections) by immunological methods (Das et

al., 2020; Ebenso et al., 2019). Some of the antigens persist for a long time after bacterial death, their presence will not correlate with the clinical activity (Long et al., 2021). The methods used for the diagnosis of leprosy disease Include but are not limited to the nucleic acid sequences by genomic probes which are done by using labeled complementary DNA/RNA sequences as probes, Polymerase Chain Reaction (PCR) methods which are more sensitive than immunological approaches (Barbosa et al., 2022; WHO, 2020a). Genomic probes may be immensely helpful for the diagnosis of early atypical Paucibacillary cases and for mass confirmation of diagnosis for epidemiological and research purposes. Leprosy is characterized by well-recognized pathological changes (Oktaria et al., 2022). These pathological characteristics are strikingly different from other infectious diseases because of the unique features of *Mycobacterium Leprea* (WHO, 2020). Leprosy patients, particularly those diagnosed with Multibacillary type of leprosy are the main source of transmission with worse symptoms among the population (Nobre et al., 2017). *Mycobacterium Leprea* is discharged into the environment in large numbers through nasal secretions and from skin ulceration of Multibacillary patients and armadillos (Das et al., 2020). Two common portals of entry are- abraded skin and nasal mucosa (Nery et al., 2019). Various factors like age, sex, race, nutrition, can influence the outcome of the infection (Pescarini et al., 2018).

2.2 Social- Demographic

Communal predictors likely to contribute to delayed patients in seeking health care as documented in an Ethiopian study may include but are not limited to health service-related issues and individual factors such as advanced age, male gender, a limited understanding of the cardinal signs and symptoms of the disease, Multibacillary leprosy type, and a lack of knowledge on main signs and symptoms (Dharmawan et al., 2021).

2.3 Clinical descriptions

2.3.1 Clinical diagnosis

Leprosy diagnosis requires a higher level of clinical suspicion (MOH, 2021), physical examination and clinical history are essential in diagnosing leprosy where one or more of the following signs are observed; skin lesions and palpation of peripheral nerves for sensitivity or swelling (WHO, 2020a), neck (great auricular nerve, clear demarcated hypopigmented skin of the feet or face with thickening of subservient sensory or motor nerves) (Das et al., 2020).

Multiple skin lesions of different sizes and shapes; extensive nerve damage (WHO, 2021). The nasal discharges contain potentially infectious *Mycobacterium Leprea* (WHO, 2021), where the patients are highly contagious. 19-60% of oral lesions in air-cooled sites have become more common (WHO, 2020a).

2.3.2 Classification of leprosy

The classification of leprosy disease is mainly categorized as per the Riddley and WHO categories as discussed below in Table 1.

2.3.2.1 Multibacillary Type of leprosy

People with Multibacillary (MB) type of leprosy often exhibit more severe and serious symptoms and a prolonged disease course of treatment and management (WHO, 2021b).In addition, they also have a lower probability of being cured compared to those with paucibacillary (PB) type leprosy (Urgesa et al., 2022). It is widely reported that in the Multibacillary type of leprosy, the immune system tends to favor a humoral immune response, which is insufficient in restricting the multiplication of *Mycobacterium Leprea* occurrence (Urgesa et al., 2021). The prevalent levels of disability reported in most developing countries underscore hurdles in early patient detection and treatment

(Urgesa et al., 2022). If patients had the opportunity for early diagnosis, they could have achieved recovery from the disease (Anantharam et al., 2021).

Table 1: Riddley and WHO classification

Ridley Jopling Classification	World Health Organization Classification
Tuberculoid leprosy (TT.) and Borderline Tuberculosis (BT)	**Paucibacillary leprosy** ▪ Zero to five skin lesions linked to leprosy ▪ Skin smear reveals negative within all the sites ▪ Distribution of lesions is symmetrical ▪ Prospects of recovery are good ▪ Severity of the disease is mild ▪ Pale/hypopigmented or reddish skin patches ▪ Thickening of the subservient sensory or motor nerves ▪ Loss or decreased sensation in the skin patch ▪ Severity of the disease is mild
Borderline (BB), Lepromatous (LL), and Borderline lepromatous (BL)	**Multibacillary leprosy** ▪ Six or more skin lesions ▪ Skin smear positive at any part of the body ▪ Distribution of lesions is symmetrical ▪ Prospects of recovery from the disease are possible with irreversible, permanent disabilities or deformities ▪ Punched out hypopigmented anesthetic centers; widespread on the nerves. ▪ Highly infectious, the nasal discharges contain potentially infectious *Mycobacterium Leprea*. ▪ The severity of the disease is exceptionally extreme if there is no treatment, and the patient can even die

Source;(Laza, 2018)

Tuberculoid Leprosy: Tuberculoid leprosy affects skin and peripheral nerves, lesions are usually seen on the face, dorsal aspects of extremities, and trunk (De Sousa Oliveira et al., 2019). Skin lesions are single or very few with sharp borders, central clearing may be seen with hair loss, and the regional nerves are enlarged with loss of pain and temperature sensation (World Health Organization, 2015), touch sensation may be preserved (Dos Santos et al., 2020), In the face, the impairment may not be as evident as in other areas (Bekala et al., 2021). Skin smears are usually negative for Acid-Fast Bacillus (WHO, 2018).

Histopathology: Tuberculoid leprosy is characterized by its well-marked tissue resistance to *Mycobacterium Leprea*, and the disease tends to be localized, rarely focal areas of fibrinoid or caseous necrosis may be seen. Acid-Fast Bacillus (AFB) is very rare and difficult to demonstrate (Muthuvel et al., 2017).

Borderline Tuberculoid Leprosy: The skin lesions are usually either macules or plaques (MOH, 2021). They may be single or multiple (10-20) which may vary in size and shape, margins may be regular and raised, and few have irregular margins (WHO, 2021). Satellite lesions may be seen and hypopigmentation, dryness, and scaling are less severe compared to TT, hair growth is diminished over these lesions (Shetty et al., 2018).

Peripheral nerves are enlarged in an asymmetrical pattern with loss of sensation over the lesion and the skin smears may be positive for Acid-Fast Bacilli (WHO, 2021a).

Borderline Borderline (BB): This is the most unstable and rare form of leprosy (WHO, 2020a). Many skin lesions that vary in size, shape, and distribution are seen (Ploemacher et al., 2020). Lesions are macules, plaques and papules (Laza, 2018).

They may be punched out with ill-defined sloping of outer margins. Hair growth is moderately diminished; nerve enlargement is asymmetrical with mild to moderate loss of sensations (Ebenso et al., 2019).

Borderline Lepromatous Leprosy: Lesions are widespread over the trunk and extremities (Li et al., 2021). They are macules, papules, and plaques, Macules are distinct but vary in size and are arranged quite symmetrically (Long et al., 2021). Lesions are smooth and shiny with a slight decrease in sweating and hair growth (Peripheral nerves are enlarged, with impairment of sensation, and skin smears show many bacilli, often clumps and globes (WHO, 2020a).

Lepromatous Leprosy: Lesions are widespread and present all over the body, macules, papules, and nodules are present on the face, ears, wrists, and elbows, and the lesions are bilaterally symmetrical (WHO, 2020a). Macules are slightly hypopigmented, shiny, and sometimes erythematous, sensation is slightly impaired with loss of sweating and hairs; peripheral nerves are enlarged (Li et al., 2021). Nodular lesions on the face coalesce together, with loss of eyelashes, eyebrows, and depression of the nasal bridge to give characteristic leonine facies (WHO, 2021a). There may be trophic ulcer formation at the extremities (MOH, 2021), muscle wasting and weakness, lymphadenopathy, involvement of eyes, testis, and other systemic organs, and skin slit smear showing plenty of AFB with many globes (Long et al., 2021).

2.3.3 Disability Grading

Close to 15% of the population of the world is disabled in some way (Véras et al., 2021). Physical impairment caused by leprosy is typically attributable to neurological loss caused by *Mycobacterium leprea*, induced chronic granulomatous inflammation (Chen & Shui, 2022). Disabilities can result from impairments, like limitations in activities requiring the application of eyes, feet, and hands together with associated stigma in social participation (Van Brakel. et al.,2018). Early diagnosis, evaluation, and management of leprosy cases play a pivotal role in averting disabilities (Dharmawan et al., 2021).

In an Ethiopian study, they reported that grade zero was predominantly linked to an early diagnosis of new patients (Barbosa et al., 2022), whereas grade II disability was chiefly associated with a delayed diagnosis time frame and in Some instances rapidly progressed to irreversible deformity within one to two years of symptom onset (Muthuvel et al., 2017).

The World Health Organization's adoption use of the Mult-drug therapeutic combnation (MDT) approach for leprosy in the 1980s marked an important period in managing leprosy disease (Gashu et al., 2021). A Study in Mozambique reported that when neuritis occurs in patients who do not receive quality treatment, the condition might become chronic, leading to the development of permanent leprosy-related disabilities (Marega et al., 2022). In addition, due to the low numbers of leprosy patients being notified globally, clinicians have little clinical argument on the leprosy presentations (Dharmawan et al., 2021), which could lead to a delay in diagnosis. Peripheral nerve damage develops during this time, resulting in permanent disability (Chen & Shui, 2022).

Understanding the characteristics of nerve involvement would thus help the clinicians in detecting leprosy early, and avoiding a delayed diagnosis (Anantharam et al., 2021). A similar study conducted in China found that the high proportion of disability grading at diagnosis reflects low levels of disease awareness in the community as well as the health system's inability to detect new cases early (Chen & Shui, 2022). Existing literature, in Somalia revealed that the proportion of individuals experiencing grade II impairments stood at 42.1%, in contrast to the global mean of 6.7% (Urgesa et al., 2021).

Other researchers document that grade II disability provides insights into other health system-related factors influencing the notification of cases, such as community awareness regarding leprosy, the ability of healthcare workers to identify the signs and symptoms early, and, to some extent, the quality of leprosy health services (Muthuvel et al., 2017). Due to these considerations, other researchers have documented the need to minimize delays in patient detection and prioritize interventions capable of notifying leprosy cases before visible deformities manifest into permanent disabilities (Tiwari &

Richardus, 2016). Addressing delays in leprosy patient identification requires an understanding of the individual patients and community-rooted predictors, facilitating the evaluation, planning, and execution of appropriate public health approaches (Ebenso et al., 2019).

2.3.4 Multidrug Therapy (MDT)

The primary intervention method in leprosy control is to provide multi-drug therapy to newly diagnosed individuals with leprosy, Other than raising awareness and providing health education,(WHO, 2021b). In addition, It has been widely recognized that eliminating leprosy using one strategy is almost impossible to achieve the elimination status in developing countries (WHO, 2020a). The new techniques like the adoption of the Single dose of rifampicin as prophylaxis for leprosy close contacts and active case finding in the community when adopted and used by the host countries will manage to control and eliminate leprosy disease (Ribeiro et al., 2023).

Clinical diagnosis of leprosy depends on recognizing signs and symptoms of the disease confirmed after the disease has manifested itself (Marega et al., 2022). Establishing whether someone with leprosy contact has been infected with *mycobacterium leprae* is always essential where they could be given prophylactic treatment to minimize the spread of leprosy disease (Tiwari & Richardus, 2016; WHO, 2021b). The table below summarizes the treatment guidelines for leprosy patients for both children and adults. (Table2)

Table 2: Management and Treatment Regimen

Age categories	Drug	Drug Dosage and	Duration	
			Multibacillary	Paucibacillary
Adults	Rifampicin	600mg once a month	Twelve months	six months
	Clofazimine	300mg once a month and 50mg daily		
	Dapsone	100mg daily		
children	Rifampicin	450 mg once a month	Twelve months	six months
	Clofazimine	150mg once a month and 50 mg on alternate days		
	Dapsone	150mg once a month and 50 mg on alternate days		
children below 10 years old or below 40 kg	Rifampicin	150mg once a month and 50 mg on alternate days	Twelve months	six months
	Clofazimine	150mg once a month and 50 mg on alternate days		
	Dapsone	2 mg/kg daily		
Treating children with weight below 40 kg requires a single formulation of medication since no Multy Drug Therapy (MDA) blister packs are available for children between 20kg and 40kg. It would be possible to follow the instructions in the operational manual. Global leprosy strategy 2021-2030 on how to partly use the (child -MB) blister packs for treatment (MB)				

Source:(MOH, 2021)

2.3.5: Diagnostic test

Bacteriological(Slit skin smear): Skin smear samples can be taken from extremities of the body heavily affected such as patch nodule areas in the ear lobes (MOH, 2021). In the affected part you, pinch the site tightly, incise, scrape, and collect the sample, smear on the slide, air dry and fix, and finally stain with the Ziehl-Neelsen stain (NTLDP, 2021)).In practice, skin smears are taken from active skin lesions as well as the peripheral extremities of the ear lobes.

Molecular technique; Polymerase chain reaction is a sophisticated technique for detecting *Mycobacterium Leprea* and determining drug resistance (Wagenaar et al., 2015). Polymerase chain reaction is a quick and accurate method that does not need

bacterial culture. However, its field usage is still minimal (Schoenmakers et al., 2021). *Mycobacterium Leprea*-specific phenolic glycolipid (PGL)-1 antibody testing has been in use for several years (MOH, 2021), however, this is common only among patients who are suffering from mycobacterium leprea spectrum of the condition (Das et al., 2020).

It's reported that there has been a major advancement in developing serological tests, such as ELISA procedures and using markers other than PGL-1. Although, their merits over PGL-1 serology are debatable (Shetty et al., 2018).

Histology; Excisional skin biopsies were collected and preserved for diagnostic purposes(An et al., 2017). On the other hand, skin or nerve biopsies undergo histological examination through the application of techniques such as Ziehl-Neelsen (Das et al., 2020).

2.4 Behavioral and socio-economic

Recent investigations published in Ethiopia and China have uncovered a possibility of a direct linkage between delayed case notification of leprosy patients and the prevalence of grade II disability (Chen & Shui, 2022; Dharmawan et al., 2021), indicating that prolonged healthcare-seeking behaviors are always associated with more severe outcomes for leprosy patients like irreversible disability (Ramona et al., 2021). Similarly, socioeconomic factors associated with prolonged leprosy case notification encompass residing in rural areas, engaging in daily wage labor, unemployment, and experiencing stigmatization (Muthuvel et al., 2017).

The findings from a study conducted in India concluded that healthcare-seeking behavior is a complex issue with unique challenges varying among countries, involving intricate social, cultural, historical, and economic aspects (Dos Santos et al., 2020).

These factors collectively shape communal perspectives, indirectly influencing the severity of *Mycobacterium Leprea* transmission (Barbosa et al., 2022).

Over the past four decades, various countries including Kenya and Mozambique have witnessed steady notification of leprosy cases, suggesting the active communal epidemiological transmission of *Mycobacterium Leprea* (WHO, 2020), in addition, the WHO advocated for the adoption of Treatment and Diagnostic Guidelines for leprosy disease, and various clinical trials assessing the efficacy of rifampicin intervention, specifically as post-exposure prophylaxis (PEP) which demonstrated effectiveness. The adoption involved administering single-dose rifampicin (SDR) to known contacts of leprosy patients(WHO, 2021a)

2.5 Household and Environment

Human-to-human transmission of *Mycobacterium Leprea* among household contacts of leprosy cases is significant in areas where studies have been conducted in African settings like Ghana and Ethiopia (Anantharam et al., 2021; Ofosu & Bonsu, 2011).

contact surveillance is critical to interrupting the transmission chain of leprosy disease (Das et al., 2020). Unfortunately, in vitro bacterial culture is impossible (An et al., 2017).

knowledge of *Mycobacterium Leprea* transmission is limited, in addition, the available literature on the transmission is inconclusive and numerous modes of spread might be possible as suggested by various scholars (Marega et al., 2022). The environment is what is within the surroundings (Wheat et al., 2014), which implies that *Mycobacterium Leprea* subsequently infects a new host (Tiwari & Richardus, 2016). The genome sequencing of *Mycobacterium Leprea* has been the most exciting scientific breakthrough where genome-based technology increases the likelihood of future

elimination of leprosy including molecular epidemiology (Long et al., 2021), as well as improves the overall diagnostic tests (Long et al., 2021).

In the current epidemiological situation, intensified, population-based, and case-based approaches are appropriate (Muthuvel et al., 2017; Wagenaar et al., 2015). Though, in endemic countries, new cases are common, healthcare resources are limited due to competing healthcare demands (Marega et al., 2022). The primary risk of leprosy disease as documented by other scholars in Ethiopia and Ghana is prolonged exposure and being in close contact with new, untreated leprosy patients (Marega et al., 2022; Ofosu & Bonsu, 2011). Household contacts will account for an increasing proportion of new patients (Teixeira et al., 2020). Consequent to that, contact tracing is helpful in the control of leprosy disease (Ebenso et al., 2019; WHO, 2021c)

2.6 Risk Factors

2.6.1 Social-demographic

2.6.1.1 Age and Sex

An observational study done by Nobre et al in Brazil,2017, found that elderly men had twice the odds of developing a Multibacillary type of leprosy compared to women and children cases (OR = 2.36, 95% CI 2.33–2.38) (Nobre et al., 2017), in addition, a similar study done in India reported that the pooled estimates for leprosy were associated with being male (RR = 1.33, 95% CI = 1.06–1.67) (An et al., 2017), compared to females which might have been attributed to long contact of exposure to infection by male gender, poor health seeking behavior associated with men which results in delayed diagnosis (Lin et al., 2020). Despite early detection, the study found that *Mycobacterium Leprea* load is higher in men than in women (An et al., 2017).

