FACTORS ASSOCIATED WITH HIV SEROCONVERSION AND FACILITATORS AND BARRIERS FOR CONCURRENT USE OF METHADONE AND ANTIRETROVIRAL THERAPY AMONG PERSONS WITH OPIOID USE DISORDER IN KISAUNI MAT CLINIC, MOMBASA COUNTY, KENYA.

BY

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A THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN FIELD EPIDEMIOLOGY

DECLARATION

I hereby declare that this is my original work and has not been presented for any award in any other university or institute for academic credit. Any material derived from other sources has been acknowledged.

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DEDICATION

I dedicate this research work to families and friends of persons suffering from opioid use disorder in the country. I also dedicate this work to my parents and all who encouraged me to pursue and complete this study.

ABSTRACT

Background: Methadone Maintenance Treatment (MMT) is the use of an approved drug, in combination with counselling and behavioural therapies, to provide a 'whole-patient approach' to treating substance use disorder. Kenya adopted MMT in 2014 as part of a multi-strategy approach to preventing the spread of HIV infections among opioid injectors. However, there is limited data on the impact of MMT on HIV in the Kisauni MAT Clinic.

Objectives: To determine the prevalence of HIV coinfection with HCV, HBV, and TB co-infections among MMT clients in the Kisauni MAT clinic, determine the HIV seroconversion rate, identify factors associated with HIV seroconversion, and explore the facilitators and barriers to concurrent methadone and antiretroviral therapy (ART) use.

Methods: This was a retrospective cohort study among those with opioid use disorder (OUD) enrolled in the Kisauni MAT clinic, in Mombasa County, Kenya. A sequential explanatory approach was used to collect quantitative and qualitative data. All the records for the clients enrolled between 2015 and 2019, and their HIV outcomes as of December 2022 were reviewed. In-depth interviews with the identified HIV seroconverts were conducted using a developed interview guide. An HIV-seroconvert was defined as any HIV-negative MMT client at enrolment who tested positive during a follow-up test. Descriptive analysis was done using measures of central tendency for continuous data and proportions for categorical data. To determine independent predictors of HIV seroconversion, Fisher's exact test and chi-square test were used. All factors with a p-value $\leq$ 0.2 at bivariate analysis were included in a logistic regression model. Factors with a p-value ≤ 0.05 and their Risk Ratios (RR) were considered significant. Qualitative data were transcribed and themes were manually categorized into key themes and sub-themes.

Results: Of the 936 records reviewed, 729 were analysed; 91.1% were male and 61% were non-injectors. HIV co-infection was as follows: HIV/Hepatitis C Virus (HCV) at 78/729 (10.7%), while HIV/Hepatitis B Virus (HBV) and HIV/Tuberculosis (TB) were at 4.7% (34/729) and 3.8% (28/729) each. In 3,386.9 total follow-up years, 14 (1.9%) clients seroconverted to HIV at a rate of 0.4 (95% CI:0.2–0.7) new infections per 100 person-years (PY) with females having a higher seroconversion rate of 1.9/100 PY (95% CI:0.7–4.2) compared to males at 0.3/100 PY (95%CI:0.1–0.5) PY. Injectors and non-injectors both seroconverted at 0.4/100 PY (95% CI:0.2–1.0 and 0.2–0.8, respectively), with a rate ratio of 1.1 (95% CI:0.3–3.7). The factors associated with HIV seroconversion were being female (Adjusted Risk Ratio [aRR] of 8.01; 95% CI: 2.64, 24.3), and a positive Hepatitis C test (aRR of 3.7; 95% CI;1.08, 12.42). Condom use during sex reduced the risk of HIV seroconversion by 74% (aRR 0.26: 95% CI; 0.09, 0.8). HIV seroconverts identified drug-using peers, community stigma, transport costs, pill burden, and side effects at the initiation of concurrent ART and methadone, as barriers to treatment adherence. Family support and accessibility of methadone at sunset during Ramadhan facilitated adherence.

Conclusion: There was no difference in HIV seroconversion rates between injectors and non-injectors who are on the MMT program (RR of 1.1; 95%CI:0.3–3.7). A positive Hepatitis C test was an independent predictor for HIV seroconversion. Females were fewer in number but were independently at higher risk of HIV seroconversion. Social and economic barriers negatively affected treatment adherence among the HIV seroconverts.

Recommendation: Scale up the program by enrolling more people with opioid use disorder in the clinic, closely monitoring Hepatitis C-positive clients for HIV risky behaviors, and addressing social and economic barriers to improve ART and MMT adherence

OPERATIONAL DEFINITION OF TERMS

Defaulter: Any Medically Assisted Therapy (MAT) client who had missed a daily methadone dose for 14 consecutive days.

Direct Observation Therapy (DOT): An approach recommended by the Ministry of Health in Kenya which involves healthcare workers observing patients take each dose of their daily methadone drug.

Duration of Follow-Up: The time between the Medically Assisted Therapy (MAT) enrolment date and the date when the client seroconverted to HIV or the end of the study period, or the date when the client had defaulted or was lost to follow-up (LFTU) or weaned off.

HIV Seroconversion: Any HIV-negative Medically Assisted Therapy (MAT) client at enrolment who became HIV-positive during a follow-up test.

Injector: Any opioid addict who predominantly consumes opioids by injection to attain a euphoric feeling.

Lost To Follow-Up (LTFU): Any Medically Assisted Therapy (MAT) client who had missed a daily methadone dose for 30 consecutive days.

Medically Assisted Therapy (MAT) alias **Methadone Maintenance Treatment (MMT):** The use of an approved drug, in combination with counselling and behavioural therapies, to provide a 'whole-patient approach' to treating substance use disorder.

Non-Injector: Any opioid-dependent person who predominantly consumes opioids by smoking, or snorting to attain a euphoric feeling.

Opioid Substitution Therapy (OST): The practice of replacing an illegal opiate (such as heroin) with a prescribed medicine such as methadone or buprenorphine that is typically administered under medical supervision.

Opioid Use Disorder: A substance use disorder characterized by opioid cravings, ongoing use despite physical and/or psychological impairment, growing tolerance with usage, and withdrawal symptoms after stopping opioids.

Person Years: Calculated by multiplying the number of eligible MMT clients by the time (in years) each client spent in the program, and then summing the total observation time across all clients.

N.B.: In this study, the terms Medically Assisted Therapy (MAT) and Methadone Maintenance Treatment (MMT) were used interchangeably since Kenya uses MMT while globally, MMT is mostly used.

LIST OF ACRONYMS

AIDs	Acquired Immune Deficiency syndrome
aRR	Adjusted Risk Ratio
ART	Anti-retroviral therapy
cRR	Crude Risk Ratio
CD4	Cluster of Differentiation 4
CI	Confidence Interval
C.S.O	Civil Society Organization
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IDU	Injecting Drug User
MAT	Medically Assisted Therapy
MEWA	Muslim Welfare Association
MMT	Methadone Maintenance Treatment
MoH	Ministry of Health
NA	Narcotics Anonymous
NASCOP	National AIDS and STI Control Program

NSDCC	National Syndemic Diseases Control Council
NSP	Needle Syringe Program
OST	Opioid Substitution Therapy
OUD	Opioid Use Disorder
PWIDs	People Who Inject Drugs
PWOUD	People with Opioid Use Disorder
PY	Person Years
R.C.T	Reachout Centre Trust
RR	Risk Ratio
SSA	Sub-Saharan Africa
UNAIDs	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
VDRL	Venereal Disease Research Laboratory test
SUD	Substance Use Disorder
WHO	World Health Organization
WWUD	Women Who Use Drugs

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENT

I would like to acknowledge the following individuals and institutions for their contributions to this project.

1. My two supervisors, Dr Davies Kimanga and Dr. Kivwanga Mwaniki for their guidance during the development of the thesis.
2. Staff at Kisauni Medically Assisted Therapy (MAT) Clinic for assisting in the retrieval of patient records, identifying the clients to be interviewed, updating the patient records, and data entry.
3. Faculty Members from the School of Public Health, Moi University, and the Field Epidemiology and Laboratory Training Program Kenya (FELTP-K) for guidance in developing the thesis.
4. Field Epidemiology and Laboratory Training Program Cohort 17 residents for their support and encouragement during the study period.
5. Centers for Disease Control and Prevention (CDC), Kenya, and the Ministry of Health, Kenya.

God bless everyone who helped make this thesis a success.

CHAPTER ONE

1.0 Introduction

1.1 Background

Opioid use is a significant public health problem globally, contributing to considerable numbers of new human immunodeficiency virus (HIV) cases and other infectious diseases yearly (World Drug report, 2018). Opioid use is a major contributor to people with opioid use disorder (PWOUD) and remains a concern in 190 of 207 countries due to the severe health consequences associated with the same (Degenhardt et al., 2023). Globally, a high proportion of people with opioid use disorder (99.4%) are aged 15–64 years. In 2019, new HIV infections globally were 1.7 million, and 10% of these were People Who Inject Drugs (PWIDs) (UNAIDS, 2020). Furthermore, an increase in persons with opioid use disorder was noted in 2019, from an estimated 220 million in 2018 to 274 million (*World Drug Report_(UNODC)_2021*, n.d.).

The Eastern and Southern African regions are the most affected by HIV, they have shown a notable 57% decline in new HIV infections in 2022 (UNAIDS, 2023). However, more efforts are needed to minimize the region's high HIV prevalence, which was projected to be 5.9% [4.9–6.9%] among adults (aged 15–49 years). According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2022 report, the number of new HIV infections has reduced from above 1,500,000 to 500,000 [370,000-670,000] (UNAIDS, 2023), indicating that the desire to eradicate Acquired Immunodeficiency Syndrome (AIDS) by 2030 remains key. Moreover, HIV prevalence among the key populations has increased by 31%, particularly among injecting persons with opioid use disorder (21.8%) and sex workers (29.9%) (Gökengin et al., 2016; Mumtaz et al., 2022). Current evidence shows that People Who Inject Drugs (PWIDs) are 29 times more likely than the average

population to be HIV positive, but remain marginalized (UNAIDS, 2015). The endemicity of HIV infections among PWIDs leads to high mortality rates among this group. For example, China reported an estimated AIDS-related death rate of 2.55 per 100 person-years among PWIDs (*Sordo et al. - 2017 - Mortality Risk during and after Opioid Substitutio.Pdf*, n.d.).

The World Health Organization (WHO), in collaboration with other international organizations, endorsed Medically Assisted Therapy (MAT) also called Opioid Substitution Therapy (OST) or Methadone Maintenance Treatment (MMT)) as a harm reduction intervention for people who inject drugs (World Health Organization, 2005). However, MMT is considered non-stigmatizing and is globally accepted. A marked reduction in the number of new Human immunodeficiency virus (HIV) infections among people who inject drugs has been reported in countries that have implemented harm reduction programs, including Switzerland, the United Kingdom (UK), and Australia (Wishner et al., 2018). In 2015, China recorded seroconversion rates of 0.20 per 100 person-years for HIV and 20.54 per 100 person-years for Hepatitis C virus (HCV) among clients. (Zou et al., 2015). Though these studies have revealed lower HIV infection rates within MMT programs (Wishner et al., 2018), the coverage of Opioid Substitution Therapy (OST) interventions continues to be insufficient at the global level. As of 2017, 86 countries reporting injecting drug use globally were implementing Opioid Substitution Therapy programs (Larney et al., 2017; Richards et al., 2022). New HIV infections among active opioids users could continue to be a problem since most countries implement OST programs in localized small-scale centres with minimal nationwide coverage and legal

backing. Additionally, even fewer countries implementing both Needle and Syringe programs (NSP) and OST Programs as harm reduction strategies (Larney et al., 2017).

The provision of sufficient access to Methadone Maintenance Treatment (MMT) in Africa could prevent 130,000 new HIV infections every year (UNAIDs, 2020). However, only seven nations in the Sub-Saharan Africa (SSA) region presently have harm reduction programs: Tanzania, Uganda, Mauritius, Senegal, South Africa, and Kenya (UNAIDs, 2020). Overall, there is a paucity of data on the effects of interventions connected to methadone usage on HIV care outcomes in the region. A study from Tanzania conducted in 2019 found that Methadone Maintenance Treatment (MMT) programs may have prevented 13.5% of new HIV infections among People With Opioid Use Disorder (Leyna et al., 2019), and suggested that scaling up MMT and Needle Syringe Program (NSP) may reduce the overall HIV incidence by 62.6%, from 2.2 per 100 person-years in 2019 to 0.7 per 100 person-years by 2030 (Fraser et al., 2021).

HIV infection among people who use opiates is a severe public health issue in low-income countries, including Kenya. The country has reported the presence of heroin use along its coastal streets since the 1980s (Beckerleg et al., 2005). Of note, Kurth et *al* reported an annual HIV incidence of 1.6% in the Kenyan Coastal region among the PWIDs (A. E. Kurth et al., 2015a). Importantly, people with opioid use disorders in Kenya face stigma and other significant barriers to accessing healthcare services including fear of law enforcement agents. These factors may further contribute to a vicious cycle that aids in the spread of HIV within the group of people with opioid use disorder (Nieburg, 2021). Furthermore, the HIV epidemic among PWIDs in the country has shown geographical and

gender diversity with a prevalence of 36% among female PWIDs versus 17% among males (NASCOP & MOH, 2018).

To prevent the further spread of HIV and mitigate the effect of injecting drugs among PWIDs, Kenya introduced the MAT/MMT program in 2014. The approved medication was Methadone (Ministry of Health, 2017). A modelled impact of Methadone Maintenance Treatment (MMT) on HIV transmission anticipated a reduction of HIV incidence of 19% among PWIDs with 40% MMT coverage (Rhodes et al., 2015). Despite the expansion of OST services and the opening of nine MAT/OST clinics around the nation, Kenya was unable to achieve the 40% target; it enrolled 5,208 people with opioid use disorders of which PWID was estimated at 26% (n=16,000) of all the PWIDs in the country (Musyoki et al., 2021). Missing the OST coverage target derails the progress of the country in achieving the vision of the global HIV response of achieving zero new HIV infections. Additionally, the Coronavirus disease (COVID-19) pandemic emerged as a key challenge to MMT programs globally leading to unintended consequences such as defaulting from MMT treatment.