The study proposes that specific disease control strategies be implemented to efficiently reach elderly people in regions where leprosy is prevalent (Ebenso et al., 2019). People

who have a low cell-mediated defensive reaction to *Mycobacterium Leprea* generate an elevated bacillary strain and are the primary source of infection in Multibacillary leprosy (Shetty et al., 2018).

Other findings from similar studies report that the male gender has been proven to exhibit a higher susceptibility to leprosy disease compared to women (Bekala et al., 2021), in most cases they experience cardinal symptoms earlier or during the first or second decade of life or later (Wheat et al., 2014).

Contrary, other recent studies have shown a decreasing proportion of leprosy cases being notified among the male gender, potentially attributed to increased leprosy detection among women over time and/or changes in exposure levels to different risk determinants in men and women (Das et al., 2020; Li et al., 2021)

2.6.1.2 Education Status:

In most studies, high literacy, and education levels were linked with lower *Mycobacterium Leprea* occurrence (Nery et al., 2019). Other scholars have attributed that basic education levels for both genders can increase health knowledge, advocate for good behaviors, improve access to better working conditions and resources, and foster greater economic stability, potentially reducing *Mycobacterium Leprea* occurrence among community members (Oktaria et al., 2018). As a result, prevention strategies should include measures to diagnose and treat Multibacillary cases (Nyamogoba et al., 2019). Conducting focused campaigns in endemic communities as a strategy for early diagnosis may help reduce active transmission of *Mycobacterium Leprea* occurrence in the community (WHO, 2020a). Other Studies in Southeast Brazil have strongly revealed the linkage of leprosy disease with individuals of all ages and genders, particularly in families residing in resource-constrained environments (De

Sousa Oliveira et al., 2019). Scholars from India indicated an elevated incidence of leprosy among contacts with low educational status (Richardus, 2013). Previous studies have also suggested a connection between education levels and the prevention of leprosy transmission in rural communities (Oktaria et al., 2018), particularly among kinship members (Nery et al., 2019). Individuals with no formal education are more likely to be diagnosed with *Mycobacterium Leprea* occurrence compared to those with formal education (van Brakel et al., 2012), as they may lack knowledge on disease transmission prevention.

The findings from the study conducted in Indonesia indicated that the high proportions of leprosy cases notified among household contacts of individuals with a Multibacillary type of leprosy could be attributed to prolonged exposure levels in the household (Ramona et al., 2021). Similar studies conducted in Brazil further revealed enhanced rates of leprosy detection among elderly male contacts (Das et al., 2020; Véras et al., 2021)

However, it is indicated that an index of leprosy patients was first reported in the household, contacts with education beyond the primary level may exhibit enhanced leprosy knowledge (Oktaria et al., 2022), good health-seeking behaviors, and access to health services, potentially leading to higher case detection rates (van Brakel et al., 2012).

2.6.2 Clinical Risk Factors

Several studies have reported that clinical factors such as type of leprosy, family contact, Social contact with known leprosy patients (Pescarini et al., 2018), malnutrition, and the existence of a Bacillus Calmette Guerin mark on the left forearm are both predisposing and protective factors for *Mycobacterium Leprea* occurrence

(Lima et al., 2020; Wagenaar et al., 2015), close Contacts of leprosy patients might have higher odds to contract the illness.

2.6.2.1 BCG

The research findings done in Ghana by Ofusu et al, in 2011 revealed that the presence of a Bacillus Callmette Gurine scar on the left upper arm had a substantial difference in the study between cases and controls (Ofosu & Bonsu, 2011), where the cases were two times likely to be protected against disease, compared to the controls (OR 11 95%CI 2.12-76.17 p= 0.0005). The results of the study were similar to what was reported in other research findings where individuals with a successful Bacillus Callmette Gurine(BCG) vaccination showed that Bacillus Callmette Gurine partly protects against Leprosy disease (OR 5 0.48; 95% CI 0.33-0.70).

The use of chemotherapy to prevent leprosy has progressed and gained use in countries where clinical trials have been reported like Brazil (Lima et al., 2020). The interventions have focused primarily on contact with leprosy patients (Pescarini et al., 2018). Chemoprophylaxis is considered to be very cost-effective, though much study is needed to establish its overall feasibility (Ribeiro et al., 2023).

The main aim here is to produce a test result based on immunologic signals that distinguish persons who manage bacterial replication from those who get the disease (Schoenmakers et al., 2021). Extensive research is currently being conducted to come up with more specific diagnostic tools (Schoenmakers et al., 2021). The results of such tests may influence the type of strategy provided to the contacts of leprosy patients (Schoenmakers et al., 2021), for example, the use of Multidrug therapy and the use of Rifampicin as a single dose to the close contact of the leprosy cases as the chemoprophylaxis interventions (Lima et al., 2020; WHO, 2020a). Similar studies

documented in Brazil indicate that 83.33% of household contacts with no leprosy index cases and who received at least one vaccination had a lower risk of developing leprosy compared to those who did not receive any doses (Nery et al., 2019).

2.6.2.2 Disability Grading

According to the WHO, a large percentage of new leprosy cases linked to grade II limitation is a significant characteristic that suggests delayed identification, operational challenges in the health system, and impediments to patient access to healthcare services (WHO, 2021b). In addition, the WHO has designated a grade II impairment as a better indication of disease severity than disease prevalence, where the number of patients starting treatment at the end of the year's calendar is closely tracked (WHO, 2020a). This indirectly, adds to the evidence that the ongoing spread of leprosy illness continues in the community, with advanced forms of the illness still prevalent (Urgesa et al., 2021).

In a similar research finding in China by Chen et al in 2022, they reported that physical impairment at the time of diagnosis has been linked to a poor prognosis for deformities (Chen & Shui, 2022). Where the prolonged delay in case detection suggests the possibility of nerve damage and irreversible impairment (Marega et al., 2022). A separate investigation conducted in China discovered that a significant percentage of disability grading at diagnosis indicates a limited local understanding of illnesses as well as the medical system's incapacity to detect new cases early (Chen & Shui, 2022). In a study done in Somalia, the proportion of people with grade II disabilities was 42.1%, compared to the global average of 6.7% (Dharmawan et al., 2021). Proportions of disability grading greater than 5% are thought to reflect delayed case detection (WHO, 2020a). According to an Ethiopian study, grade zero disability was associated with a more brief examination frequency among new cases, while grade II disability

was associated with a more prolonged diagnosis time frame (Bekala et al., 2021), and some cases rapidly progressed to permanent disfigurement within one to two years of symptom onset (Urgesa et al., 2022). Other patients, despite a disease duration of more than ten years, did not advance to permanent disability (Urgesa et al., 2021). The WHO's adoption of multidrug therapy in the 1980s was a watershed moment in the control of *Mycobacterium Leprea* occurrence (WHO, 2021b). Over the last three decades, many countries have seen consistent case detection (Muthuvel et al., 2017), implying community epidemiological transmission of *Mycobacterium Leprea* (Dos Santos et al., 2020).

In 2018 the WHO recommended that the Treatment and Diagnostic Guidelines be adopted as post-exposure prophylaxis with single-dose rifampicin administered to leprosy patients' contacts is one of several experiments on the use of rifampicin intervention that have established to be beneficial (Schoenmakers et al., 2021). Furthermore, due to the low numbers of leprosy cases being reported, clinicians have little clinical argument on the leprosy presentations, thus prolonged identification of leprosy patients (WHO, 2018). Indirectly, recognizing the features of neurological damage would thus aid clinical workers in confirming leprosy early and avoiding a later diagnosis (Ramona et al., 2021). Besides the global success in leprosy control, prolonged diagnosis and resulting grade II disabilities remain significant public health challenges (Dharmawan et al., 2021). The prolonged delay in patient detection demonstrates a likelihood of nerve damage leading to the progression of permanent disability (Muthuvel et al., 2017).

2.6.2.3 Malnutrition

Malnutrition's precise significance to susceptibility to leprosy and progression to the clinical stage is uncertain because the majority of data comes from other diseases,

particularly tuberculosis, identifying whether or not leprosy is a consequence or a result of nutritional deficits is challenging (Oktaria et al., 2018; Wagenaar et al., 2015). *Mycobacterium Leprea* is an intracellular pathogen, and immune responses that involve cells play an important role in human resistance (WHO, 2021a), protein-energy malnutrition and adequate vitamin and mineral intake have been linked to decreased immune response immunity (Das et al., 2020).

The study hypothesizes deficiencies will cause the body to respond to *Mycobacterium leprae,* resulting in clinical disease (Wagenaar et al., 2015), in addition, poor people have little or no money to spend on food and consume fewer animal-sourced foods, and fruits, and vegetables as a result they become vulnerable to *Mycobacterium Leprea* transmission (Oktaria et al., 2018). Research findings revealed in Brazil, that there may be a possibility of association between high rates of leprosy cases notified in endemic regions with households experiencing food scarcity coupled with poverty in rural communities (Nery et al., 2019). Interestingly, other scholars have not documented a connection between leprosy and food shortage in households with low socio-economic status (Anantharam et al., 2021).

2.6.3 Behavioral and Socioeconomic

2.6.3.1 Behavioral

Studies have suggested that even in harsh environments, *Mycobacterium Leprea* can endure for months without a host (Oliveira et al., 2019). *Mycobacterium Leprea* may remain in the bed linen or clothing items if not frequently cleaned allowing for more time for contact and spread to the client (Wheat et al., 2014). Studies done in Brazil revealed that a low frequency of changing bed linen (OR 5.81; 95% CI 1.30-2.52), regular weekly baths in open water bodies (OR 5 1.77; 95% CI 1.12-2.81), such as rivers and swamps as being associated with an increased risk of *Mycobacterium Leprea* transmission (Ploemacher et al., 2020). Bathing in open water bodies is common in our

rural homes, including communities living along larger water bodies (Oliveira et al., 2019), similarly, communities living along larger bodies of water rely on fishing as an economic activity (De Andrade et al., 2019).

Studies conducted in Brazil have documented that water can act or has been proposed as storage for *Mycobacterium leprae* to thrive (Ploemacher et al., 2020). A similar study done by Hansen and Looft, 2019 revealed that leprosy lesions in patients were most commonly found on the feet in Norway's West Coast, where leprosy disease was endemic during the nineteenth century. Many walked barefoot and crossed swamps to get to their neighboring villages. Hansen et al, also discovered that walking barefoot aided in *Mycobacterium Leprea* occurrence (Goulart et al., 2008). Another study in Brazil reported a strong link between leprosy and frequent water contacts, such as rivers and lakes (Nery et al., 2019), suggesting that the people had inadequate access to clean water for domestic use, where both the animals and human beings use the same source of water for domestic and recreation purpose (Ploemacher et al., 2020), even in cold-climate nations, *Mycobacterium Leprea* can persist and thrive in water plants such as Sphagnum specie (Das et al., 2020).

In other studies reported globally, social and cultural settings have played an important role in leprosy transmission prevention and remain vital in any country to reducing the leprosy burden in both contacts and across the populations (Ebenso et al., 2019). Existing literature on leprosy indicates that cultural factors such as leprosy being inherited or being associated with witchcraft in the African setting, fear of being lonely, and loss of identity have all been demonstrated to interfere with early cases being identified (Urgesa et al., 2021). These might all be community-related challenges that may be linked with prolonged case detection (Véras et al., 2021), however, Health care workers and health service-related factors, such as inadequate training on leprosy and

leprosy-related symptoms and health service inaccessibility might contribute to the prolonged delay in case detection (Ebenso et al., 2019).In similar study done in Brazil by De Sousa Oliveira et, al in 2019, reported that neuritis can become endemic in people who do not receive effective treatment, leading to the development of persistent leprosy-related impairments (De Sousa Oliveira et al., 2019).

2.6.3.2 Socio-economic

In cohort research in Brazil, the results showed that those with the lowest degree of education attainment as the head of the household had the greatest rise in leprosy risk (Pescarini et al., 2018), with a two-fold greater than those who completed their education after high school (2.09, 1.62-2.72). Similarly, those with an average income of less than 0.25 times the minimum wage were 40% more likely to contract leprosy than those who earned more than the minimum pay (1.46, 1.32-1.62; 1.47, 1.34-1.61) (Nery et al., 2019). This was consistent with research done in Northeast Brazil, which discovered a link between leprosy incidence and low levels of education (aOR 5.87; 95% CI 1.29–2.74) (Nery et al., 2019).

Additionally, the cohort study revealed that leprosy was linked to a significant increase in households without access to waste disposal at 1.35 (1.30-1.40) in the overall cohort and 1.55 (1.37-175) (Pescarini et al., 2018). In addition, food scarcity, which causes hunger (aOR 5.54; 95% CI 1.45-1.63), is a common characteristic of households with lower incomes (Wagenaar et al., 2015). This is thought that poor nutrition impairs the immune system, leading to *Mycobacterium Leprea* occurrence. (Anantharam et al., 2021).

Studies documented in Ethiopia have revealed a possible connection between water and potential routes of *Mycobacterium Leprea* occurrence (Emerson et al., 2020). However,

there is limited scientific information on sanitation as a potential transmission route as reported in a similar study (Emerson et al., 2020).

Findings from a study done in Brazil, in 2020, indicate that soil analysis has shown the presence of *Mycobacterium Leprea*, but the mechanism of transfer from person to inanimate objects remains unexplained (Ploemacher et al., 2020). It is possibly thought that the shedding from the skin, rather than stool, is the likely mode of transmission, as *Mycobacterium Leprea* is not known to be excreted in the stool (Emerson et al., 2020). Open defecation has been linked to leprosy in Ethiopia, serving as an indicator closely associated with factors such as low socio-economic status exposure to soil-related infections, and household crowding, thus facilitating the risk of *Mycobacterium Leprea* occurrence (Emerson et al., 2020).

Further, a similar study on WASH (Water, Sanitation, and Hygiene) indicators in Ethiopia reported low basic sanitation levels, especially in populations diagnosed with leprosy disease (Emerson et al., 2020), suggesting a correlation between leprosy endemicity and low WASH (Water, Sanitation, and Hygiene)-related indicators like open defecation, inadequate handwashing practices, and poor sewerage disposal (Ploemacher et al., 2020). The study further revealed that the majority of people with leprosy had access to an improved water source, but twenty percent had water access in their households, suggesting inadequate access to clean water (Emerson et al., 2020).

Sanitation facilities were lacking for some individuals, and none had access to a functional toilet at homesteads or shared with neighbors, more than fifty percent of leprosy patients lacked access to soap and water for handwashing (Emerson et al., 2020). Limited water sources, lack of decent premises, water access, absence of soap,

poor handwashing practices, and open defecation were associated with a higher proportion of leprosy cases being reported (Emerson et al., 2020).

2.6.4 Household and Environment

2.6.4.1 Household contacts

A study conducted in Ghana's Sene District showed that close contact with an individual who is suffering from leprosy within the same household was closely linked to later developing leprosy disease (Ofosu & Bonsu, 2011). However, this is not in agreement with a similar study done in Indonesia where the multivariate analysis results demonstrate that close contact was not linked with the manifestation of leprosy (OR - 0.72 95% CI 0.11-4.61; (Oktaria et al., 2018). Another study done in Brazil by Das et al,2020, revealed that leprosy direct mode of spread is still unclear (Das et al., 2020), it has been discovered that long-term contact with someone who has leprosy facilitates leprosy infection. The larger proportion of leprosy patients linked with household exposure compared to the general population suggests that household contacts with a low-income status may benefit from tailored and working strategies to reduce transmission (Li et al., 2021), such as activating contact screening. While immunotherapy and chemoprophylaxis pose challenges, clinical evaluation and examination of household contacts continue to be the working approach to mitigate risks as demonstrated in a study done in Mozambique and Uganda (Ribeiro et al., 2023) (Aceng et al., 2019).

In addition, to household contact surveillance, the World Health Organization (WHO) has endorsed and introduced various global surveillance guidelines to expand the surveillance of social contacts (Marega et al., 2022). However, its implementation in the African setting remains a challenge due to the stigma associated with the leprosy disease and, in certain regions, inadequate training of both clinicians and community staff (Ribeiro et al., 2023).

Strengthening public health interventions, including targeted contact screening and social interventions like the provision of footwear to the affected population will help reduce the burden of leprosy among the population (Wangara et al., 2019). Existing literature from prior studies supports Rifampicin as an effective leprosy post-exposure chemoprophylaxis in post-exposure prophylaxis, with single-dose rifampicin administered to contacts of leprosy patients (Marega et al., 2022; Schoenmakers et al., 2021).

In 2018, the World Health Organization included a recommendation to implement chemoprophylaxis guidelines as a strategy to reduce transmission prevention among household contacts (Schoenmakers et al., 2021). It's worth noting that in one cohort study done in Northeast Brazil, where the absence of lighting and overcrowding at homes had shown a 1.2-fold association of enhanced spread of leprosy disease among children (1·19, 1·05–1·35) (Nery et al., 2019). The same research also showed that overcrowding was significantly associated with the spread of *Mycobacterium Leprea* (1·21, 1·01–1·44)(Nery et al., 2019)

Another experimental study where the soil samples were randomly collected revealed that 25.4% of samples had evidence of *Mycobacterium Leprea* (Barbosa et al., 2022), on the other hand, all control samples were negative, indicating that *Mycobacterium Leprea* could survive extracellularly under different conditions (Barbosa et al., 2022). A study done in Ghana by Ofusu et al in 2011, revealed that there was no linkage between domestic animals like cats, pigs poultry, and dogs with leprosy spread among cases and controls (Ofosu & Bonsu, 2011), this also confirms other existence literature that *Mycobacterium Leprea* primarily infects humans (Ofosu & Bonsu, 2011).