The HIV seroconversion during MMT has not been researched in the country. The few studies published were on HIV seropositivity (A. E. Kurth et al., 2015a; Wanjihia et al., 2018). A study among MMT clients in Nairobi reported an HIV seropositivity of 19.9% (Wanjihia et al., 2018). From 2014 to 2021, clinics operating in Nairobi reported zero cases of HIV seroconversion (Ciheb, 2021). In 2019, a cross-sectional study at the Kisauni MAT Clinic discovered that 1% (4/391) of the MMT clients were newly diagnosed with HIV but did not delve into risk factors for HIV acquisition (Mwanyalu et al., 2024). Since Methadone has been associated with reducing the risk of acquiring HIV by over 54%, there

is a need to evaluate the HIV prevention benefits among the MMT clients in the Kisauni MAT clinic (MacArthur et al., 2012). Therefore, the study aimed to evaluate the HIV prevention benefits of an MMT program in a resource-limited setting.

1.2 Problem Statement

In Kenya, key populations, including people who inject drugs, account for one-third of all the new HIV infections in the country (MOH & NASCOP, 2020). Mombasa County is among the counties with a higher burden of opioid use, with an estimated 16% of the PWIDs residing in the county (Health, 2019; National AIDS and STI Control Programme (NASCOP), 2014). The HIV incidence rate for people who are actively injecting drugs within the country is 3.8 per 100 person-years (Rhodes et al., 2015). The latest HIV progress reports placed the county among the top high HIV incidence counties contributing to over 1,000 new HIV infections in the country (MOH & NASCOP, 2020). Despite revealing that 1% of the clients were newly diagnosed with HIV in 2019 (Mwanyalu et al., 2024) implying the high HIV vulnerability for this population despite being on methadone. Overall, there is a dearth of accurate information on seroconversion rates and the drivers of HIV infections among clients on MMT treatment. Given the foregoing, there is a need to understand these factors among people with opioid use disorders enrolled in MMT treatment.

1.3 Justification

In order to develop measures to reduce the negative impacts of opioid usage on HIV prevention and control, it is necessary to assess the risky behaviours of clients utilizing harm reduction services. Medically Assisted Therapy clients who turn HIV positive are identified as a core group with a high potential to spread the disease to the general population (NASCOP & MOH, 2018).

Since the inception of the MMT program in the coastal part of Kenya, there has been no evaluation of its HIV prevention benefits. The study will provide insights into the integration of ART and Methadone programs, promoting a holistic approach to the management of HIV and opioid dependence. This can improve the overall quality of care by ensuring that patients receive coordinated and continuous care. The findings can guide the creation of public health strategies that aim to reduce HIV transmission among opioid-dependent individuals and also serve as a tool for advocacy, highlighting the importance of supportive policies that facilitate access to and continuity of care for vulnerable populations. Additionally comparing both injectors and non-injectors, will offer a clearer understanding of how MMT impacts the risks unique to injecting drug users and non-injecting drug users accessing the program.

1.4 Research Question

What was the HIV seroconversion rate, related risk factors, and experiences regarding the concurrent use of Antiretroviral therapy (ART) and methadone among Methadone Maintenance Treatment (MMT) clients attending Kisauni MAT Clinic, Mombasa County, Kenya?

1.5 Broad Objective

To determine the HIV seroconversion rate, related risk factors, and facilitators and barriers for the concurrent use of antiretroviral therapy (ART) and methadone among MMT clients in Mombasa County, Kenya.

1.5.1 Specific Objectives

1. To determine the HIV seroconversion rate among injectors and non-injectors with opioid use disorder enrolled in the Methadone Maintenance Treatment (MMT) program in the Kisauni MAT clinic, 2015–2022.

2. To establish the proportion of HIV, HCV, HBV, and TB infections and their co-infections among the enrolled Methadone Maintenance Treatment (MMT) clients in the Kisauni MAT Clinic, 2015–2022.
3. To identify risk factors associated with HIV seroconversion among clients enrolled in the Methadone Maintenance Treatment (MMT) program in the Kisauni MAT Clinic, 2015–2022.
4. To explore the facilitators and barriers to concurrent methadone and antiretroviral therapy (ART) use for HIV seroconverts in a Medically Assisted Therapy program in the Kisauni MAT Clinic, 2015–2022.

CHAPTER TWO

2.0 Literature Review

Substance use refers to the harmful or hazardous use of psychoactive substances, including opioids and unlawful drugs. According to scientific studies, opioid dependence is a lasting condition that leads to frequent relapses (Noble & Marie, 2019). Opioid dependence has commonly been compared with other chronic conditions like hypertension, diabetes, and asthma since it occurs in both high-income countries, with low middle-income countries (LMIC) countries representing 6% of global opioid consumption (Manjiani et al., 2014). Illicit drugs disproportionately affect young people in every part of the world. A range of illicit drugs abused includes cocaine, heroin, hashish, tobacco, Khat, alcohol, heroin, bhang, prescription drugs, etc. Worldwide, the lifetime uses of cocaine, heroin, and prescription drugs are nearly three folds higher among people aged 18–24 compared to the rest of the population (*World Drug Report_(UNODC)_2021*, n.d.). Illicit heroin is generally consumed by oral ingestion, injection, or inhaling the fumes produced by the heating.

The coastal part of Eastern Africa has been identified since the 1980s as the heroin trade route to reach the growing heroin market in the Middle East, Europe, and North America (Ross et al., 2008). Since the 1980s, the use of heroin has been documented among Kenyans. Seaports near Mombasa, on the coast of Kenya, are susceptible to drug trafficking, and there is a well-established flow of heroin from Pakistan and Iran to East Africa (World Health Organization, 2012). As in the rest of the countries in Africa, the Kenyan population is relatively young, with the prevalence of opioid use between 0.16% to 1.3% for the ages of 15–64 years (United Nations Office on Drugs and Crime, n.d.). In

Kenya, heroin goes by ‘slangs’ such us; *Unga, daba, kichuri, stuff, ondo, and keindo*. Studies have shown that opioid use and dependency have been associated with high rates of HIV, hepatitis B, and Hepatitis C infection, drug overdose, and criminality (‘WHO | Treatment of Opioid Dependence’, 2016).

2.1 Injecting Drug Use

Injecting drug use has been reported in 148 countries worldwide, accounting for 5% of the world’s population and of the over 11 million persons with opioid use disorder, 84% (9.2 million) inject heroin (united Nation Againist Drugs and Crime, 2021). People Who Inject Drugs tend to share their syringes, needles, and other injection equipment with their fellow Injecting Persons with opioid use disorder (IDUs) (A. Kurth et al., 2018). In addition, people with opioid use disorder may engage in risky sexual relations and sex work to finance their addiction (Brookmeyer et al., 2019; Khoei et al., 2019).

Overall, substance abuse is widespread across the entire globe. In Asia, many countries have reported people who inject drugs (PWIDs); Indonesia has 74,326, Vietnam at 271,000, and China has over 2.6 million PWIDs (Asia, 2010). The records for China are figures for drug injectors, across the country, as reported by police. These figures might be underestimations since the overall persons with opioid use disorder population in the country has been increasing to over 10 million (Monk-Turner et al., 2021). Likewise, Canada and the United States of America have an estimated 3,694,500 (95% confidence interval [CI], 1,872,700–7,273,300), while Latin America has 540,000 people who inject drugs residing in Brazil (Bradley et al., 2022).

The estimates for PWIDs in the Middle East and North African countries range from 7,000 in Libya to over 20,000 in Iran (*World Drug Report 2018*, n.d.). Sub-Saharan countries continue to see an increase in injecting persons with opioid use disorder in all countries, including Mauritius and Seychelles. Given the availability of strong, cheap heroin in the Coastal parts of East Africa, Dar es Salaam City, Tanzania has documented over 25,000 people who inject drugs (*Pioneering Methadone Programme in Dar Es Salaam Gives Hope to Thousands*, n.d.). Kenya estimates the number of PWIDs at 16,063, of which 11% of the people who inject drugs are younger than 18 years old (Health, 2019). The PWIDs size estimate data for Nairobi, Kilifi, Mombasa, and Kwale collectively accounted for 85% of the PWIDs estimates in the country (Health, 2019).

2.2 Injecting Drug Use and HIV infections

The high rate of HIV transmission among people who use drugs is mainly linked to the injection of drugs. Drug use by injection is a widespread issue that has been reported in at least 158 nations and territories (united Nation Againist Drugs and Crime, 2021). Globally, 5%–13% of HIV infections result from injection drug use (UNAIDS, 2015). In addition, 5.5 million people with drug use disorder are hepatitis C positive, and one million are coinfected with HIV and hepatitis C infections (Gen, 2016).

Developing countries have been shown to have the highest burden of HIV prevalence among PWIDs. China, which has invested a lot in HIV prevention among the community of persons with opioid use disorder in the country, has reported a low HIV prevalence at 6% (n=2 million) compared to Indonesia, Pakistan, and Vietnam at 36%, 37%, and 40%, respectively (United Nations Office on Drugs and Crime, n.d.; Zhang et al., 2021).

Afghanistan has reported an HIV prevalence of 4.4% of the projected PWIDs 40,900 (13,500-80,000) residing there (Global AIDS Monitoring, 2019).

The burden of opioid use in the SSA in 2006 was estimated at 778,500 PWID of which nearly 221,000 were HIV positive (Degenhardt et al., 2017). Close to 30 million people living with HIV in 2018 are in Africa (United Nations Office on Drugs and Crime, n.d.). In Mozambique, HIV prevalence was at 44.9% (95% CI:37.6–52.3) among the PWIDs, and 29.5% (95% CI: 22.2–36.8) were coinfected with HIV/HBV (Semá Baltazar et al., 2020). In Eastern and Southern Africa, there are approximately 410,000 injecting persons with opioid use disorder, 21.8% of whom are HIV positive (Gen, 2016). In Kenya, according to National AIDS and STI Control Program (NASCOP) now the National Syndemic Diseases Control Council (NSDCC), People who inject drugs (PWIDs) have a high HIV prevalence burden of between (18 to 30%) compared to the general population (National AIDS and STI Control Programme (NASCOP), 2014). The country estimated that 18.7% of new HIV infections on the Kenyan coast and 7.5% of cases nationally are attributed to opioid injection (A. Kurth et al., 2018). The estimated size for PWIDs in Nairobi was 6,107 while in Mombasa it was 2, 000 (Okal et al., 2013).

To reduce the spread of HIV, Hepatitis B, and Hepatitis C (HCV), the Government of Kenya has committed significant resources over the past few years toward achieving “an HIV-free society.” This fight is spearheaded by the National AIDS Control Council (NACC) and the National AIDS and STI Control Program (NASCOP), in collaboration with multiple local and international partners. With the high HIV prevalence among PWIDs, the government of Kenya, with civil society and international partners, introduced needle and syringe programs to stop the high-risk behaviour of sharing needles among

these groups with an over role goal to prevent the spread of HIV disease (A. E. Kurth et al., 2015b). The HIV epidemic among the People Who Inject Drugs has shown geographical and gender diversity. A prevalence of 36% among females to 17% among males (*Third-National-Behavioural-Assessment-of-Key-Populations-in-Kenya-Polling-Booth-Survey-Report-October-2018-1.Pdf*, n.d.).

2.3 Medically Assisted Therapy

Medically Assisted Therapy has been acknowledged as a useful intervention for both preventing HIV among persons with opioid use disorder and improving the adherence of HIV-positive individuals taking anti-retroviral (ARV) therapy (‘WHO | Treatment of Opioid Dependence’, 2016). Opioid Substitution Therapy (OST) is the practice of replacing an illegal opiate (such as heroin) with a prescribed medicine such as Methadone or buprenorphine that is typically administered under medical supervision (World Health Organization, 2005). Both drugs have repeatedly been proven to reduce opiate dependence and the frequency of injecting drugs, which in turn considerably lowers the incidence of HIV by several studies (Gowing et al., 2008). The National Institute of Health and Clinical Excellence in the United Kingdom recommends both buprenorphine and Methadone as the first line of treatment for Medically Assisted Therapy Programs (MAT) from heroin or other opioids for maintenance purposes (Sanger et al., 2018). Medically Assisted Therapy Programs (MAT) give illicit persons with opioid use disorder a substitute prescribed drug, such as Methadone or buprenorphine, which is usually administered orally as directly observed therapy (‘WHO | Treatment of Opioid Dependence’, 2016).

Methadone Maintenance Treatment (MMT) has been reported as an effective treatment for heroin dependence, risk reduction related to injection drug use, HIV transmission

prevention, and improving PWID adherence to Ante-Retroviral Therapy (MacArthur et al., 2012; 'WHO | Treatment of Opioid Dependence', 2016). It has been associated with a 54% reduction in HIV infection. The beneficial effects of opioid substitution therapy with methadone and buprenorphine have been seen not solely in economically developed nations but additionally in economically disadvantaged or resource-constrained nations and across different cultural contexts, such as in China, Indonesia, Iran, Thailand, Lithuania, Poland, and Ukraine. It has also been seen to reduce risky injecting behaviour, improve quality of life, improve health, and reduce criminality. Those who are untreated or who have ceased opioid substitution therapy have a higher risk of developing HIV than those who are receiving continuous treatment.