The research findings of a case-control study in Northeast Brazil, where variables for risk factors for close contact transmissions such as household crowding and close contact with domestic animals did not show a significant association with leprosy (De Andrade et al., 2019). Scientists have documented that *Mycobacterium Leprea* occurrence was first documented in wild armadillos belonging to the D. novemcinctus species in America and Brazil (Oliveira et al., 2019).

Global focus on natural infection in wild armadillos has gained momentum sharply over the last five decades In Brazil, where researchers are actively investigating the dynamics of leprosy (Ploemacher et al., 2020), there remains much to be discovered regarding *Mycobacterium Leprea* occurrence (Das et al., 2020). It is recommended that scientists engaged in zoonotic studies, both in Brazil and globally, direct their attention toward the bacterium (Long et al., 2021).

Existing literature suggests the presence of environmental reservoirs for *Mycobacterium Leprea* occurrence (Ploemacher et al., 2020). Some scholars have attempted to link shared or reused water from a primary leprosy case to environmental reservoirs (Nery et al., 2019). Contaminated water may transmit active *Mycobacterium Leprea* occurrence, consistent with other studies documenting potentially viable bacteria in contaminated untreated water (Ramona et al., 2021). Although proving the transmissibility of bacteria in the environment is challenging, *Mycobacterium Leprea* occurrenc*e* does not occur in laboratory conditions, as reported in studies done in Brazil (Oliveira et al., 2019). Unlike other studies that have failed to prove the survivability of *Mycobacterium Leprea* in soil, those focusing on environmental reservoirs have primarily relied on the Reverse-Transcriptase Polymerase Chain Reaction of leprosy to assess the reliability (Oliveira et al., 2019). Researchers have also documented an elevated risk of *Mycobacterium Leprea* occurrence among people living in deplorable

environmental conditions, along with high proportions of non-treatment adherence (Nobre et al., 2017).

2.6.5 Conceptual Framework

The conceptual framework demonstrates the mutual dependence of socioeconomic factors, household and environmental factors, behavioral factors, and clinical factors in the context of *Mycobacterium Leprea* occurrences. The framework displays the phases involved in the operation of factors to cause disease at the distal and proximal levels. Distal factors rarely have a direct impact on illness outcomes. They do, however, follow a series of linked events that lead to infection. Social and economic factors do not directly increase the risk of leprosy disease, but they may indirectly affect other factors proximally and so directly affect the risk of disease. (Fig: 1)

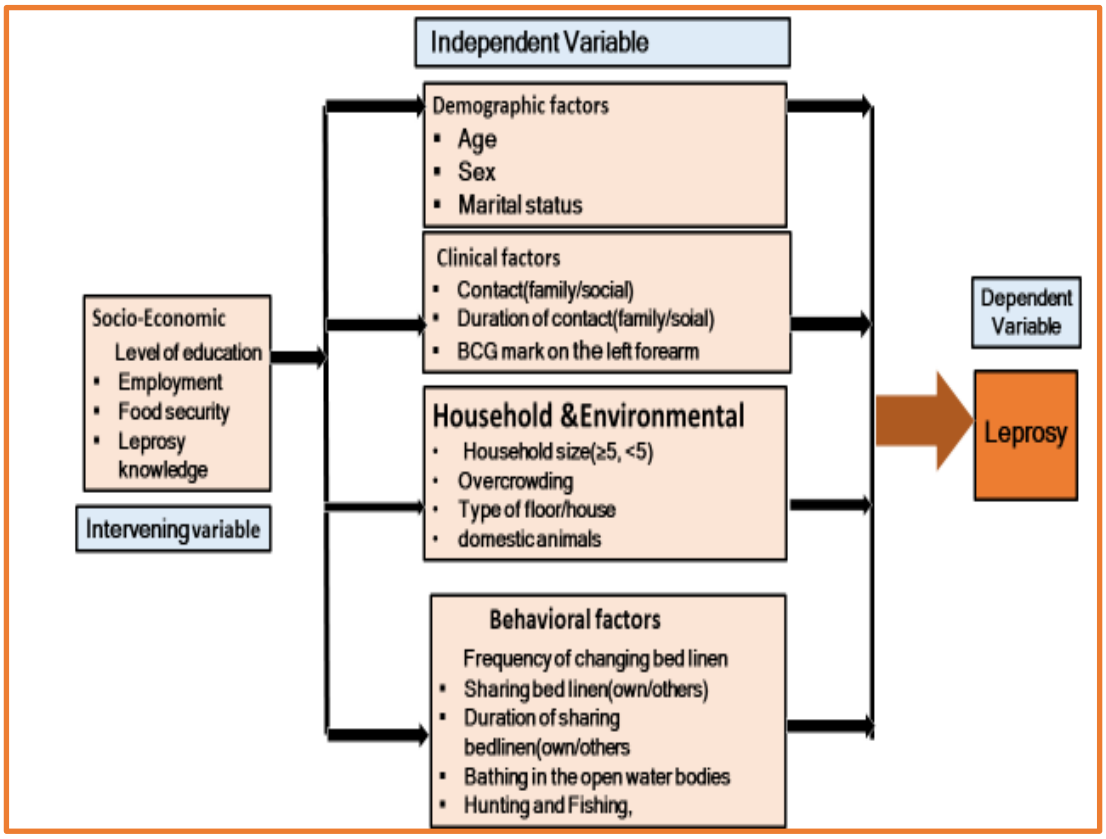

Figure 1: Conceptual framework

Source: Adapted and modified from the International Journal of Epidemiology 2006, on risk factors for Leprosy disease in North East, Brazil.

CHAPTER THREE

3.0 Materials and Methods

3.1 Study site

The study was carried out in Kwale County, one of the six counties that make up Kenya's coastal region. It neighbors Taita Taveta to the North, Kilifi to the Northeast, and South to Tanzania. The County has four sub-counties: Lunga Lunga, Matuga, Msambweni, and Kinango, with 20 wards (Kwale & Together, 2022). The county has a population estimated at 820,199 people, 422,358 being males and the rest female, as projected by the 2019 census. Individuals in the County had an overall poverty headcount rate of 47.4%, compared to 36.1% nationally, implying that nearly half of the population is poor. The County is divided into urban and rural areas. Ukunda is the central town, with formal housing, slums, and improvised household structures thatched with coconut tree leaves, but no piped water or sanitation facilities, posing a risk of leprosy transmission. The estimated number of people living with HIV in Kwale County is 16,692, resulting in an HIV prevalence rate of 2.9%. 992 Tuberculosis cases were diagnosed in 2019 (Kwale & Together, 2022). The county has five (5) level 4 hospitals, ten health centers, and ninety dispensaries. All the level four facilities are treatment centers for Tuberculosis and leprosy in the County (Figure 2 below)

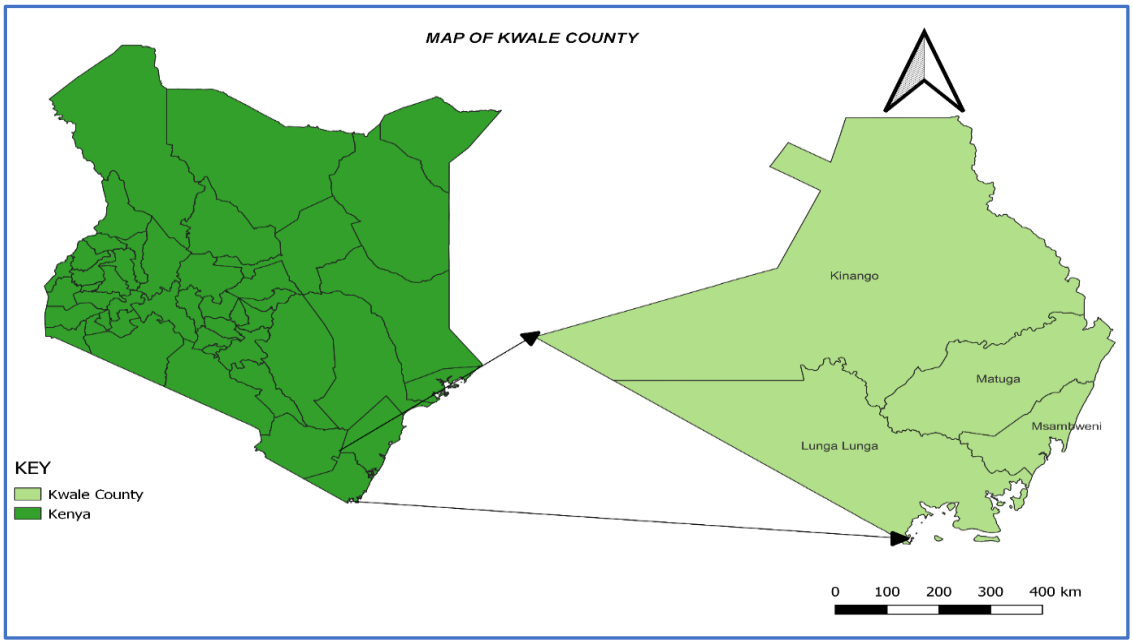

Figure 2: Study site

3.2 Study design

Case-control

3.3 Study population

Residents of Kwale County

3.3.1 Case

Any person in Kwale County who is presenting with signs of a hypopigmented skin patch with loss of sensation, one or more enlarged nerves, and the presence of leprosy bacilli with or without positive skin smear for *Mycobacterium Leprea* as a typical clinical sign, including patients released from treatment 24 months earlier.

3.3.2 Controls

Residents in Kwale County who are from the same village as the cases and are of the same age group and sex, with no indications of disease, no history of leprosy treatment, and no report of leprosy kinship.

3.4 Inclusion criteria

Residents of Kwale County who were actively on treatment and those recently released/discharged from treatment up to 24 months. Residents from the same villages as the cases, of the same age group and sex, free of the disease, with no history of leprosy treatment

3.5 Exclusion criteria

Individuals in Kwale County who are mentally ill. For Controls, every person in Kwale County who has ever been diagnosed and treated for leprosy.

3.6 Study Variables

Among the factors that were investigated include **socio-demographic factors**; age, sex, and marital status. **Clinical factors;** type of leprosy, family contact with an individual identified to be a leprosy case, social contact with an individual known to have the illness though not from the same family, the duration of such contact (5 years previously), the existence or absence of acillus Calmette Guerin mark on the left forearm to confirm Bacillus Calmette Guerin (BCG) vaccination, close association with a domestic animal such as dogs, cats, chicken, goats, and cattle. **Behavioral factors**; frequency of changing bed line (current and previous), sharing own bed linen (current and previous), sharing other bed linen (current and previous), duration of sharing own bed linen (5 years previously), involved in fishing and hunting within the last five years, bath in open water sources**. Socio-economic variables;** level of education attained, ever experienced food shortage, sewerage disposal, **Household and environmental factors**; type of housing, type of floor, household size of ≥ 5 members, crowding within the household, worked in agricultural farm within the last five years

3.7 Sample Size Determination

The Kelsey formula was used to compute the sample size (Charan & Biswas, 2013). A total of 260 study participants (65 cases and 195 controls) were included in the study, with 1 case to 3 controls (1:3). The least extreme odds ratio (OR) to be detected of 2.6 at a significance level of 95%, and a power of 80% (% detection power). Where close contact with known leprosy cases represents the exposure, the hypothesized proportion of cases with exposure was 79.59%, and the hypothesized proportion of controls with exposure was 60% (Ofosu & Bonsu, 2011)

$$P_0 = \frac{(OR)P_1}{(OR)P_1 + (1 - P_1)}$$

$$\mathbf{OR} = \frac{P_1(1 - P_0)}{P_0(1 - P_1)}$$

$$n_{cases-Kelsey} = \frac{\left(z_{\alpha/2} + z_{1-\beta}\right)^2 * p * (1 - p) * (r + 1)}{r * (p_0 - p_1)^2}$$

Variable Notations

α - The probability of type I error (significance level) is the probability of rejecting the true null hypothesis

β - The likelihood of type II error (1 - the power of the test) is the probability

of failing to reject the false null hypothesis.

P0 - The proportion of cases

P1- The proportion of controls

OR - The calculated odds ratio

r - The ratio of case-control (1 case/ 3 control)

Kelsey- Required sample size for cases using Kelsey's formula

Assumptions:
Two-sided confidence level (1-alpha): = 95

Power (% chance of detecting): = 80

The ratio of Controls to Cases: = 3

The hypothetical proportion of controls with exposure =60

The hypothetical proportion of cases with exposure: = 79.59%

Least extreme Odds Ratio to be detected: =2.6

Based on Kelsey's formula estimated sample size was;

Cases = 65

Controls = 195

Total = 260

3. 8 Sampling Procedure

3.8.1 Selection of the cases at the health facility

The County Tuberculosis and Leprosy Coordinator (CTLC) provided the list of all the leprosy treatment facilities in Kwale County. The CTLC generated a list of all leprosy cases, including those who were recently released/discharged from treatment from the Leprosy registers across the treatment facilities in the County.

The data extraction tool (appendix 8) was used to extract the data from the register. With the guidance of the CTLC, the Principal Investigator (PI) signed the data confidentiality declaration form (appendix 12) within the treatment facilities to

ensure that the patient's records are kept confidential.

The line list generated by the CTLC contained variables such as the name of the patient, phone numbers/alternate numbers, village, and nearest landmarks such as schools and churches.

The data protection method of de-identification was applied where the replacement of personal characteristics (names) with unique numbers, making it impossible to re-establish a link between someone's identity and his or her data.

The identified/line listed cases were traced to their respective villages and places of residence under the guidance of the respective Sub-Cunty Tuberculosis, Leprosy Coordinator (SCTLC) and the Community Health Promoters (CHPs) who were recruited, trained to assist/guide the research assistant in locating the exact households of the cases. The Community Health Promoters (CHP) signed the data confidentiality declaration form to uphold patient data confidentiality.

Consent and assent were sought at the household level. Only individuals who gave consent/assent were enrolled in the study. Kwale County notifies an average of 25-30 leprosy patients each year; for example, as of November 2022, 24 leprosy patients were on treatment. Patients who had completed the treatment course and were released/discharged from treatment registers were enrolled sequentially until the required sample size of 65 cases was reached.

To achieve a sample size of 260. The controls were recruited from the same communities as the cases. The selected cases and controls were matched based on gender, age (+/-10 years), and location of residence (frequency matching).

Using close contact with known leprosy cases as the exposure of concern, approximately 60% of controls were considered exposed to *Mycobacterium Leprea.* Using 65 cases and 195 controls (1 case to 3 controls), it was possible to detect

variations in exposure to leprosy disease between cases and controls with a 95% confidence interval and a power of 80%.

The 195 Controls were screened (appendix 9) to ensure that they had no visible signs and symptoms such as hypo-pigmented patches, were present on any region of their body. The presence of swollen nerves, thicker earlobes, and plaque-like lesions suggestive of leprosy was investigated.

Among the cases and controls, the scar on the left forearm was utilized to identify individuals who had received the Bacillus Calmette Guerin vaccination(BCG).

When screening for the controls, no new cases were enrolled for the study. Socio-demographic, Clinical, household and environmental, and behavioral and social-economic variables were assessed. Upon the study participants' consent/assent, the questionnaire was administered to the respondents.

3.8.2 Selection of the control in the village

Controls were identified and followed from the exact village as cases. Once the area was identified, the village elder/community leader was contacted. The community elder generates a list of all the households. A pen was spun to identify the first household from the direction where the tip of the pen points. The investigation team selected the first household following the direction of the pen's tip. In this regard, the first household was selected systematically; if the household was skipped, the pen was pinned again and again as they moved to the next home from the direction of the pen's tip until all the households were covered.

3.8.3 Selection of the controls at the household

At home, permission was asked to conduct interviews in the household, irrespective of age. If there was no person on the homestead, the household was dropped, and the next household was selected. A list of people staying in that residence was developed, the

individuals in the age category of the Case were identified, and if they are more than one, one was randomly selected through secret balloting by the use of papers marked yes or no. Consenting and assenting (minors) controls were asked screening questions using a structured checklist (appendix 9) denoting signs of leprosy infection such as hypopigmented skin patches, weakness of the feet/hand, and finally, the presence of some form of visible deformities to ensure they meet the inclusion criteria. The questionnaire was administered later. In the event of a refusal, the next home was chosen. This was repeated until each village had the required target of control.

3.9 Data Collection

3.9.1 Questionnaire

A pre-tested questionnaire was developed to collect socio-demographic, clinical, household environmental, behavioral, and socioeconomic data from cases and controls. Trained and competent research assistants were responsible for interviewing cases and controls in English, Kiswahili, or the local language at the household level. The questionnaire was structured to capture all the necessary vital information that incorporates all the variables for the study, including control selection at the village level. To account for the long period of incubation, cases, and controls were asked for factors linked with *Mycobacterium Leprea* occurrence. All patients diagnosed and discharged from treatment up to 24 months previously of leprosy disease that fit the inclusion criteria for a case and controls were interviewed.

3.9.2 Pretesting of the questionnaire

The questionnaire was pilot-tested in Kilifi County at the County referral Hospital as the link facility.

3.10 Data Management and Analysis

3.10.1 Cleaning of data

Data cleaning was performed, which included, among other things, the deletion of all formatting, the removal of duplicates, the change of text cases, the identification and correction of errors, spell check, the conversion of numbers stored as texts into numbers, the selection and filling of blank cells, and the removal of extra spaces.