Tanzania became the first sub-Saharan African country to have established methadone treatment clinics in the region (*Ratliff et al. - 2013 - An Overview of HIV Prevention Interventions for Pe.Pdf*, n.d.). To prevent the further spread of HIV and other morbidities, decrease the risk to their health, and stop injecting, the Ministry of Health (MOH), through the National AIDS and STIs Program(NASCOP), adopted the Medically Assisted Therapy (MAT) program in the country (Kenya) in 2014 (MOH & NASCOP, 2018). The country advocates for Direct Observation Treatment (DOT) for the enrolled clients as per the Methadone dispensing recommendations. However, because people must leave their homes to travel to obtain therapy, DOT is linked to decreased client retention on treatment. During the COVID-19 pandemic, there was a low MMT retention rate, hence the program introduced the take-home dose. Moreover, during the holy month of Ramadhan MMT facilities in the coastal region, including Malindi and Mombasa MMT sites, practice moonlight methadone dose dispensing. This allows people with opioid use

disorder who fast during the day to take their daily methadone dose at night, shortly after completing their fast.

2.4 Clinical Pharmacology of Methadone

Methadone is a synthetic version of an opioid agonist that, like heroin, morphine, and other opioids, bonds to Mu-opiate receptors (MOR) in the brain (Kristensen et al., 1995). The binding affinities of racemic methadone and its optical isomers R-methadone and S-methadone were evaluated for the opioid receptors mu1, mu2, delta and kappa, in comparison with that of morphine. The analgesic R-methadone had a 10-fold higher affinity for mu1 receptors than S-methadone (IC50 3.0 nM and 26.4 nM, respectively). At the mu2 receptor, the IC50 value of R-methadone was 6.9 nM and 88 nM for S-methadone, respectively. As expected, R-methadone had twice the affinity for mu1 and mu2 receptors than the racemate. All of the compounds tested had low affinity for the delta and kappa receptors. This result suggests that S-methadone does not essentially contribute to the opioid effect of racemic methadone. R-methadone has a receptor binding profile which resembles that of morphine (Kristensen et al., 2020). It is one of the most extensively used drugs for the treatment of opioid addiction worldwide. Methadone and buprenorphine have been demonstrated to help alleviate the symptoms of opioid withdrawal and cravings. The two medications often function on the same brain targets as other opioids, but they do not provide patients with the "high" sensation associated with opioid use. The treatment rebalances the brain areas that have been harmed by addiction. This treatment allows the brain to heal while working towards recovery (Schuckit, 2016).

Evidence suggests that methadone treatment, when administered in accordance with the proper standard of care, is a safe substitute drug for opioid dependence, effectively keeping people in treatment and preventing heroin usage. Methadone is normally provided orally in liquid form once a day, with the greatest effects occurring 2-4 hours after intake, but the effects typically last 24 to 36 hours; thus, it is taken once daily. Even though everyone's metabolism for methadone is different, the majority of individuals who take it on a daily basis don't experience opioid withdrawal or intoxication between doses, and side effects are scarce (Schuckit, 2016).

Methadone used as MMT has an initial dose of 15-30 mg daily, which is increased every 3-5 days depending on how to control side effects and withdrawal symptoms. According to the studies, higher dosages of methadone than either moderate or low doses are linked to more pronounced drops in heroin usage. After 4-5 half-lives, or roughly 3–10 days, methadone enters a steady state in the body (when drug removal equals drug administration rate) (Kristensen et al., 1995). When used properly, methadone is a safe drug for both acute and chronic doses. Each patient with an opioid use disorder experiences a different level of success with methadone treatment. (OUD).

Most people who have used heroin experience few side effects from Methadone. Once the therapeutic dose is reached, blood concentrations remain steady (Kristensen et al., 1995). Methadone's effects on the brain are very different from the highs and lows of chronic heroin usage. When people who have been stabilised on methadone use an illegal opiate like heroin, they don't get as "high" as they would have if they hadn't been on methadone (Schuckit, 2016). As a result, individuals are also less prone to overdose on opioids, though they are still capable of doing so when using a mix of opioids and other sedatives.

It is crucial to remember that individuals who regularly use methadone experience opioid withdrawal if their therapy is abruptly stopped or interrupted. Opioid withdrawal symptoms will start off more gradually than withdrawal from short-acting opioids, like heroin, but they can be considerable and linger for a longer time, up to several weeks. It is easier for individuals with opioid dependence to quit using opioids in the future and to continue with the treatment sessions on a regular basis as they benefit from the impacts of methadone maintenance treatment. (Schuckit, 2016).

2.5 Factors Affecting Treatment Outcomes

Factors that have been identified as improving retention and treatment outcomes in developed countries include:

- The provision of ancillary services such as counselling, medical treatment, and job training;
- Clinic accessibility in terms of location and hours;
- Constructive (non-punitive) responses to client problems; and
  the provision of adequate doses of substitute drugs.

There is a correlation between the use of illicit opioids and decreases in the substitution therapy of opioid dependency with methadone alone. Nonetheless, there is proof that adding psychosocial therapy to methadone replacement treatment programmes synergistically increases their efficacy (McLellan et al., 1992). As a result, while counselling may be beneficial to those in need, mandating it might be counterproductive.

On the opposite spectrum, criminalization, stigmatisation, and marginalisation of persons with opioid use disorder are impediments to harm reduction access, according to Michelle

Bachelet, High Commissioner for Human Rights of the United Nations, in her May 2022 report on human rights and HIV.

Budgetary constraints also affect the effectiveness of MMT programs. Overall, Harm reduction services are significantly under resourced in many low middle-income countries. For example, only 8% of the funds allocated to HIV prevention in Kenya during the 2016–2017 fiscal year (including, but not limited to, harm reduction) were provided by the government. There are no additional harm reduction services financed by the national government in South Africa, with the exception of one scheme in the city of Tshwane. International financing is also necessary for Tanzania's harm reduction initiatives to continue.

2.6 Prevention and Control

In many regions, MAT/OST has proven to be highly successful in reducing opioid-dependent people's injecting drug use, hence lowering their probability of spreading blood-borne infections (Bertschy, 1995). According to the findings of a review of harm reduction studies undertaken in North America, Europe, and Asia, Opioid Substitution Therapy is associated with the prevention of 54% of new HIV infections among people who inject drugs (MacArthur et al., 2012). Opioid Substitution Therapy has also been shown to enhance ART access and adherence, decrease overdose and associated death, minimize criminal behaviour, and, more broadly, improve persons with opioid use disorder ' physical and mental well-being (A. E. Kurth et al., 2015b). According to Roberto Muga, HIV infection has a significant effect on survival, especially among HIV-positive women (Muga et al., 2014). Each year, 130,000 new HIV infections outside of sub-Saharan Africa may be avoided if OST was adequately accessible (UNAIDs, 2020). The WHO, UNODC, and

UNAIDS Technical Guide (2009) state that an OST coverage of less than 20% of opioid-dependent people is considered low, between 20% and 40% is considered medium, and over 40% is considered high (UNDP; et al., 2012). In a variety of settings and groups, methadone therapy increases ART use and Viral suppression. However, despite the clear benefits of MAT, most MMT programs are yet to be scaled up with only 8% of the injecting persons with opioid use disorder worldwide believed to be receiving MMT (Harm reduction international, 2022, p. 1).