3.10.2 Coding of data

The goal of variable coding was to convert qualitative data into quantitative data. The lead researcher cleaned the data to make computer processing with statistical software easier during data analysis.

3.10.3 Data entry

Coded data was entered into Microsoft Excel software and STATA version 16

3.10.4 Data Analysis

Data was clean, double-entered, edited, and analyzed using MS Excel and STATA version 16. Univariate analysis for continuous variables, proportions, and frequencies for categorical variables were analyzed in the bivariate analysis, where stratification was done to identify the confounders and effect modifiers.

The second step, multivariate analysis was undertaken as per the conceptual framework. Univariate, integrated, and block-wise multivariate analyses were undertaken through the application of logistic regression within STATA with cases/control as the main dependent variable (outcome).

Age and sex were adjusted to help control for the relevant confounding factors. The independent variables ($p<0.2$), were incorporated in the integrated analysis.

The adjusted analysis was carried out in two stages. In the first one, the odds ratio and confidence intervals for each variable were calculated, adjusting for all variables for both independent and dependent variables (exposure comparison of cases and controls).

In the second step, the socioeconomic variables were adjusted by relevant variables that are statistically significant for the other objective. A positive association between variables was considered for $p<0.05$ for a confidence interval of 95%).

Confounding and interaction between variables were investigated. The researcher applied frequency matching for age and sex and kept both sex and age in the multivariate models.

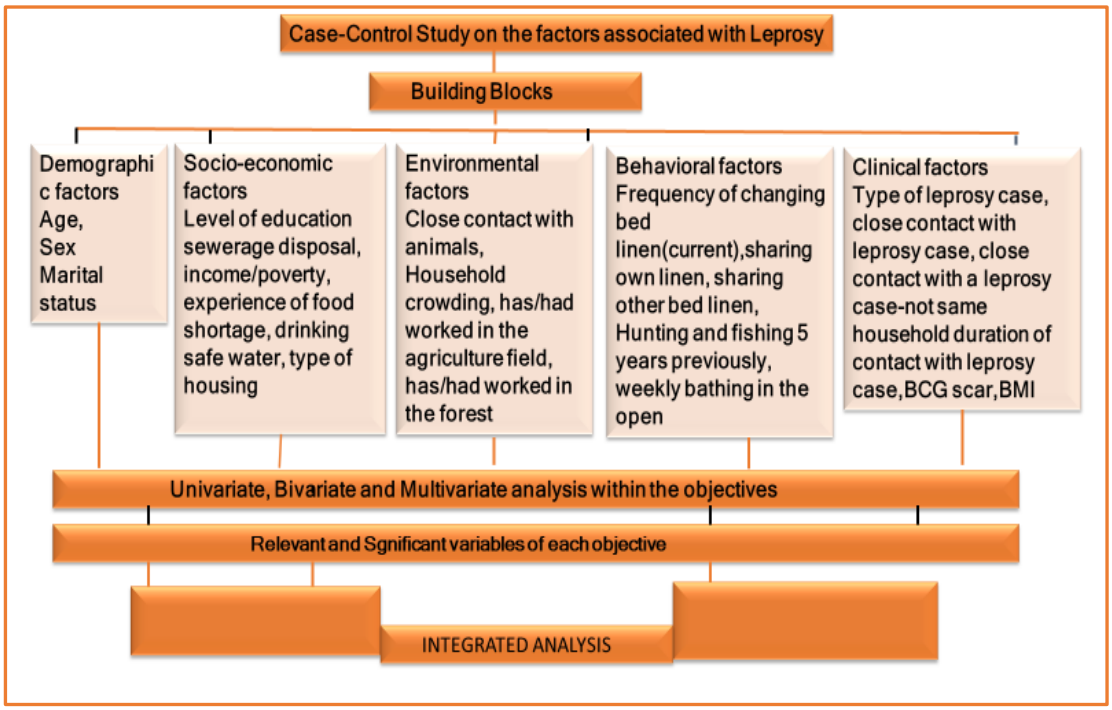

Figure 3: Data analysis flow Chart

3.11 Study Limitations

The selection bias of controls was one of the limitations of this study since cases and controls were defined based on residence. Recall bias during patient interviews could not be avoided due to the study design,

3.12 Ethical Considerations

a) This study was carried out after clearance from the supervisor' approval of my research topic and research proposal;

b) The Institutional Ethics and Research Committee (IREC), Moi University-**Appendix 1**

c) National Commission for Science, Technology, and Innovations (NACOSTI)-**Appendix 2**

d) The Kwale County Health Management Team-**Appendix 3**

e) Written and verbal permission was sought from all study participants.

3.13 Data Confidentiality

The data confidentiality method of de-identification of the patient records where of personal identifiers with unique numbers so that it would be difficult to re-establish a link between the individual and his or her data.

Measures were taken to ensure the confidentiality of the collected data by use of passwords on computers and the storage of completed manual questionnaires under lock and key with backup via cloud internet.

All the study participants were required to sign the informed consent/assent forms and for the study participants who cannot read and write the thump print was used. The Principal Investigator, the research assistants, and the Community Health Promoters both sign the data confidentiality declaration forms(appendix 10) as a requirement in medical ethics.

3.14 Risks and benefits

There were no known risks or benefits for the study participants in the study. However, the overall impact on the community may be significant because the risks associated

with leprosy disease, among other tested objectives, may be crucial in addressing the health problems associated with Mycobacterium Leprea occurrence.

Consent: The study participants are free to withdraw from the study whenever they want, there is no penalty.

3.15 Dissemination of data

The study results will be disseminated to the Kwale County Health Management Team, the National Tuberculosis Programme, the Ministry of Health, and other Key stakeholders.

CHAPTER FOUR

4.0 RESULTS

4.1 Distribution of Cases and Controls-Kwale County

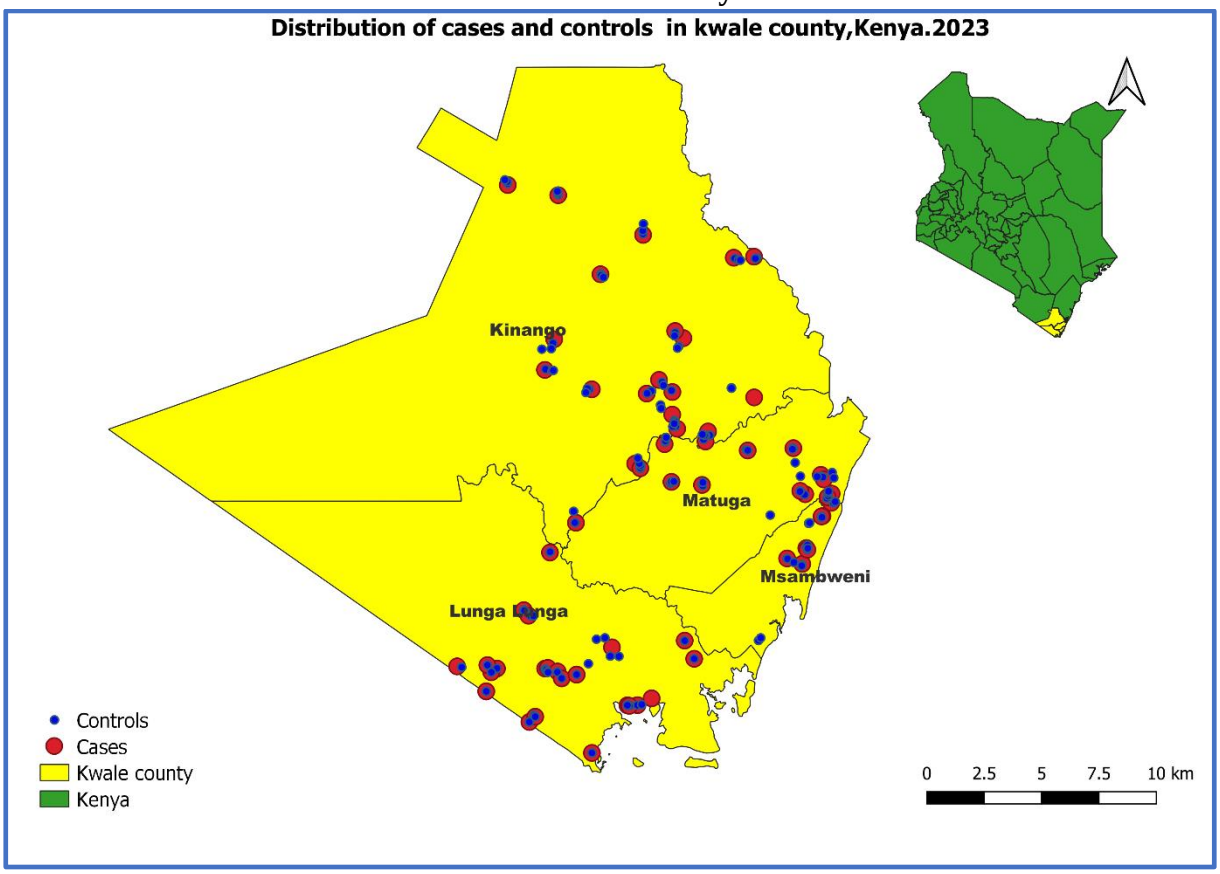

Figure 4: Distribution of cases and controls

4.2 Socio-demographic characteristics of leprosy cases and controls

The study analyzed data from 65 cases and 195 controls. Among the study participants, 39 (60.0%) of the cases and 108 (55.6%) of the controls were male. The age range was 10 to 83 years. The mean age was 55 years (SD±16 years) for the cases and 54 years (SD±15 years) for the controls. Those above 50 years accounted for 44 (68.2%) and children 0-14 years contributed 1(1.5%). More than half of the cases (56.6%) and most of the controls (71.1%) were married. Widowed individuals comprised 30.5% of cases and 18.5% of controls. Lunga and Kinango sub-counties contributed over a third of

25(38.4%), and 23(35.4%) of cases respectively. Over half (55.6%) of cases lacked formal education. (Refer to table 4 below)

Table 3: Social-demographic characteristics of the cases and controls

Variable Factors	Disease outcome		
	Totals(n=260) %	**Cases(n=65) %**	**Controls(n=195)%**
Sex			
Male	147(56.5)	39(60.0)	108(55.4)
Female	113(43.5)	26(40.0)	87(44.6)
Age			
Mean, Standard deviation	**55(±16)**	**55(SD±16)**	**54(SD±15)**
Minimum and maximum	10-83	12-81	10-83
0-14	3(1.5)	1(1.0)	2(1.1)
15-29	23(9.2)	5(8.7)	17(8.9)
30-49	57(21.5)	14(22.1)	43(21.9)
50 and above	177(67.8)	44(68.2)	133(68.1)
Marital status			
Married	176(67.7)	37(56.9)	139(71.3)
Single	28(10.8)	8(12.3)	20(10.3)
Widowed	56(21.5)	20(30.8)	36(18.5)
Education level attained			
None	117(45.0)	36(55.4)	81(41.5)
Primary	102(39.2)	23(35.4)	79(40.5)
Secondary	36(13.9)	4(6.1)	32(16.4)
Tertiary	5(1.9)	2(3.1)	3(1.5)
Sub-County			
Matuga	43(16.5)	11(16.9)	32(16.4)
Kinango	92(35.4)	23(35.4)	69(35.4)
Msambweni	26(10)	6(9.3)	20(10.2)
Lungalunga	99(38.1)	25(38.4)	74(38.0)

4.3 Clinical characteristics of cases and controls

More than half of the cases 38 (58.5%) had family contact, compared to 44 (21.4%) of controls. Over half of the cases 35 (53.3%) had social contact, while only 32.3% of controls did. Most cases 33 (86.8%) had close contact for over five years. 28 43.3% of cases lacked the Bacillus Calmette-Guérin mark, compared to 32 (16.5%) of controls. Only 2 (3%) of cases had tuberculosis as a comorbidity. More than a fifth of cases (28.1%) had close associations with domestic animals, compared to 17.1% of controls. (Ref table 4 and 5 below)

Table 4: Clinical characteristics of cases and controls

		Disease outcome	
characteristics	**Totals(n=260) %**	**Cases(n=65)%**	**Controls(n=195)%**
Family contact			
Yes	82(31.5)	38(58.5)	44(22.6)
No	178(68.5)	27(41.5)	151(77.4)
Social contact			
Yes	98(37.7)	35(53.9)	63(32.3)
No	162(62.3)	30(46.1)	132(67.7)
Duration of family contact			
Less than 5 years,	10(12.2)	5(13.2)	5(11.4)
More than 5 years	72(87.8)	33(86.8)	39(88.6)
Duration of social contact			
Less than 5 years	22(22.4)	6(17.1)	22(22.4)
More than 5years	76(77.6)	29(82.9)	76(77.6)
BCG scar			
Present(yes)	200(76.9)	37(56.9)	163(83.5)
Absent (No)	60(23.1)	28(43.1)	32(16.5)
Comorbidities			
TB	9(3.0)	2(3.0)	7(3.5)
None	193(74.6)	48(73.8)	145(74.5)
NCD	21(8.0)	5(7.8)	16(8.2)
Others	37(14.4)	10(15.4)	27(13.8)

4.3.1 Clinical characteristics of cases

Majority of the cases, 59 (90.8%) had the Multibacillary type of leprosy while only 6 (9.2%) had paucibacillary. At diagnosis 14 (29.2%) presented with disability grade I, and over half of 38(58.5%) presented with disability grade II. At discharge from treatment, only 4 (6.2%) developed disability grade I, compared with 15 (21.2%) who developed disability grade II. only 1 (1.5%) lost vision. 46 (70.8%) never developed disability at the end of treatment. About a fifth of the cases 12 (18.5%) were underweight, more than a fifth 18 (27.7%) had normal weight and 125 (38.5%) had missing records. The most frequently noticed symptoms was numbness of the peripheries at 53 (81.5%), Painless swelling/lumps on the face or ear lobes at 37 (57.2%), painless ulcers and wounds at 34 (51.4%), thick and stiff skin at 36 (54%), hypopigmented patched 31(48.4%) and finally the enlarged nerves at only 10 (15.1%).

Diagnosis delay was estimated at 45 months on average, with an interquartile range (IQR) of 12 to 69 months. The average time to detect a case was 51.2 months, with a standard deviation of 47.2 months. The cases had a minimum delay of 2 months and a maximum delay of 143 months. Only 14 (21%) of the participants were identified within 12 months of noticing their first symptom, even though 51 (77.5%) of the cases experienced a lengthy delay in case detection of more than 12 months from the beginning of their first symptom (refer table 5 below)

Table 5: Clinical characteristics of cases

	Disease status
Factors	**Cases(n=65) %**
Type of leprosy	
Multibacillary (MB)	59(90.8)
Paucibacillary (PB)	6(9.2)
Disability grading, at diagnosis	
Disability grade 0	2(3.1)
Disability grade I	14(29.2)
Disability grade II	38(58.5)
Never	6(9.2)
Disability grading at the end of treatment	
Disability grade I	4(6.2)
Disability grade II	15(21.5)
Lost vision	1(1.5)
Never	46(70.8)
Disability grading at diagnosis	
Yes	59(90.8)
No	6(9.2)
Disability at the end of treatment	
Yes	19(29.2)
No	46(70.8)
Body Mass Index (BMI)	
Underweight	12(18.5)
Normal Weight	18(27.7)
Overweight	10(15.4)
Undocumented	25(38.5)
Frequent signs and symptoms for cases	
Hypopigmented patches	31(48.4)
Numbness	53(81.5)
Enlarged nerves	10(15.4)
Painless ulcers and wounds	34(51.9)
Thick and stiff skin	36(54.9)
Painless swelling	37(57.3)
Others	1(2.2)
Prolonged delay in case detection	
Median time, median(IQR)months	**45(IQR 12-69)**
Minimum and maximum(months)	**11-43**
Less than 12months	14(21.5)
More than 12months	51(77.5)

4.4 Behavioral and Socioeconomic Characteristics

Among the study respondents, the majority 52 (80.0%) of cases had frequently changed bed linen (more than one week) over the past 5 years, compared to over sixty 130 (66.6%) of controls. Only 13 (20%) of cases frequently changed bed linen weekly. Over 5 years, over 41(63.1%) of cases and more than half 102 (52.4%) of controls reported sharing their bed linen, while 24 (36.9%) of cases and 96 (49.2%) of controls shared other bed linens.

Among the respondents, the majority 37 (90.2%) of cases and 85(83.3%) of controls reported sharing bed linen for 5 years. Additionally, most 19(79%) of cases and 77(80.0%) of controls reported sharing other bed linens for 5 years. Fishing was practiced by only 11(16.6%) of cases and 26 (13.3%) of controls over 5 years while hunting in the forest was practiced by only 9.2% of cases and over 20(10.0%) of controls. Over 43.3% of cases and 27.7% of controls had no bathrooms in their compound, and 78.6% of cases and 84.9% of controls practiced open bathing. Regarding health-seeking behavior, 35(53.3%) of cases sought treatment at public health hospitals, 22(33.6%) from traditional medicine men, and 8 (12.3%) at private health institutions. More than half of the cases 38(58.8%) and 97(49.2%) of controls had knowledge of leprosy and its symptoms.