2.7 Conceptual framework

The Figure below shows the conceptual framework that outlines the relationship and influence between the independent and dependent variables.

Independent variables **Independent variable** **Dependent Variables**

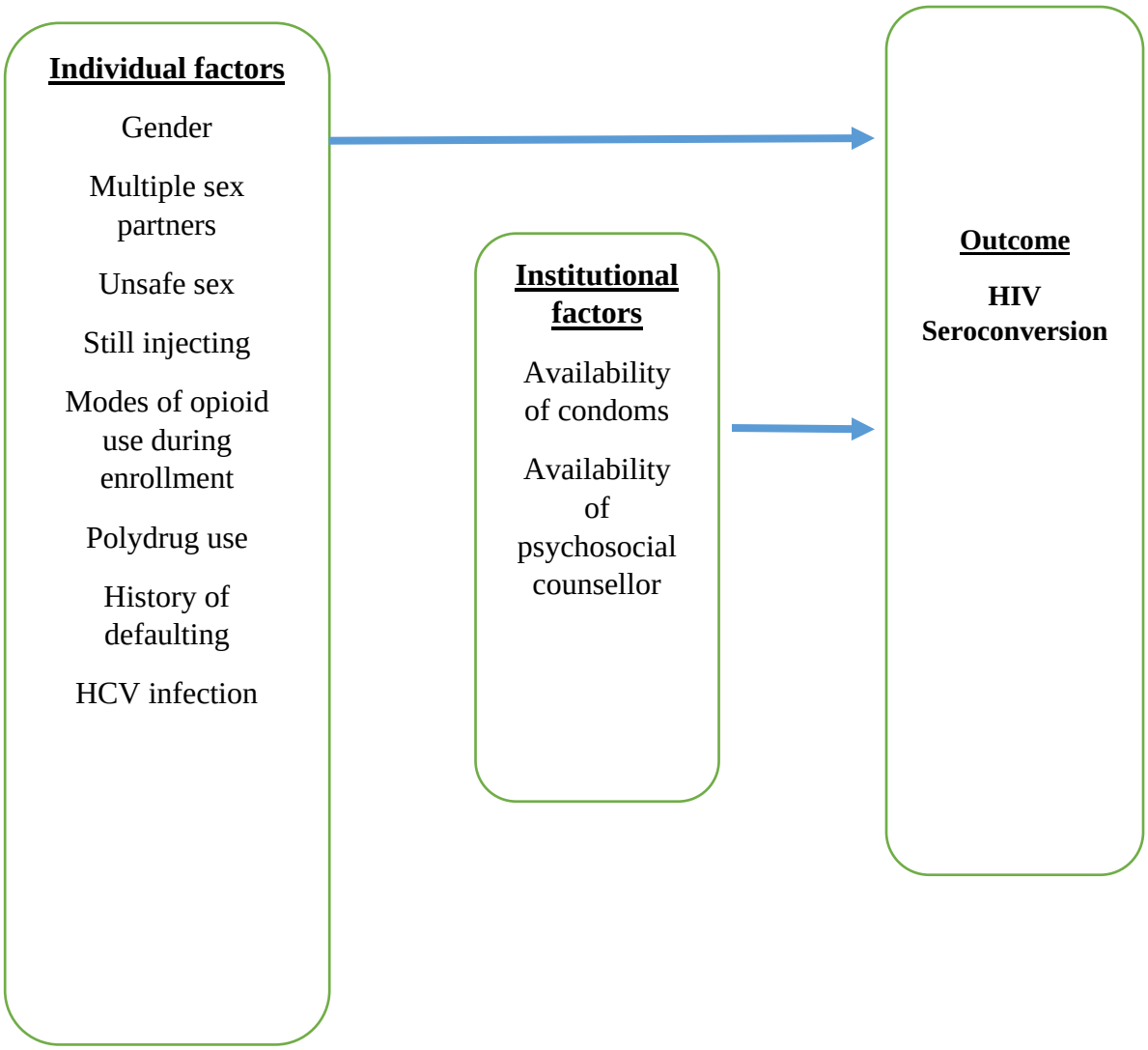


Figure 1: Conceptual framework showing interaction of potential risk factors for HIV seroconversion

CHAPTER THREE

3.0 Methodology

3.1 Study Area

Mombasa County is the second largest city in Kenya. It is situated along the Kenyan coastline of the Indian Ocean and harbours the largest port in East Africa and an international airport (*Welcome to Mombasa - Kenya*, n.d.). Mombasa County is the country's tourism centre, with 68% of wage employment arising from tourism activities (Kenya National Bureau of Statistics, 2018). Mombasa is among the major cities impacted by illicit drug use challenges, partly due to its strategic geographical position harbouring one of the largest seaports in East Africa. With a county population of around 1.3 million people, it is believed that over 2,000 persons inject opiates (MOH & NASCOP, 2020).

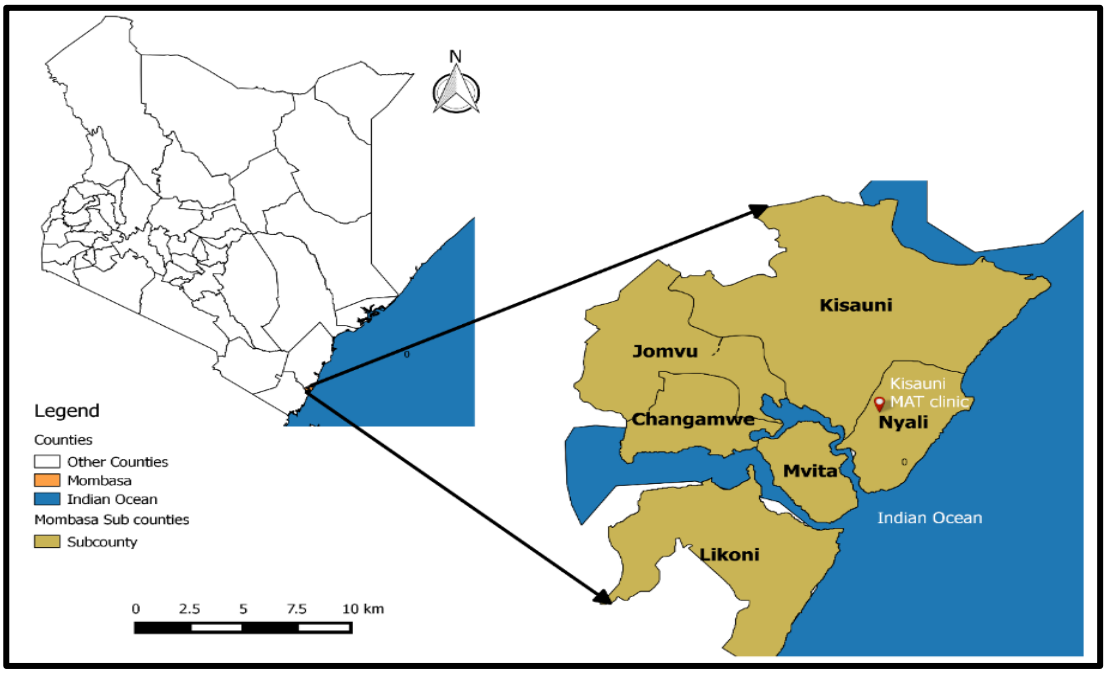


Figure 2: Kisauni MMT clinic in Mombasa County, Kenya.