Among the cases, more than 41(63.1%) of the cases were unemployed compared to 115(44.23%) of controls. Informal employment was reported in 21(32.23%) of cases and 138 (53.08%) of controls, while formal employment was minimal 3 (4.7%) of cases and 3 (2.7%) of controls). Food shortages were experienced by 50 (76%) of cases and 125 (64.1%) of controls over the past 5 years. Only 15 (23%) of cases had three meals a day previously, with 29 (44.6%) struggling to afford one meal and 21(32.1%) unable to afford two meals. In the control group,53(27.2%) could afford one meal a day. Most

cases 51 (76.1%) and controls 141 (72.6%) depended on dams for water. Proper sewerage disposal was lacking for 35 (53.8%) of cases and 81(41.5%) of controls. (Ref table 6 and 7 below)

Table 6: Behavioural and socio-economic characteristics of the study participants

Variable / Factors	Disease outcome		
	Totals(n=260) %	Cases(n=65) %	Controls(n=195) %
Frequency of changing bed linen			
Less than a Week	78(30.0)	13(20.0)	65(33.1)
More than a Week	182(70.0)	52(80.0)	130(66.9)
Sharing own bed linen			
Yes	143(55.0)	41(63.1)	102(52.3)
No	117(45.0)	24(36.9)	93(47.7)
Duration of sharing own bed linen			
More than 5 years	122(85.3)	37(90.2)	85(83.3)
Less than 5 years	21(14.7)	4(9.8)	17(16.7)
Sharing other bed linen			
Yes	120(46.2)	24(36.9)	96(49.2)
No	140(53.8)	41(63.1)	99(50.8)
Duration of sharing other bed linen			
More than 5 years	96(80)	19(79.2)	77(80.0)
Less than 5 years	24(20)	5(20.8)	19(20.0)
Fishing, 5 years previously.			
Yes	37(14.6)	11(16.9)	26(13.8)
No	222(85.4)	54(83.1)	168(86.2)
Hunting,5 years previously			
Yes	26(10)	6(9.2)	20(10.0)
No	234(90)	59(90.8)	175(90.0)
Owning a bathroom			
Yes	178(68.5)	37(56.9)	141(72.3)
No	82(31.5)	28(43.3)	54(27.7)
Regular bathing in the open			
Open bathing place	67(91.8)	22(78.6)	45(84.9)
River	1(1.4)	1(3.3)	2(3.4)
Dam	5(6.8)	5(17.8)	6(11.7)
Health seeking behavior			
Public hospital	–	35(53.8)	–
private clinic	–	8(12.3)	–
Medicine men	–	22(33.8)	–

Table 7: Behavioural and Socio-economic Characteristics

Variable		Disease outcome	
Factors	**Totals(n=260) %**	**Cases(n=65) %**	**controls(n=195) %**
Ever experienced food shortage			
Yes	175(67.3)	50(76.9)	125(64.1)
No	85(32.7)	15(23.1)	70(35.9)
Employment			
Informal Employment	138(53.08)	21(32.3)	117(60.0)
Formal Employment	7(2.7)	3(4.6)	4(2.7)
Unemployed	115(44.23)	41(63.08)	74(37.9)
Main meals			
One meal	82(31.5)	29(44.6)	53(27.2)
Two meals	93(35.8)	21(32.3)	72(36.9)
Three Meals	85(32.7)	15(23.1)	70(35.9)
The main source of water supply			
Piped water	36(13.9)	6(9.2)	30(15.4)
Dam	192(73.9)	51(78.5)	141(72.3)
Borehole	32(12.2)	8(12.3)	24(12.3)
Sewerage disposal			
Yes	144(43.8)	30(46.2)	114(58.5)
No	116(56.2)	35(53.8)	81(41.5)
Knowledge of leprosy disease			
Yes	134(51.5)	38(58.5)	96(49.2)
No	126(48.5)	27(41.5)	99(50.8)

4.5 Household and Environmental Characteristics

In this study, a significant proportion of cases 58 (89.2%) resided in houses with mud/sand floors, compared to 161(82.2%) of controls. Conversely, only 8(12.3%) of cases and slightly more than 10 29(14.4%) of controls lived in dwellings with well-maintained floors and permanent structures. The average household size for cases was 7.6 individuals (SD ±2.8), ranging from 2 to 17 members. For controls, household size ranged from 2 to 19 individuals, with an average of 5.7 (SD ±2.8). Notably, the majority 59 (90.0%) of cases had household densities of ≥5 members, while slightly less than sixty 115 (59.0%) of controls had similar densities. Overcrowding, defined as more than ≥4 people per sleeping space, was reported by 36 (55.5%) of cases, compared to 46 (22.2%) of controls. Regarding contact with domestic animals, slightly less than half 32 (49.2%) of cases reported contact, versus 87 (44%) controls. These findings highlight significant differences in living conditions and household densities between cases and controls, potentially implicating these factors in disease transmission dynamics (Ref table 8 below).

Table 8: Household and environmental characteristics of cases and controls

Variable Factors	Disease status	Disease outcome	
	Totals(n=260) %	Cases(n=65) %	Controls(n=195) %
Type of floor			
Mud floor	219(82.4)	58(89.2)	161(82.5)
Cemented/tiled	41(17.6)	7(11.8)	34(17.5)
Type of housing			
Permanent house	37(14.2)	8(12.3)	29(14.1)
Grass thatched house	223(85.8)	57(87.7)	166(85.9)
Family size (household density)			
<5 members	86(33.1)	6(9.2)	80(41.0)
>5 members	174(66.7)	59(90.8)	115(59.0)
Household Sleeping space			
0-3 sleeping space	218(83.8)	57(87.7)	161(83.3)
>4 per sleeping space	42(16.2)	8(12.3)	34(16.7)
Overcrowding			
0-3 persons per room	180(69.2)	29(44.6)	151(77.4)
4 or +(plus) persons per room	80(30.8)	36(55.4)	44(22.6)
Animals in the compound,			
Yes	119(45.8)	32(49.2)	87(44.6)
No	141(54.2)	33(51.8)	108(55.4)

4.6 Bivariate analysis of socio-demographic

The variables were analyzed at the bivariate level to determine the socio-demographic variables that had a p=value≤0.2 that were subjected to the multivariate level where stepwise backward elimination was applied and the integrated logistic regression to determine the associated factors that enhance the risk of *Mycobacterium Leprea* in the study setting. Age group category (0-14,15-29,30-49, ≥50 years), sex, and marital status variables at the socio-demographic level were not associated with enhanced risk of *Mycobacterium Leprea* occurrence. Inadequate understanding of the leprosy spread was significantly linked with *Mycobacterium Leprea* occurrence (p=0.198) at the bivariate level. (Ref table 9 below)

Table 9: Bivariate analysis of Socio-demographic factors

Variable	**Disease status**		**Disease outcome**	
Risk factor	**Cases(n=65) %**	**Controls(n=195) %**	**COR (95% CI)**	**P-value**
Sex				
Male	39(60.0)	108(55.4)	1.23(0.68-2.14)	0.516
Female	26(40.0)	87(44.6)	Reference	
Age				
0-14	1(1.0)	2(1.1)	Reference	
15-29	5(8.7)	17(8.9)	0.71(0.05-7.74)	0.791
30-49	14(22.1)	43(21.9)	0.65(0.05-7.74)	0.734
50 and above	44(68.2)	133(68.1)	0.67(0.06-7.47)	0.738
Marital status				
Married	37(56.9)	139(71.3)	0.67(0.27-1.63)	0.514
Single	8(12.3)	20(10.2)	Reference	
Widowed	20(30.8)	36(18.5)	1.4(0.52-3.72)	0.514
Education level				
None	36(55.4)	81(41.5)	0.67(0.12-4.16)	0.664
Primary	23(35.4)	79(40.5)	0.44(0.69-2.77)	**0.113***

Secondary	4(6.1)	32(16.4)	0.19(0.11-4.16)	0.664
Tertiary	2(3.1)	3(1.5)	Reference.	
Sub-County				
Matuga	11(16.9)	32(16.4)	1.15(0.37-3.59)	0.815
Kinango	23(35.4)	69(35.4)	1.11(0.40-3.10)	0.841
Msambweni	6(9.3)	20(10.2)	Reference.	
Lungalunga	25(38.4)	74(38.0)	1.13(0.41-3.12)	0.819

4.7 Bivariate analysis of clinical factors

In this study, family contact, social contact, and Bacillus Calmette-Guérin (BCG) vaccination status (absence of the BCG mark on the left forearm) were independent factors associated with an increased risk of *Mycobacterium leprae* occurrence at the bivariate level. Participants reporting family contact were 4.8 times more likely to contract leprosy (cOR = 4.83, 95% CI: 2.66-7.78, p = 0.001) compared to controls, with 38 (58.5%) of cases and 82 (31.5%) of controls reporting family contact. Social contact was linked to a 2.4-fold increase in leprosy development (cOR = 2.44, 95% CI: 1.38-4.33, p = 0.002), with 35 (53.9%) of cases and 82(37.3%) of controls reporting social contact with leprosy (affected individuals outside their household).The duration of family contact (cOR = 0.84, 95% CI: 0.23-3.18, p = 0.805) and social contact (cOR = 1.65, 95% CI: 0.58-4.69, p = 0.351) were not statistically significant for increased *Mycobacterium leprae* risk. Absence of the BCG mark increased leprosy risk by 3.9 times (cOR = 3.85, 95% CI: 2.07-7.17, p = 0.001), with 28 (43.3%) of cases and 32 (16.9%) of controls lacking the BCG mark. Conversely, 37 (56.9%) of cases and 163 (83.6%) of controls had the BCG mark, highlighting its protective effect against leprosy disease. Close association with domestic animals and being a resident in Kwale County were not associated with an increased risk of *Mycobacterium leprae* occurrence (p < 0.2). The study highlights the public health importance of family and social contact, as

well as BCG vaccination status, in understanding leprosy disease dynamics. (Ref. table 9 below)

Table 10: Bivariate analysis for the clinical factors

Variable Risk factor category	Disease status Cases(n=65) %	 Controls(n=195) %	Disease outcome cOR(95% CI)	 P-value
Family contact				
Yes	38(58.5)	82(31.5)	**4.83(2.66-8.78)**	**<0.001****
No	27(41.5)	178(68.5)	Reference	
Social contact				
Yes	35(53.9)	98(37.7)	**2.44(1.38-4.33)**	**0.002****
No	30(46.1)	162(62.3)	Reference	
Duration of family contact				
< 5 years	5(13.2)	10(12.2)	Reference	
>5 years	33(86.8)	72(87.8)	0.84(0.23-3.18)	0.805
Duration of social contact				
<5 years	6(17.1)	22(22.4)	Reference	
>5years	29(82.9)	76(77.6)	1.65(0.58-4.69)	0.351
BCG scar				
Present (Yes)	163(83.6)	37(56.9)	Reference	
Absent (No)	32(16.4)	28(43.1)	**3.85(2.07-7.17)**	**<0.001****

**P<0.05, *P<0.2

Abbreviation: OR=Crude odd ratio, I=Confidence Interval=Total sample size

4.8 Bivariate analysis of behavioral and socio-economic factors

Information was collected and analyzed from 65 cases and 195 controls. The bivariate analysis results are summarized in Tables 10a and 10b below. A low frequency of changing bed linen was associated with a higher risk of leprosy (cOR = 2.69, 95% CI: 1.02-3.94, p = 0.045), with 52 (80%) of cases changing bed linens after one week, one month, or even three months, instead of biweekly. Lack of a bathroom in the compound increased the risk of leprosy by 1.97 times (cOR = 1.97, 95% CI: 1.10-3.84, p = 0.022) compared to controls, where only 82 (31.5%) lacked a bathroom. Sharing bed linen and the duration of sharing bed linen in the past five years was associated with an increased risk of leprosy ($p < 0.2$). Hunting and fishing five years previously were not associated with *Mycobacterium leprae* occurrence in the univariate regression analysis.Skipping meals to cope with food shortage was significantly associated with an increased risk of leprosy disease (OR = 2.55, 95% CI: 1.25-5.24, p = 0.011). However, working in informal employment, experiencing food shortages, poor sewerage disposal, using dams as the main water source, and knowledge about leprosy were not significantly associated with increased leprosy risk at the bivariate level.

Table 11: Bivariate analysis of behavioral and socio-economic factors

Variable	Disease status		Disease outcome	
Risk factor	**Cases(n=65) %**	**Controls(n=195) %**	**cOR(95% CI)**	**P-value**
Frequency of changing bed linen				
≤Week	13(20.0)	78(30.0)	Reference	
> Week	52(80.0)	182(70.0)	**2.69(1.02-3.94)**	**0.045****
Sharing own bed linen				
Yes	41(63.1)	143(55.0)	1.55(0.88-2.77)	**0.132***
No	24(36.9)	117(45.0)	Reference	
Duration of sharing own bed linen				
≥5 years	37(90.2)	122(85.3)	1.85(0.58-5.86)	**0.029****
< 5 years	4(9.8)	21(14.7)	Reference	
Sharing other bed linen				
Yes	24(36.9)	120(46.2)	0.60(0.34-1.07)	**0.086***
No	41(63.1)	140(53.8)	Reference	
Duration of sharing other bed linen				
≥5 years	19(79.2)	96(80)	0.93(0.31-2.83)	0.909
<5 years	5(20.8)	24(20)	Reference	
Hunting,5 years previously.				
Yes	11(16.9)	37(14.6)	0.88(0.34-2.32)	0.811
No	54(83.1)	222(85.4)	Reference	
Fishing,5 years previously				
Yes	6(9.2)	26(10)	1.31(0.61-2.84)	0.484
No	59(90.8)	234(90)	Reference	
Owning a bathroom				
Yes	37(56.9)	178(68.5)	Reference	
No	28(43.3)	82(31.5)	**1.97(1.10-3.54)**	**0.022****

*P<0.2
**P<0.05

Table 12: Bivariate analysis of behavioral and socio-economic factors

Variable Risk factor category	Disease status Case(n=65)%	Controls(n=195) %	Disease outcome cOR(95%CI)	P=value
Employment status				
Unemployed	21(32.3)	138(32.3)	0.73(0.70-3.46)	0.701
Formal Employment	3(4.6)	7(2.7)	Reference	
Informal Employment	41(63.1)	115(44.4)	0.23(0.05-1.14)	0.074
Experienced food shortage				
Yes	50(76.9)	125(64.1)	1.86(0.98-3.56)	**0.059***
No	15(23.1)	70(35.9)	Reference	
Main meals				
One meal	29(44.6)	53(27.2)	**2.55(1.25-5.24)**	**0.011****
Two meals	21(32.3)	72(36.9)	1.36(0.65-2.85)	0.414
Three Meals	15(23.1)	70(35.9)	Reference	
The main source of water supply				
Piped water network	6(9.2)	30(15.4)	Reference	
Dam	51(78.5)	141(72.3)	1.80(0.71-4.60)	**0.213***
Borehole	8(12.3)	24(12.3)	1.66(0.51-5.47)	0.399
Sewerage disposal				
Yes	30(46.2)	114(58.5)	Reference.	
No	35(53.8)	81(41.5)	1.64(0.93-2.89)	**0.085***
Knowledge of leprosy				
Yes	38(58.5)	96(49.2)	Reference	
No	27(41.5)	99(50.8)	0.68(0.39-1.22)	**0.198***

*P<0.2
**P<0.05
Abbreviation: cOR=Crude odd ratio, CI=Confidence Interval=Total sample size

4.8 Bivariate analysis of household & environmental variables

Among the six variables in the household and environmental objective. Two variables were statistically significantly associated with leprosy disease. The study respondents from households with ≥5 members had over six times the likelihood of contracting leprosy (cOR = 6.84, 95% CI: 2.62-16.61, p = 0.000), with a mean household size of 7.6 individuals (SD ±2.8). Most 59 (90.8%) of cases had more than five household members compared to 166(66.6%) of controls. Household crowding was also significant, with cases being 4.3 times more likely to experience leprosy (cOR = 4.26, 95% CI: 2.35-7.71, p = 0.000). More than fifty 36(55.6%) of cases had ≥4 persons per sleeping space ,compared with a third 80(31.5%) of controls.Living in a house with a mud floor was associated but not significant to *Mycobacterium leprae* occurrence (p < 0.2). However, living in grass-thatched houses and lack of close interaction with domestic animals were not significantly associated with leprosy in the study setting. The findings highlight the contribution of household size and crowding on *Mycobacterium Leprea* occurrence.

Table 13: Bivariate analysis of household & environmental factors

Variable	Disease status		Disease outcome	
Risk factor	**Cases(n=65) %**	**Controls(n=195) %**	**cOR(95% CI)**	**P-value**
Type of floor				
Earth floor	58(89.2)	161(82.5)	0.57(0.24-1.36)	**0.206***
Cemented/tiled	7(11.8)	34(17.5)	Reference	
Type of the house				
Permanent house	37(14.2)	8(12.3)	Reference	
Grass thatched house	223(85.8)	57(87.7)	1.24(0.54-2.88)	0.609
Family size				
<5 members	86(33.1)	6(9.2)	Reference	
>5 members	174(66.7)	59(90.8)	**6.84(2.82-16.61)**	**<0.001****
Household crowding				
0-3 persons per room	180(69.2)	29(44.6)	Reference	
4 persons per room	80(30.8)	36(55.4)	**4.26(2.35-7.71)**	**<0001****
Ever had animals in the compound				
Yes	119(45.8)	32(49.2)	1.20(0.69-2.11)	0.518
No	141(54.2)	33(51.8)	Reference	

*P<0.2
**P<0.05

4.10 Multivariate logistic regression model

Socio-demographic: There was no difference in the Socio-demographic variables like age, sex, and marital status for the cases and controls. People who missed meals to cope with food scarcity were closely linked with *Mycobacterium Leprea* occurrence at the bivariate level. No variable remained significant in the multivariate.

Clinical: Three out of six variables were statistically significant in the clinical category where family contact, social contact, and absence of Bacillus Calmette Guerin vaccination (BCG) mark on the left forearm. In addition, vaccination against Bacillus Calmette Guerin (BCG) provides a protective linkage against *Mycobacterium Leprea* occurrence. All variables in the clinical category remained statistically associated in the final multivariate model ($p<0.05$.

Behavioral and socio-economic: This study examined behavioral and socioeconomic variables associated with leprosy at the bivariate analysis level. Key findings include: Individuals working in informal settlements showed associations with leprosy.

People who skip meals were linked to an increased risk of leprosy. Those who have never experienced food scarcity also showed associations with leprosy and A low frequency of sharing bed linen showed associations with leprosy

Environmental variables: Two out of five variables in the environmental category were associated with leprosy at the bivariate and only one remained statistically associated at the multivariate level. The household size with a mean of 7.6 people per household had an enhanced risk of having leprosy.

Final model; a step-wise backward elimination technique, the unconditional logistic regression analysis revealed factors associated with *Mycobacterium Leprea* occurrence. Household density of ≥5 members, with a mean of 7.6±2.8 people per household, family contact, social contact, and the absence of the Bacillus Calmette

Guérin (BCG) mark on the left forearm were significantly associated with *Mycobacterium Leprea* occurrence (refer to Table 14). In the study final analysis, the adjusted odds ratios (aOR) were quite similar to crude odds ratios (cOR), with little variations/ negligible confounding effects observed in the analysis.

The final study findings include: The study participants from households with ≥5 members were 6.99 times more likely to contract leprosy disease (aOR = 6.99; 95% CI: 2.71–18.06), compared to households with less than five members. Among the study respondents who reported close family contact had a 4.33-fold increase in *Mycobacterium Leprea* occurrence (aOR = 4.33; 95% CI: 2.18–8.58), compared to those who did not. Persons with social contact had a 2.24-fold higher risk of leprosy transmission (aOR = 2.24; 95% CI: 1.16–4.32), compared to the general population. Missing the BCG mark on the left forearm was associated with a 2.24-fold increase in leprosy development (aOR = 2.24; 95% CI: 1.11–4.53). The study findings highlight/ reveal that BCG vaccination partly has a protective effect against *Mycobacterium Leprea* occurrence corresponding vaccine effectiveness of 50% as reported by other previous studies. Further, the study results underscore the public health importance of household density, family contact, and social contact in leprosy occurrence among rural populations.

Table 14: Multivariate logistic regression model

Variable	Disease status		Disease outcome	
Risk factor category	**Cases(n=65) %**	**Controls(n=195) %**	**aOR (95% CI)**	**P-value**
Household crowding				
<5 members	6(9.2)	80(41.0)	Reference.	
≥5 members	59(90.8)	115(59.0)	**6.99(2.71-18.06**	**<0.001****
Family contact				
Yes	38(58.5)	44(22.6)	**4.33(2.18-8.58)**	**<0.001****
No	27(41.5)	151(77.4)	Reference	
Social contact				
Yes	35(53.8)	63(32.3)	**2.24(1.16-4.32)**	**0.016****
No	30(46.2)	132(67.7)	Reference	
BCG scar				
Present	37(57.0)	163(83.6)	Reference	
Absent	28(43.0)	32(16.4)	**2.24(1.11-4.53)**	**0.024****
Knowledge of leprosy				
Yes	38(58.5)	96(49.2)	Reference	
No	27(41.5)	99(50.8)	0.54(0.27-1.06)	0.072

**P<0.05

CHAPTER FIVE

5.0 DISCUSSIONS

Family contact, social contact, household size of more than 5 members, and the missing of the Bacillus Calmette Querin (BCG) mark on the left forearm were independently associated with increased *Mycobacterium leprea* occurrence in the study setting. However, at the bivariate level of analysis, the following three variables were significantly associated with leprosy; frequency of changing bed linen, and food scarcity. The study believes the study findings are linked in some way to increased *Mycobacterium Leprea* occurrence in the study setting.

5.1 Socio-demographic factors

The study found no statistically significant variations in the cases and controls gender, age, or marital status, considering the cases and controls were selected from the same villages and did not differ significantly from one another given the study's design, and their socio-demographic, and cultural characteristics.

Studies have documented findings in agreement with the study, where a study by Ofusu et al in Sene District, Ghana reported that the age group categories and the marital status are less likely to contract leprosy disease (Ofosu & Bonsu, 2011), however, other studies have strongly linked leprosy to the elderly age group and male gender, particularly those living in resource-constrained settings (De Sousa Oliveira et al., 2019; Pescarini et al., 2018)

5.2 Clinical factors

The study revealed that among the cases that had close family contact with cases were 4 times more likely to develop leprosy disease compared with the controls. The study results agree with similar study findings in West Africa that revealed that close contact had higher odds for enhanced *Mycobacterium Leprea* occurrence (Ofosu & Bonsu,

2011). Other studies that reported similar findings in Ethiopia and Brazil revealed that prolonged household contact with a leprosy patient facilitates leprosy infection due to the bacillus's long phase of incubation and its clinical manifestation (Bekala et al., 2021; Nery et al., 2019), suggesting the highest likelihood of *Mycobacterium Leprea* occurrence might have happened before (Marega et al., 2022). The study believes that the findings highlight a national programmatic malfunction of leprosy surveillance monitoring systems, undocumented and missed cases of leprosy in the rural communities.

The study results showed that Persons with social contact had a 2.24-fold higher risk of leprosy transmission compared to the control group. Previous studies with similar findings in Ethiopia, seem to confirm that social contacts for leprosy disease are vulnerable to *Mycobacterium Leprea* occurrence (Bekala et al., 2021). Therefore, the study suggests that household contact tracing or household contact surveillance for leprosy contacts should extend beside the nuclear families and involve distant and immediate relatives, social friends, and even workmates since the results have significantly linked family and social contacts to increased *Mycobacterium Leprea* occurrence in the study area as opposed to the general population. In addition, this might indicate that associating with leprosy patients for a prolonged timeframe without treatment could predispose people to *Mycobacterium Leprea* occurrence (WHO, 2020). However, Similar studies in Ghana have reported findings in contrast with our current results that there was no linkage between social contact and the leprosy disease (Ofosu & Bonsu, 2011), The study results might have been attributed to the selection design of the controls.

Another study done in Ethiopia, on prolonged delay in leprosy case detection hotspots revealed that families with kinship of leprosy cases might have an enhanced risk of

leprosy disease transmission (Urgesa et al., 2021), especially in households with elderly contacts (Marega et al., 2022). Research findings in Mozambique revealed that enhancing health programs like contact line listing, household contact surveillance as well as social programs that explicitly target the vulnerable population appear to lower *Mycobacterium Leprea* occurrence (Ribeiro et al., 2023), previous research findings revealed that the administration of rifampicin as a single dosage for leprosy treatment therapy, particularly for known leprosy contacts might play pivotal role in the elimination strategy for *Mycobacterium Leprea* occurrence (Schoenmakers et al., 2021). Furthermore, the World Health Organization has recommended its use as chemoprophylaxis in its 2018 guidelines for the diagnosis, treatment, and prevention of leprosy (WHO, 2018). However, very limited information is known about its effectiveness and feasibility in countries reporting higher leprosy cases (Marega et al., 2022). Interestingly, the findings revealed that the amount of time of exposure did not correlate significantly with the occurrence of leprosy.

The study findings were consistent with other previous work documented in Ghana that highlighting the selection of the control may have contributed to the similarity of the results given the considerable growth period of the leprosy disease (Ofosu & Bonsu, 2011), this suggests that the controls may have been in the Sub-clinical phase and had a comparable susceptibility than the cases (Véras et al., 2021), despite, what is known from the current research, that long-term interaction among individuals who have leprosy has been found to facilitate *Mycobacterium Leprea occurrence* (Oktaria et al., 2018; Ribeiro et al., 2023). In addition, the World Health Organization maintains that the median period of incubation for leprosy varies between seven years, but can be as long as seventeen or even more years (WHO, 2020).

The study results revealed that among the cases who did not have the Bacillus Calmette Guerin mark on the left forearm had a 2.24-fold chance of enhanced *Mycobacterium Leprea* occurrence compared with the controls. Similar studies conducted in Brazil had agreed findings reporting that individuals who did not receive any dose of the Bacillus Calmette Guerin vaccine had a higher probability of leprosy disease when compared to those who did more than two doses (Lima et al., 2020).

The study discovered a discrepancy between cases and controls in terms of the existence or absence of a BCG mark on the left forearms, only 16.9% of the controls had no BCG scars, compared with the 43.1% of the cases .Another study in Ghana by Ofusu et al revealed that the existence of a BCG mark partly offers protection against *Mycobacterium Leprea* bacilli, with 52% effective in protecting against *Mycobacterium Leprea* (Ofosu & Bonsu, 2011).

In a study conducted in the study area by Bandika et al, in 2018, in Kenya showed the proportion of fully immunized children stood at 63.7% in the Msambweni region far below the WHO target of 80% in rural settings (Bandika et al., 2018). The same study further revealed that the national vaccination coverage for BCG was 99.5% against 87% in the study area. The study showed that the immunization coverage for BCG in the study setting is low and strategic interventions tailored to the County should be encourage by the National Expanded Programme on Immunization (EPI) and the County Health leadership to improve the BCG uptake, while the study found an association between the absence of BCG mark and *Mycobacterium leprea* occurrence, further understanding is needed to contradict the linkage between Bacillus Calmette Guerin vaccination and the *Mycobacterium Leprea*.

5.2.1 Clinical description of leprosy cases

The study results showed that 90.8% of the cases identified had the Multibacillary type of leprosy, other similar studies done in Ethiopia and India are in agreement with the study findings where they reported over 90% of their patients are diagnosed with the advanced form of leprosy (Muthuvel et al., 2017; Urgesa et al., 2022), furthermore, patients with a Multibacillary type of leprosy have worse symptoms and a prolonged illness progression (WHO, 2015).

The study results showed that the median prolonged delay for leprosy patients was 45 months. The findings are 3 times higher than the global average of 14.8 months reported in 2020 (WHO, 2020b). The study might attribute the delay to patient-related factors like inadequate knowledge of leprosy-related symptoms, cultural beliefs, or even health-related factors. However, in a similar study done in Ethiopia, they reported a prolonged delay of 12 months (Dharmawan et al., 2021), The study believes that the clinical argument among the healthcare workers in Ethiopia is relatively higher. The data showed an average delay in case detection of 51.3 months. However, in a similar study done in Zimbabwe, they reported a mean detection of 17 months (Ribeiro et al., 2023).

The study assumes that different countries have varying periods for the observed delay, owing to how different countries handle their health systems, as well as different cultures and beliefs. As a result, in a recent study conducted in Ethiopia, an upper limit of 6 or 12 months was adopted as an accepted criterion for long detection delay in leprosy (Dharmawan et al., 2021). The study adopted an acceptable limit of twelve months, the study believes the late diagnosis of leprosy patients might be attributed to both the patient and health system challenges.

The study findings further revealed that the vast majority of cases (78%) were detected at a health facility within twelve months after the start of their initial signs and symptoms. Similar results published in Brazil in 2023 agree with our findings that revealed 84% of the patients had 12 months of prolonged delay in seeking health care services (Ribeiro et al., 2023). The study believes that insufficient access to health treatments, regional differences, and various cultural views may all contribute to the delay.

In the study, 21% of the cases were diagnosed with impairment grade II, compared to the global average of 6.7%. This indicates our results are five times higher than the global average. Countries with a proportion of more than 5% are thought to have a higher burden of leprosy transmission and undetected leprosy cases in the population(WHO, 2015).

5.3 Behavioral and social-economic factors

The study results showed that individuals who skipped meals to deal with hunger often ate one meal (46%) or even slept hungry were two times more likely to develop leprosy disease compared to the controls. This seems to suggest that people with little income have little money to spend on food making them vulnerable to *Mycobacterium Leprea* occurrence. Similar findings were reported in a study, in Brazil in 2018 by Oktaria et al, where the cases with low Body mass index had higher odds of contracting leprosy disease (Oktaria et al., 2018).

In Ethiopia, Urgesa et al, demonstrated that persons who frequently face food scarcity are more vulnerable to leprosy disease than those who are food secure (Urgesa et al., 2021), where they have a weakened immune system as a result of malnutrition is a risk factor for leprosy disease (Bekala et al., 2021). Alternatively, this variable could represent a catalyst for other health conditions associated with extreme poverty and

hunger such as risky behavior to increasing exposure (Anantharam et al., 2021). Wagenaar et al,2015, in India, argue that additional research is needed to determine the direct link between the host response to latent leprosy disease severity and hunger (Wagenaar et al., 2015).

The study reported that a low frequency of changing bed linen had a 2.7-fold increased risk of *Mycobacterium Leprea* occurrence, Other studies that had similar findings included a study done in Brazil on social determinants of leprosy cases by Nery et al,2019, which attributed the result findings to inadequate access to basic clean water supply, poverty, and personal hygiene (Nery et al., 2019). Similar findings were documented in a study done in Ethiopia in 2020 by Emerson et al where they suggested that water that is reused or shared by a leprosy patient is likely to be an environmental reservoir of leprosy disease transmission (Emerson et al., 2020). If water is limited the mothers may not wash their bed linen (Emerson et al., 2020).

Other studies with agreeable findings in Brazil by Oliviera et al,2019 suggested that families that do not maintain good hygiene practices like changing of bed line have a higher association with the development of leprosy disease (Oliveira et al., 2019), the same study further reported that *Mycobacterium Leprea* can survive and thrive in inanimate surfaces (Oliveira et al., 2019; Richardus, 2013). Previous results by Oktaria et al,2020, hypothesized that *Mycobacterium Leprea* occurrence could assist its development and multiplication on bed linen, hence increasing the bacillus family infection (Oktaria et al., 2018).In addition, recent literature has linked water to possible routes of infection (Ploemacher et al., 2020), nevertheless, viable *Mycobacterium Leprea* has been reported in soil samples, but the path of its spread from person to surroundings is uncertain (Oliveira et al., 2019), in addition, some scholars believe this might be from the shedding’s from the leprosy patient skin (Oliveira et al., 2019).

5.4 Household and Environmental Factors

The study results revealed that among the cases households that had household members of five or more members with a mean household of 7.6 individuals per household, a ±standard deviation of 2.8 had a 6.99-fold chance of enhanced *Mycobacterium Leprea* occurrence compared with the controls who had a mean household size of 5.7 individuals per household, the standard deviation of 2.8.The study observed a discrepancy between the cases family size and the controls.

A similar study in Brazil revealed that viable *Mycobacterium Leprea* has been reported in soil samples, but the path of its spread from person to surroundings is uncertain. Overcrowded houses have an increased contact timeframe for the household members and the leprosy cases (Pescarini et al., 2018). Another study conducted in Ethiopia had similar findings that suggesting that there is an epidemiological linkage between overcrowded families and the vulnerability to leprosy disease (Bekala et al., 2021). The study findings highlighted that overcrowding is a sign of poverty, which may promote the association between disease progression and occurrence at the family or household level. In addition, Study findings from an observational research done in Ethiopia revealed that children from overcrowded homes were more vulnerable to leprosy disease (Bekala et al., 2021). However, research done in India by Wagner et al,2015, revealed that there was no evidence of the linkage of household density with enhanced leprosy spread (Wagenaar et al., 2015).

Existing research links *Mycobacterium Leprea* with animals, particularly armadillos, however, the study results suggest no association between leprosy disease with domestic animals and forest hunting. This validates the existing literature that *Mycobacterium Leprea* primarily infects humans (Marega et al., 2022).

5.5 Study Limitations

One of the limitations of this study is the selection bias. The controls were chosen using a screening checklist, and prior treatment history.

Recall bias among the study participants due to the study design. The study considered recall bias when creating the questionnaire and pre-testing. It is a characteristic of leprosy that determining the precise period and frequency of exposure and infection starting is impossible. It is therefore a weakness of any epidemiological approach that, due to the long and variable incubation period, risk factors would be sought that may or may not have existed 5 years or more previously.

The use of a Bacillus Calmette Guerin (BCG) mark on the left forearm as a substitute for immunity established against leprosy disease from Bacillus Calmette Guerin immunization. This might have introduced a bias since not all persons who develop vaccination marks on the left forearm partly develop immunity.

The study was unable to inquire about social and cultural attitudes about leprosy, the study did not investigate comprehensively health-seeking behaviour among interviewees, and the study did not investigate stigma and discrimination experiences.

Anthropometric information and nutritional profiles for the cases and controls were not evaluated since the outcome of the study was already known. Despite its limitations, the study appears to have several strengths. It employed a frequency-matched case-control study, which is a reliable study design for rare conditions.

5.6 Conclusion

Summary: Persons with missing Bacillus Calmette Guerin (BCG) vaccination mark on their left forearm are 2.24 times more likely to develop leprosy compared to those who do have the mark. Households crowded with five or more members with a mean of 7.6

individuals per household, have a 6.99-fold increased risk of leprosy compared to households with an average size of 5.7 individuals. Individuals who had close family contact with leprosy cases were four times more likely to develop leprosy compared to those who did not have it. In addition, People who had social contact with leprosy patients are 2.24 times more likely to develop leprosy compared to those without such contacts. Households with a low frequency of changing bed linen have a 2.7-fold increased risk of leprosy compared to those with more frequent changes.