MEWA Drop-In-Centre (DIC) and Reach Out Trust Centre (RCT) are Civil Society Organizations (CSOs) that identify opioid-dependent clients to be enrolled in the MMT program offered at the Kisauni MMT Clinic (National AIDS and STI Control Programme & MoH, 2016). Kisauni MMT Clinic is an outpatient Government of Kenya (GoK) facility in Mombasa County offering MMT services. Several services, including the assessment of clients' eligibility for MAT, HIV testing and counselling (HTC), issuance of methadone to enrolled clients, antiretroviral therapy (ART), prevention and treatment of sexually transmitted infections (STIs), condom programs for MMT clients and their sexual partners, and counselling are offered at the clinic. The Kisauni MAT Clinic was the only facility offering MMT services to 1,200 enrolled MAT clients residing across the county between 2016 and early 2021 (*KHIS Aggregate*, n.d.). In addition to two clinicians, two laboratory technologists, and two pharmacy technicians, the institution has a health records officer, a nurse, and a pharmacist. The psychosocial department is integral to the overall rehabilitation process, and is manned by two psychologists assisted by a medical social worker. In 2020, the clinic had the highest number of active clients recovering from opioid use disorder in the country accessing their daily methadone dose at this clinic (*2020 World AIDS Day Report Kenya HIV Progress Indicators,* n.d.).

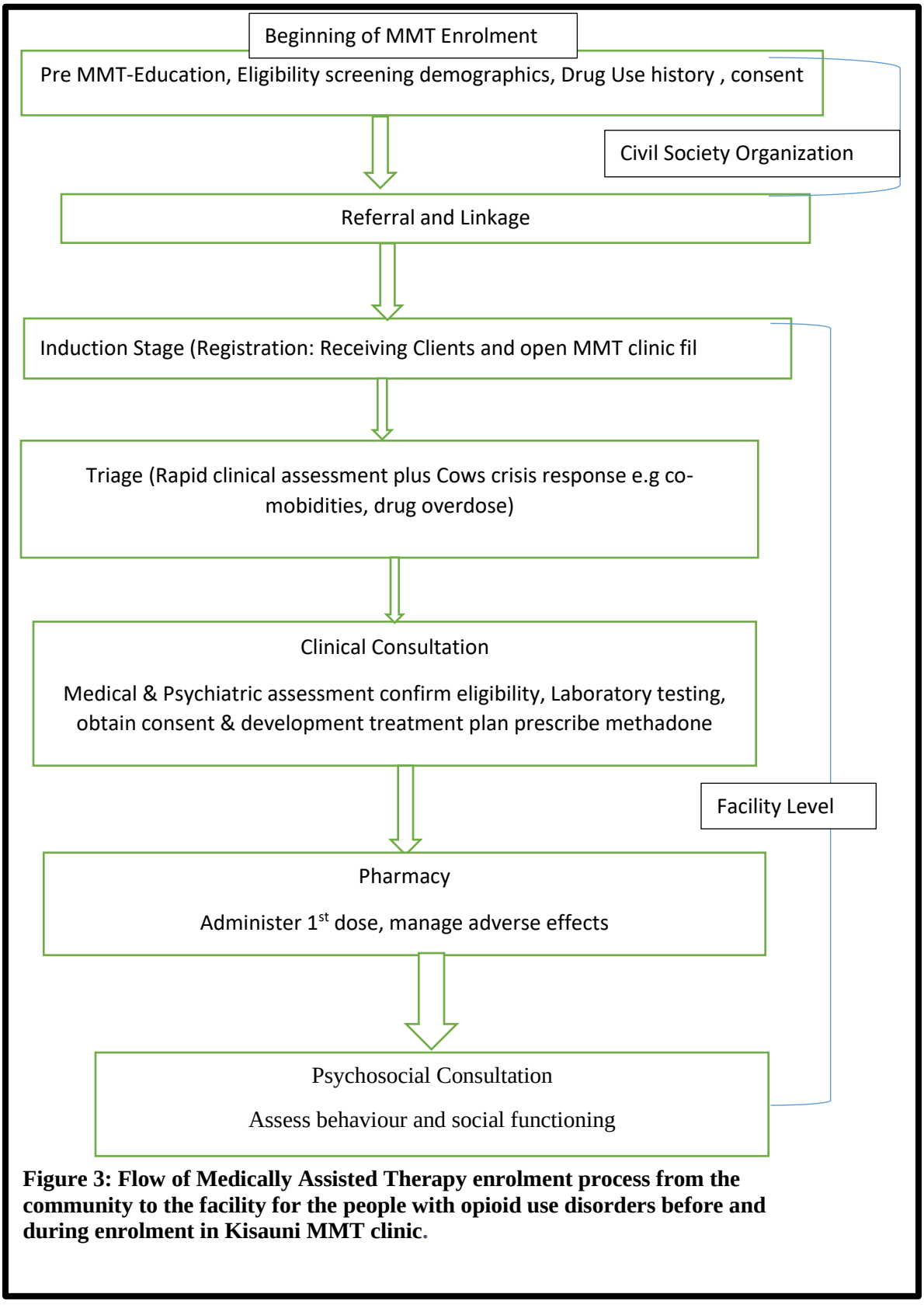


Figure 3: Flow of Medically Assisted Therapy enrolment process from the community to the facility for the people with opioid use disorders before and during enrolment in Kisauni MMT clinic.

3.2 Study population

The study involved people with opioid use disorder accessing Methadone Maintenance Treatment (MMT) services in the Kisauni MAT Clinic enrolled between 2015 and 2022. The records for these enrolled clients were also used to retrieve data. Furthermore, clients who acquired HIV during MMT treatment were included in the in-depth interviews.

3.3 Study Design

This was a mixed methods study that used a retrospective cohort for the quantitative study and in-depth interviews for the qualitative part conducted in the Kisauni MAT Clinic, Mombasa. The quantitative data collected were used to establish the HIV seroconversion rate, associated risk factors, and HIV co-infections. Additionally, since the main goal was to gather quantitative data, a sequential explanatory approach was adopted to guide the sort of qualitative data to be collected, which aided in explaining and understanding the quantitative findings, as proposed by Creswell (J. Creswell, 2013).

The sequential explanatory approach is a research methodology that is divided into two phases: a quantitative phase and a qualitative phase; the method is centred around quantitative data (J. W. Creswell, 2009). By combining the strengths of quantitative and qualitative research, this method was essential in achieving an in-depth understanding of our research problem on HIV seroconversion and exploring the facilitators and barriers to concurrent use of methadone and ART. In this approach, it advocates for the collection of quantitative data first before proceeding to qualitative data (J. Creswell, 2013). Following the completion of the quantitative phase, the findings on factors leading to HIV seroconversion and facilitators and barriers to methadone and ART use after the seroconversion were explored. In-depth interviews were then used

to obtain qualitative data and probed deeper into the discovered patterns, giving context and meaning to the quantitative results. The sequential explanatory technique enabled triangulation of the data, improving the overall study's validity and reliability (J. Creswell, 2013). Furthermore, this approach delivered a more solid comprehension of the intricate phenomena of HIV seroconversion and the concurrent use of methadone and ART by combining quantitative precision with qualitative depth.