Clinical factors:

The study results indicate that the family/kinship occurrence of *Mycobacterium Leprae* highlights significant factors in the spread of leprosy disease. Close interactions within nuclear families, distant relatives, workmates and social friends can enhance the occurrence of leprosy disease. Therefore, raising the need for targeted household interventions.

The study findings conclude the significance of BCG vaccination in partly preventing *Mycobacterium leprea* occurrence. The missing BCG mark on the left forearm, suggests to lack of vaccination, is significantly associated with an enhanced risk of *Mycobacterium Leprea* occurrence.

Behavioral and socioeconomic factors:

The study concludes that patterns of skipping meals to cope with hunger suggest food insecurity in rural communities and its effect on the health of the broader community members.

The study concludes that promoting good hygiene practices, specifically regular changing of bed linen and other clothing, is an important public health behavior in reducing the occurrence of *Mycobacterium Leprae* in rural communities. Bad hygiene

practices are likely to predispose the families to the spread and multiplication of the bacterium within homes.

Household and environmental factors:

The study concludes that overcrowding in rural households may be a significant factor for the enhanced *Mycobacterium Leprea* occurrence in the study setting. Larger family sizes are closely associated with facilitating more regular close contact, which might increase the occurrence of *Mycobacterium Leprae*

among rural populations.

The study concluded that the County government enhance target household contact tracing/household contact tracing surveillance beside household members and involve distant relatives, workmates, and social friends as a strategy to eliminate leprosy transmission in the community.

5.7 Recommendations

Clinical factors

Enhance and encourage BCG Uptake:

1. The Ministry of Health to enhance and expand the uptake of BCG vaccination coverage among all eligible persons, especially children.
2. Strengthen community surveillance systems to identify, and monitor households with known contacts of leprosy.

Enhance Surveillance and Early leprosy detection

1. Encourage door-to-door screening interventions for the affected persons, such will ensure timely diagnosis, treatment, and referrals

2. The County to encourage community-facility active case finding as a strategy to eliminate the disease.

Behavioral and Socioeconomic Factors

Encourage Good Household Hygiene Practices:

1. The County government to promote and encourage rural families to practice good household hygiene practices, like regular cleaning of sleeping areas, personal bedlinen, and personal hygiene. Public Health technicians and Community Health Promoters should reinforce these practices during routine household visits such as community dialogue and action days

Community-Health seeking practices:

1. Communities should be encouraged to seek early treatment remedies if any family member develops signs and symptoms related to leprosy. Immediate treatment intervention might prevent and control the disease progression to other family members and the entire community

Community resource -food security:

1. Promote and enhance the use of community resources such as value chain additions, local food programs, communal gardens, and subsidy purchasing for vulnerable persons to enhance food security.
2. Engaging with local rehabilitative programs and support networks can help facilitate the households have access to adequate and sustainable nutrition, thus reducing their susceptibility to the *Mycobacterium Leprea* occurrence

Community Social support and health education:

1. The County Government to initiate rural economic empowerment models and support groups like income-generating activities, marry-go-round, and social interventions like supplying specialized footwear for the affected community populations
2. Develop and implement advocacy and community engagement plans tailored to families with leprosy cases. Health networks like Health care workers, CHPs, and CBOs, should focus on early detection of leprosy, the modes of transmission, and preventive measures to reduce the dangers of spreading the disease within families.

Advocacy and Community Engagement Plan:

1. The Ministry of Health/County Government to develop an advocacy and community engagement Plan to enhance awareness levels on the signs and symptoms related to leprosy.
2. The County to develop and enhance dialogue and action days guidelines for community-targeted outreach and screening activities in the community.

Households and environmental factors

Encourage and enhance practices to reduce Overcrowding;

1. The County Government to encourage practices that reduce overcrowding within homes, like actively engaging healthcare workers in rural areas to conduct regular screening, especially in larger households, maintaining good household hygiene, and ensuring adequate ventilation. This could involve door-to-door visits and collaboration with local opinion leaders.

Encourage and promote community preventive measures:

1. Promote and encourage families with leprosy disease to practice preventive measures to reduce the dangers of disease transmission. These measures can include avoiding close physical contact with affected individuals, taking children for BCG vaccination, maintaining personal hygiene, and awareness creation to families on interventions that can halt the spread of the disease.

Enhance active community-facility surveillance;

1. The County to enhance household contact surveillance for all leprosy cases besides household family contacts and involve social contacts like workmates, and social friends as a strategy to eliminate leprosy transmission in the community.

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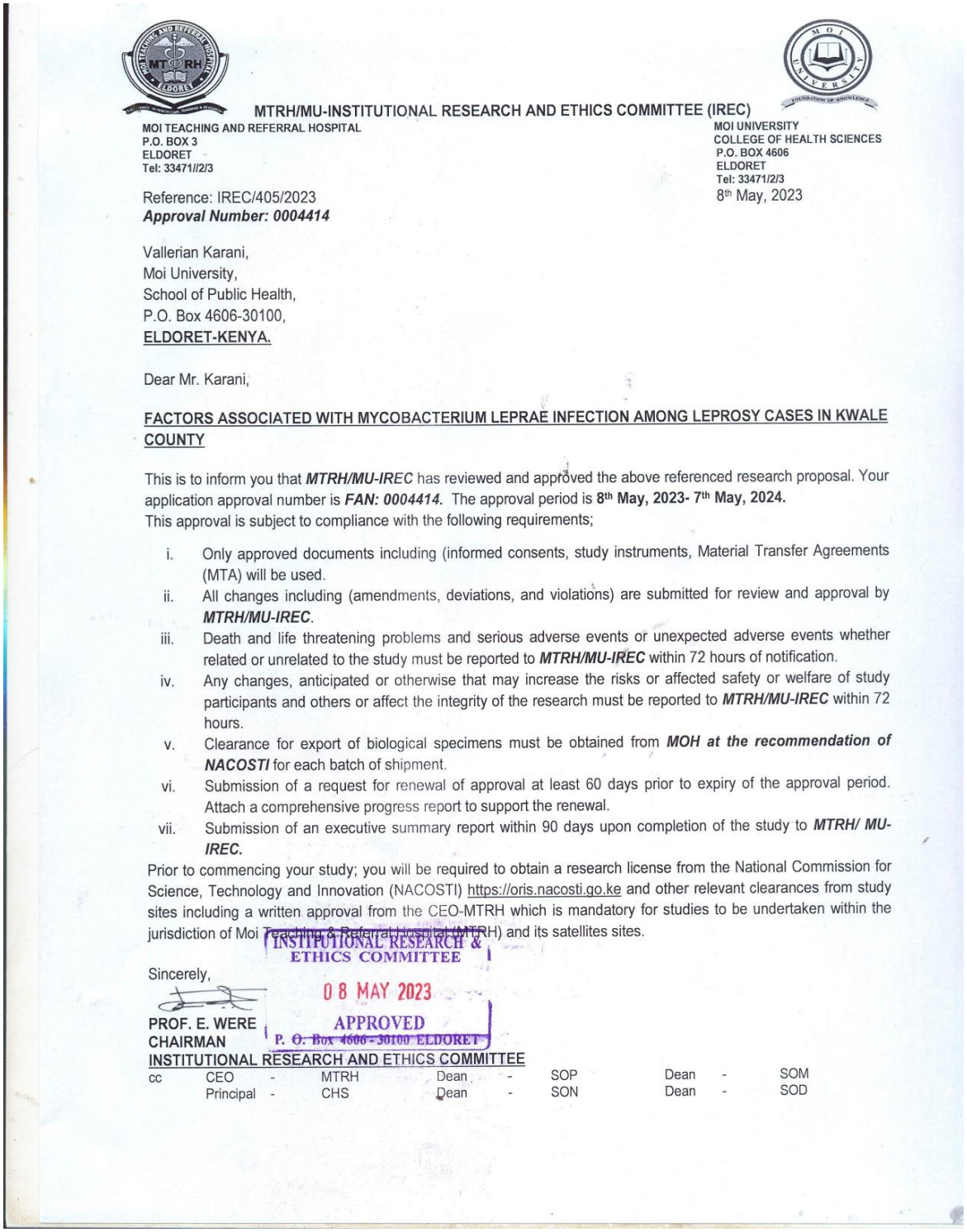
Appendices

Appendix 1 IREC Approval



MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/405/2023
Approval Number: 0004414

8th May, 2023

Vallerian Karani,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Mr. Karani,

FACTORS ASSOCIATED WITH MYCOBACTERIUM LEPRAE INFECTION AMONG LEPROSY CASES IN KWALE COUNTY

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved the above referenced research proposal. Your application approval number is ***FAN: 0004414.*** The approval period is **8th May, 2023- 7th May, 2024.**
This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MTRH/MU-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MTRH/MU-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MTRH/MU-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from ***MOH at the recommendation of NACOSTI*** for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MTRH/ MU-IREC.***

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
08 MAY 2023
APPROVED
P. O. Box 4606 - 30100 ELDORET

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

Appendix 2:NACOSTI License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **896014**

Date of Issue: **18/May/2023**

RESEARCH LICENSE

This is to Certify that Mr.. vallerian karani of Moi University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Kwale on the topic: Factors Associated with Mycobacterium Leprea Infection Among Leprosy Cases in Kwale County,Kenya for the period ending : 18/May/2024.

License No: **NACOSTI/P/23/26028**

896014

Applicant Identification Number

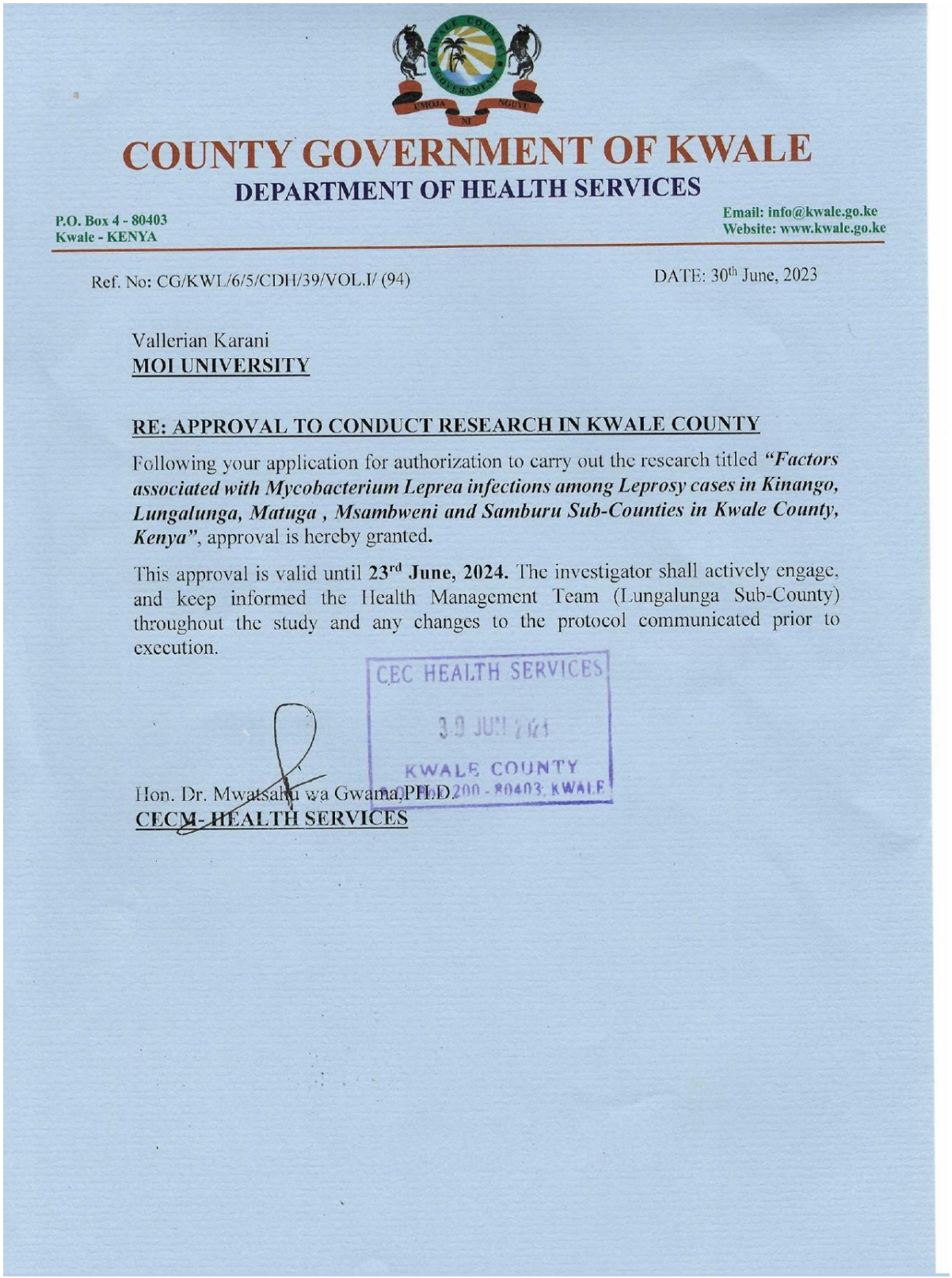
Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

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.

See overleaf for conditions

Appendix 3:Kwale County Approval



COUNTY GOVERNMENT OF KWALE

DEPARTMENT OF HEALTH SERVICES

P.O. Box 4 - 80403
Kwale - KENYA

Email: info@kwale.go.ke
Website: www.kwale.go.ke

Ref. No: CG/KWL/6/5/CDH/39/VOL.I/ (94)

DATE: 30th June, 2023

Vallerian Karani
MOI UNIVERSITY

RE: APPROVAL TO CONDUCT RESEARCH IN KWALE COUNTY

Following your application for authorization to carry out the research titled ***"Factors associated with Mycobacterium Leprea infections among Leprosy cases in Kinango, Lungalunga, Matuga , Msambweni and Samburu Sub-Counties in Kwale County, Kenya"***, approval is hereby granted.

This approval is valid until **23rd June, 2024.** The investigator shall actively engage, and keep informed the Health Management Team (Lungalunga Sub-County) throughout the study and any changes to the protocol communicated prior to execution.

CEC HEALTH SERVICES
30 JUN 2023
KWALE COUNTY
P.O. BOX 200 - 80403, KWALE

Hon. Dr. Mwatsahu wa Gwama,PH.D.
CECM- HEALTH SERVICES

Appendix 4 Questionnaire

Study Title**: 'Factors Associated with *Mycobacterium Leprea occurrence* among People With leprosy In Kwale County, Kenya**

Questionnaire number……..... Date of interview:(dd/mm/yyyy)

GPS Coordinates…….

Instructions: **This questionnaire is to be administered in an environment, in which ensures privacy and confidentiality have been strictly adhered**

Consent permitted □ Consent denied □

Interviewee category: Self-□ Proxy (Parent/Legal Guardian)

1. Sub County: …….....
2. Link Facility Name…….
3. Ward…….
4. Village…….

Part 1 – Demographic and Social Information

1. Age _____(In years)

2. Gender; Male □ Female □

3. Marital status?

Married □ single □ divorced □ widowed □ widower □

4. What is the religion of the Main respondent?

Christian□ Non-practicing□ Muslim□ Hindu□ Others, specify_____

5. What is the education level of the participant?

Uneducated □ primary level □ Secondary level □ Tertiary level□

6. What is the main income activity/occupation in this household?

Farming□ Livestock keeping□ Business□ Hunting□ Salaried/Employed□ Fishing□ Unemployed□ Others, specify_____

7. Has the participant ever experienced a food shortage in her lifetime?

Yes □ No □

If yes, On a normal day how many meals do you have?

One meal□ two meals □ three meals □ four meals □

8. When in the usual homestead, where have the participants been getting water for drinking/domestic use?

Piped water □ Borehole□ Spring□ Well□ River/lake/dam□ Others, Specify_____

Type of participant: Case □ Control □

Part II: Clinical information and treatment (For Cases only)

9. Date of onset of illness: _____

10. Date of enrollment for treatment---------- (Ask for the hospital appointment card)

11.Date released from treatment----------(Ask for the hospital appointment card)

12. How long did it take from the first symptom to seeking treatment? (In months/years):

_____

13. Type/Classification of the participant's disease (Ask for the hospital appointment card to check the treatment regimen if the participant is not sure)

Paucibacillary□ Multibacillary□

14. Did the participant experience/develop any of the following disabilities/deformities before going for treatment in the hospital?

Grade 0; no impairment□ Grade 1; loss of sensation in hand/foot□

Grade 2, visible impairment□ Others, specify ……

15. Did the participant experience/develop any of the following disabilities/deformities in the course/after treatment completing treatment?

Grade 0; no impairment □

Grade 1; loss of sensation in hand or foot□

Grade 2, visible impairment□

Others, specify ……

16. Did the participant seek any treatment/advice elsewhere before going to the hospital?

Yes □ No□ If not, skip to Question 18.

17. if yes, where did he/she seek treatment/advice before going to the hospital?

Traditional healer □ Local chemist□ Private clinic□ Others (Specify) _____

Part III. Risk factors /Exposure History assessment

18. How long have you lived in this area?
More than 5 years □ Less than 5 years? □
19. When in the usual homestead, does the participant have any other Household member diagnosed with the disease previously?
Yes□ No□ If No, skip to Qs 22
21. if yes, how long have you stayed /lived with a member of your Household/family?
Up to 5 years □ 6+ years□ Other specify……
22. When in the usual homestead, has the participant had any contact with someone who has the disease but not from your Household/family diagnosed with the disease?
yes □ No □ if no, skip to QS 24
23. If yes, how long have you been in contact with them?
Up to 5 years □ 6 Years+ □ Others specify……
24. Does the participant have a BCG scar on the left arm?
Yes □ No □
25. Using a MUAC, assess the Body Mass Index (BMI)/Zscore of the participants……..
26. Does/Has the participant been diagnosed with any of the following diseases previously
Tuberculosis□ 2.HIV/AIDS□ 3. TB/HIV□ 4. Cancer□
Diabetes/Hypertension □ other specify……

Part iv: Human Behavioral Factors

27. Does the participant usually share their own(current) bed linen?
Yes□ No□
28. Does the participant usually share other bed linens?
Yes □ No□
29. How frequently does the participant change their bed linen?
<Biweekly□ >Bimonthly□ Quarterly□ Biannually□
30. Does the participant have a bathroom?
Yes□ No□
31. Between the sunset and the time (s) he goes to sleep, for the previous 5 years, have you ever been bathing in the open (dam, river, lake)
Yes □ No□
32. Are domestic animals available in this home?
Yes□ No□ If no, go to Qs. 38
33. Are there usually animals at night in this houseyard where (s) he is used to sleeping? (including animals located outside in animal accommodation pens)
Yes□ 2. No□
34. During the last 5 years, did the participant practice hunting in the forest?
Yes□ No□
35. During the last 5 years, did the participant practice fishing?
Yes□ No□
36. During the last 5 years, did the participants ever live in the following areas

as places of usual residence or in search of pastures/relatives?

Kilifi/Kwale/Mombasa□ Bungoma/Busia□ Homabay/Siaya/Kisumu/Migori□ Others, specify_____

Part v: Household and Environmental factors

37. Between the sunset and the time (s) he goes to sleep, what are the number of rooms in the homestead

<3□ 3-5□ >6□ other, specify……

38. Between the sunset and the time (s) he goes to sleep, what is the number of your household members, including the participants?

<5□ 5-10□ >10 □ others, specify……...

39. During the last 5 years, did the participant ever worked/work on an agricultural farm?

Yes□ No□

Observation: Ask the participants or the caretaker to show you the room where the participant sleeps when they are in the House (if there are several rooms, ask for the main room and as well observe availability and use of the toilets)

40. What type of floor in the room where they use for sleeping? observe

Earth □ Earthen □ Cemented/tiled□ A mixture of animal dung□ Others specify…….

41. What is the type of House in the participant's usual home? Robert

Temporal grass thatched house□ Permanent house□ Manyatta□

Semi-permanent house□ others, specify_____

42. In the usual homestead, where does the participant usually go for toilet purposes for the previous 5 years? Observe

Personal Latrine/Toilet□ In the Neighbour's Latrine□ In the bush/open field□ others specify……

Part VI: General Knowledge and Practices of Leprosy in Kwale County

43. Are you aware of the disease? (Before illness for cases)

Yes□ No□

44. How can one get leprosy (Do not read)

Airborne□ Contact with infected person□ witchcraft□ inheritance□

Others, specify_____

45. What are the signs and symptoms of leprosy? (Do not read)

loss of sense in the hands and feet□ Any weakness in hands and feet□ Any wounds on hands and feet Any problems in relationships or participating in festivities, work, or meetings□ Others, List_____

46. How can someone with leprosy be cured? (Do not read)

Drugs from health facility□ Traditional medicine □ No, cure□ Do not Know□ Others, specify

47. Do you know anyone who got sick, has been treated, hospitalized, on medication, or died because of leprosy?

Yes□ No□

48. Do you think leprosy is a severe problem in your community?

Very serious□ Serious□ Not serious□ Do not know□

49. Have you received any information about leprosy in the last 6 Months?

Yes□ No□

50. If yes, what were your Sources of information on leprosy?

Radio/Television□ Health care worker□ Flyers/Brochures□ Chief□ CHV,s□ Others specify----------

51. Do you practice any of the following leprosy prevention and control measures? (Read

Furthermore, allow the participant to name others not listed?)

□Use of bed nets □Use of insect repellants for humans □Use of insect repellants for animals □Indoor spraying with insecticide □Filling cracks on walls □Fighting rodents □Cutting trees □Killing dogs □ Others specify_____□ I don't practice any

52. Would you wish to receive more information on leprosy?

Yes□ No□

53. What were the preferred sources of receiving more information about leprosy?

Radio Health care worker Flyers/Brochure Chief Barraza's Television 7. Megaphone/Public address systems CHV, s Others (Specify)_____

Appendix 5 Informed Consent Form in English

Introduction:

Greetings!

I am Mr/Mrs/Miss _____; a research assistant working for Moi University School of Public Health in the Department of Epidemiology and Field Epidemiology and Laboratory Training Programme (FELTP), Kenya. The study researche titled *Factors Associated with Mycobacterium Leprea occurrence among Leprosy cases*, which is one of the prevalent neglected tropical diseases in your County. The interview may take up to 30-40 minutes. I will give you information and invite you to be part of this research, you are free to consult further in taking part or withdrawing from the study now, and whenever you want, there is no penalty.

There may be some words that may seem unfamiliar during the interview or that you need help understanding. Please ask me to stop the study through the information, and I will take the time to explain. If you have any questions, concerns, or complaints about the study later, you can ask them for me by calling the principal researcher, Valerian Karani, at this number (+254) 729785029)

Purpose of the research

The significant geographical pattern variations of most new leprosy cases in Kenya over 10 years have been documented in Coast (64.4% and Western (14.4%) regions with Kwale Count contributing 20.3% for all reported leprosy cases in the Country. This may indicate the need to determine the independent risk factors associated with *Mycobacterium Leprea occurrence* among leprosy cases in Kwale County, Kenya. In the last five years, all four sub-counties in Kwale County have reported at least one or more active leprosy disease, with more cases reported in Kinango and Msambweni sub-counties. The County Government of Kwale offers free, timely diagnosis and treatment

services of leprosy disease across all the Health facilities, with the primary objective being to provide health education, case management of leprosy cases, sensitize the catchment populations on the risk factors for leprosy disease, targeting community active cases search, contact tracing, increasing clinical suspicion index among health care workers with the ultimate aim of halting the trend and reducing morbidities and disabilities associated with leprosy disease.

Confidentiality

The study does our best to protect all the information about you and your name will not be written on the interview form. You will not be named in any of our reports. Only the study staff and investigators will know your answers to the questions.

Your rights as a participant: This research has been reviewed and approved Institution Research and Ethics Committee at Moi University.

Participant's selection:

Cases: The data extraction tool (Appendix 8) was used to extract the data for all the leprosy cases documented in the Leprosy register including patients discharged from treatment 12 months earlier. Patients were selected from consenting participants at their residences/villages in the list generated in the TB and leprosy clinics within Kwale County. To achieve a sample size of 260. The Selected cases and control f were matched according to sex, age (+/-10 years), and place of residence.

The controls were drawn from the same villages (neighbors) as the cases and controls were interviewed in their households. From previous records over 5 years, an average of 30 -35 cases of leprosy disease are reported annually in Kwale County. The cases are distributed across all the diagnostic and treatment facilities in the County. To achieve the sample size of 65 cases, The study will enroll all leprosy cases including

those previously treated and discharged from treatment 24 months. Upon consenting of the Cases and controls a structured questionnaire was administered.

Controls in the village: Controls were drawn from the same villages as cases, and their frequency was matched by the cases' age (+-10), gender, and place of residence. Controls were identified using simple random sampling by identifying the villages where the cases live. Once the area had been identified, A pen was spun to identify the first household from where the tip of the pen points. The Research Assistant will select the first household following the direction of the pen's tip. In this regard, the first household is selected systematically; if the household is skipped, the pen will have to be pinned again and again as it moves to the next home from the direction of the pen's tip until all the control households are covered.

Controls at the Household level: At the household level, permission was requested to conduct interviews, irrespective of age. A list of individuals living in that household was developed, the individuals in the age category of the Case were identified, and if they are more than one, one was randomly selected through secret balloting by the use of papers marked yes or no. If there was no person on the homestead, the household was dropped, and the next household was selected.

Consenting individuals were asked screening questions using a checklist (Appendix 5) to ensure they met the inclusion criteria, and later the questionnaire was administered. In Case of refusal of consent or absence of household occupants, the following household was selected. This was done until each village's required controls were attained.

Risks and benefits: There were no known risks or benefits to you as a person participating in this study research. However, the overall impact on your community may be significant because the risks associated with leprosy disease, among other tested

objectives, may be crucial in addressing the health problems associated with this infection.

Confidentiality: All information you will provide is treated with utmost confidentiality.

Consent: You are free to withdraw from the study now and whenever you want, there is no penalty.

Whom to contact: If you ever have questions about this study, you should contact the principal investigator: Vallerian Karani Box 45, Busia, MOH-FELTP Kenya, Mobile number (254)729785029.

For questions about your rights as a participant, you may contact/call the professor. Lameck Diero's Mobile number is +2547914883519 and Dr. Ahmed Abaade+254722818237 who are the supervisors of this study.

Signature: ……...

Do you agree?

Participant agrees ☐

Participant disagrees ☐

By signing this form, "I authorize the use of my records, any observations, and findings found during this study for education, publication, and/or presentation."

I voluntarily agree to participate in this research program

□ Yes □ No

Questions: If you have any questions, concerns, or complaints about the study, please call **Valerian Karani-PI** at (+254) 729785029, **Co-investigators: Professor Lameck Diero**-Moi University and **Dr.Ahmed Abade**-FELTP Resident Advisor who are the Supervisors for the study

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

_____ _____

Signature of a participant or Guardian Date

_____ _____

Signature of interviewer Date

_____ _____

Signature of Principal Investigator Date

Appendix 6: Translated consent (Kiswahili)

Bw/Bi_____ Daktari Vallerian Karani, Mimi ni mwanafunzi kutoka chuo Kikuu cha Moi nikifanya Shahada ya uzamili ya somo la Uwanja wa Epidemiologia na Mafunzo ya Mahabara Field Epidemiology and Laboratory Management'. Ninafanya utafiti juu ya hatari na sababu ambazo zinaweza kuwa zinachangia kueneza kwa ugwonjwa wa Ukoma katiku Jimbo la Kwale.Lengo la Utafuti: Sababu ya utafuti huu ni kuweza kuangalia hatari na visababuambazo zinachangia kueeneza kwa ugwonja wa "Leprosy" katika jimbo la kwale. Utafiti huu utafanywa kwa watu wanaoish katiku jimbo la Kwale hizi mbili kulingana na mikakati ambazo zimewekwa juu ya uteuzi kwa wanao kubali kushiriki kwenye utafiti huu.Utafiti huu unalenga kutafuta sababu za kueneza kwa ugonjwa huu na pia kuweza kuona madara ya ugonjwa huu kwa wanao adhirika na pia kwa jamii kwa minajili ya kusaidiana na serikali na washirikadau waa afya haza wanaousika na ugonjwa huu ili wapate njia mwafaka wa kusuia na kuepukana na maradhii hayo.Utafiti huu pia unalenga kuwauzisha watu miambili na sitini (260) kwa muda wa utafiti huu. Mahojiano yatahudumiwa kwa watakaohojiwa kwa muda wa dakika ishirini na tano wakitumia muundo dodoso wakilenga kuuliza mambo ya idadi ya watu haza umri, jinzia na zinginezo na pia hatari za kueneza kwa ugonjwa wa Ukoma'. Hatari na Faida: Utafiti huu hauna kusidio ya hatari yeyote ambayo tunajua na pia utafanywa na madaktari walioitimu. Utafiti huu niwa kitaalamu na haina faida ya ubinafsi kwa wale watashiriki kweye mahojiano, bali matokeo yake yanaweza kuwa ya faida muda mrefu kwa kuweza kukabiliana na changemoto za afya katika Jamii haza kwa hatari zinazo ambatana na ugonjwa huu wa 'Visceral Leishmaniasis'.Usiri: Habari zozote ambazo utapeana yatakuwa ya faraghana siri kati yako na muhoji. Kumbukumbu zote zitafichwa kwa upatikanaji kwa watuambao hawaitaji kikuliangaliabila idhini yako, nambari zitapewa badalaya majina kamili kwenye muundo dodoso kwa usalama ya habari yako. Ridhaa: Unaruhusiwa kukubali kushiriki au kukata kushiriki utafiti huu kwa sasa na kwawakati wowote upendavyo bila tisho la tashushi au adhabu. Mawasiliano: Ukiwa na swali lolote, tashushi au lalamishi kuusu utafiti huu, unaruhusiwa kupigasimu kwa Vallerian Karani nambari ya simu; (+254) 729785029, Barua pepe; vallerian08@gmail.com

_____ _____

Sahii ya Muhusika Tarehe

_____ _____

Sahii ya Muhoji Tarehe

_____ _____

Sahii ya Mtafiti Mkuu Tareh

Appendix 7 Assent form

Factors Associated with *Mycobacterium Leprea occurrence* among Leprosy Cases, Kwale County.

My name is Vallerian Karani. I am a student at Moi University and I am currently pursuing a master's degree. I am inviting you to participate in a research study about **" Factors Associated with *Mycobacterium Leprea occurrence* Among Leprosy Cases in Kwale County, Kenya 2023."**

Your caregiver knows about this study and permitted you to be involved. If you agree, I will ask you some questions about yourself and information related to leprosy among children. These questions will help us to understand why The study of *Mycobacterium Leprea occurs* among children in this County. This process will take about 40 minutes or less if you agree to be part of the study. You do not have to be in this study. No one will penalize you if you decide not to participate in this study. Even if you start the study, you can stop later if you want. You may ask questions about the study at any time. If you decide to be in the study, I will not tell anyone else how you respond or act as part of the study. Even if your parents or teachers ask, I will not tell them about what you say or do in the study.

Signing here means that you have read this form or had it read to you and you are willing to be in this study.

Name of the Participant (Write your name in the line): _____

Signature of the Participant (Put your signature in the line): _____

Date:_____

Appendix 8: Data abstraction tool

Social- Demographic information			
Serial Number		District registration Number	
Health Facility		County	
Patient Name			
Sub-County		Ward	
Village		Physical Address, email address, phone number	
Alternative Phone Number			
Age		Sex	
Marital Status			
Clinical information			
BMI		Type of leprosy	
Type of patient		Disability of the eye	
Disability of the hand		Disability of the feet	
Disability Grade		Skin smears Results	
The date started on MDT			
TB Co-infection		HIV Status	
Other Co-infection			
Treatment Outcome			

(MOH, 2021)

Appendix 9 A screening checklist

YES/NO		
1	Do you have difficulty with seeing, even when wearing glasses?	
2	Do you have difficulty walking or climbing steps?	
3	Do you have difficulty washing all over or dressing?	
4	Are there activities that you cannot perform?	
5	Do you have loss of feeling in the hands and/or feet?	
6	Do you have any weakness in your hands and/or feet?	
7	Do you have any wounds on your hands and/or feet?	
8	Do you have any problems in relationships or in taking part in festivities, work, meetings, etc?	
9	Have you ever been diagnosed with leprosy previously?	
10	Has any member of your family been diagnosed with leprosy?	
11	Has any of your friends been diagnosed with leprosy	
12	Presenting signs/ symptoms	
13	Duration of symptoms in months	
14	History (of similar symptoms and treatment	
15	Skin examination: Total anesthetic Patches: (No.	
16	Skin infiltration: Yes/No	
17	Skin anhidrosis: Yes/No	

Nerve examination	Ulnar		Median		Radial		LP		PT		
	R	L	R	L	R	L	R	L	R	L	
Thickened											
Tender											

Disability status at the time of diagnosis	
Diagnosis	
18	signs of the disease with demonstrated presence of bacilli in skin smear or histopathological confirmation
19	Hypo-pigmented skin lesions with loss of sensation

Appendix 12: Data Confidentiality Agreement

I_____as a principal Investigator/Research Assistant/CHV of the 2023 leprosy verification exercise, understand that I may have access to confidential information about Health facilities and clients. By signing this statement, I am indicating my understanding of my responsibilities to maintain confidentiality and agree to the following confidentiality requirements:

I WILL treat all information collected for this data extraction process as confidential before, during, and after the assessment period. I will not use such information for any purposes other than for the work assigned to me during this exercise.

I WILL NOT share any information about the sampled clients and facilities with persons outside the analysis team. This information may include their HIV status.

I WILL refer all data-related questions asked of me that I am not authorized to disclose to the appropriate data analysis team leader or supervisors.

I WILL maintain all related data/material in a secured location at all times. I will also make sure that persons not involved in this exercise do not have access to the analysis material.

I WILL report the loss of any assessment data/material whether in paper or electronic format immediately to the analysis team lead, who is responsible for reporting this information to the TB Programme.

If I use a phone or tablet to enter or store collected information, I WILL keep that information password-protected.

I will destroy any hard copies of materials that I may have generated in the course of the analysis before leaving the health facility.

I WILL NOT produce copies or back-up of datasets except as required.

I WILL NOT misuse any information security privileges that I may have from working on this exercise.

I WILL ensure that the backup datasets are also stored according to the confidentiality guidelines mentioned above. I WILL NOT use the results of the assessments in any way without prior authorization from the Ministry of Health.

If I cause a breach or become aware of a breach in confidentiality, I WILL take immediate steps to secure the sensitive information and inform my analysis team lead who will inform TB Programme/Moi University.

I WILL fully comply with any other data confidentiality procedures that I am instructed to follow during this analysis. I understand that failure to comply with these rules and regulations could result in disciplinary action.

My signature below indicates I have reviewed, understand, and accept the above requirements.

SIGNATURE:_____ DATE (dd/mm/yy):