3.4 Procedures on enrolment to MMT Clinic

All potential MMT clients underwent the following procedures before their enrolment in the MMT program. To be eligible for enrolment in the MMT program at the clinic, individuals had to be ≥18 years old, present with opioid dependence, and test positive for opiates, mainly heroin, through urine toxicology tests conducted at the laboratory department in the clinic. Before enrolment, the eligible MMT clients undergo pre-MAT counselling from the respective Civil Society Organizations (CSOs); MEWA or RCT, and the MMT site during induction. If found eligible, clients sign a written informed consent before accessing MMT services. The patient files, MMT card, and respective hospital registers are used to record the baseline health status survey for the eligible client. After enrolment, clients undergo socio-economic, behavioural, and clinical information reviews and periodic screening and testing. Furthermore, clients receive psychosocial counselling from the Psychosocial Department. A medical social worker and two psychologists serve the enrolled clients. The information is captured and recorded in the respective patients' files. While in the program, the MMT clients can access HIV services at the MMT clinic or the recruiting Civil Society Organizations (MEWA or RCT). This study targeted the already enrolled clients accessing services in the Kisauni MAT Clinic.

3.4.1. Laboratory Tests, HIV Testing, and Counselling for MMT clients.

All key populations from the community and MMT clinics are required to be voluntarily counselled and tested for HIV (National AIDS and STI Control Programme & MoH, 2016). Additionally, the clients undergo a urine toxicology test to detect a range of drugs, including alcohol, amphetamines, barbiturates, benzodiazepines, cocaine, cannabis, methamphetamine, and opioids. Urine toxicology testing is the final crucial criterion for confirming opioid use before clients are initiated on methadone. Every client seeking to enrol in MMT needs to undergo the following laboratory investigations, which are performed according to existing national guidelines.

A Baseline Tests on Day 1 at MMT Clinic

As per the Standard Operating Procedures (SOP) for Medically Assisted Therapy clinics, tests undertaken on day one are: Urine drug screening, HIV testing, Sexually Transmitted Infections (STI), i.e., syphilis through the use of Venereal Disease Research Laboratory (VDRL), screening for viral hepatitis (HBV and HCV), TB screening for suspected cases, pregnancy test (for females) and alcohol breathalyzer test (National AIDS and STI Control Programme & MOPHS, 2013).

B. Additional Tests as per Clinician Discretion

The clinician can request additional tests if necessary. These tests may include, and are not limited to, liver function tests, a haemogram, and Cluster of Differentiation 4 (CD4) count or Viral Load.

C. Follow-up Tests

The Ministry of Health (MoH) and National AIDs and STIs Control Program (NASCOP) recommend voluntary HIV Testing and Counselling (HTC). However, the MMT Standard Operating Procedures for Medically Assisted Therapy program provides a clear follow-up schedule for the clients to undergo quarterly HIV testing when in the MMT program for clients in MMT clinics across the country (NASCOP & MoH, 2021). Additional laboratory tests and follow-ups are performed whenever clinically indicated as part of individualized client management.

3.5. Seroconversion Definition

Seroconversion was defined as any MMT client with a negative HIV test result during enrolment in the MMT program but who turned HIV positive during a follow-up test after enrolment.

The date of seroconversion was approximated as the midpoint between the last HIV-negative result and the date they received an HIV-positive result during MAT.

The duration of follow-up was determined as: the time between the MMT enrolment date and the date when the client seroconverted to HIV or the end of the study period, or the date when the client defaulted or lost to follow-up (LFTU) or weaned off or died. A defaulter was defined as any Medically Assisted Therapy (MAT) client who had missed a daily methadone dose for 14 consecutive days, while a lost to follow-up (LFTU) was defined as any Medically Assisted Therapy (MAT) client who had missed a daily methadone dose for 30 consecutive days as per the national guideline (Ministry of Health, 2017).

3.6. Inclusion & Exclusion Criteria

All clients enrolled between July 2015 and June 2019 with initial or baseline HIV test results during induction, and their treatment outcomes were eligible. Only participants with baseline HIV tests were included for follow-up.

Exclusion criteria

1. Clients transferred in and out of the Kisauni MAT Clinic.
2. Clients without a follow-up HIV test during MMT.
3. Clients with missing HIV baseline test results.
4. Clients who tested HIV positive during enrolment.

3.7 Sample size determination

The study included the records of the clients enrolled between 2015 and 2022 in the Kisauni MAT Clinic. The first step in quantitative data was to determine the number of records to be reviewed by calculating the sample size using the following assumptions:

That:

a) The HIV incidence rate for people with opioid use disorder when not on MMT is at 3.8/100 person -years (Rhodes et al., 2015).
b) With the assumptions that MMT coverage was at 50%, Needle Syringe program at 75% and/or a 90-90-90 United Nations AIDS (UNAIDs) strategy for people with opioid use disorder living with HIV, then HIV incidence is estimated to be reduced by 64% (95% CI: 54.4–75.6) in Coastal region when on MMT (Stone et al., 2022).

Therefore, a formula for comparing two proportions was adopted to determine the sample size for this study.

The formula for comparing two proportions:

Sample size (n0) $= \frac{(Z\alpha/2+Z\beta)2*[p1(1-p1)+p2(1-p2)]}{(p1- p2)2}$

Where:

$Z_{\alpha/2}$ = 1.96 (for a 95% confidence level)

$Z\beta$ = 0.84 (for 80% power)

p 1 = 0.038 (incidence rate when not on MMT)

p 2 = incidence rate when on MMT

p 2 = p 1 * (1-estimate reduction in HIV infection when on MMT)

then p 2 = ((0.038 * (1–0.64)) = 0.038*0.36 = 0.01368

substitution of the values in the formula then;

sample size $n0 = \frac{(1.96+0.84)2*[0.038(1-0.038)+0.01368(1-0.01368)]}{(0.038-0.01368)2}$

$$n0 = \frac{(2.80)2 * [0.038(0.962) + 0.01368(0.98632)]}{(0.022432)2}$$

$$n0 = \frac{7.84 * [0.0366 + 0.0135]}{0.00059}$$

$$n0 = \frac{0.39078}{0.00059}$$

$$n0 = 662.3$$

Based on the above assumption that the HIV incidence among non-MMT clients was 3.8 per 100 person-years, a predicted 64% reduction in incidence among MMT clients (as estimated by Stone et al.) at least 663 records were required to detect a difference with 80%

power and a 5% significance level to achieve the study's objectives of determining HIV acquisition for enrolled MMT clients and related risk factors.

After the analysis of the quantitative data, HIV seroconverts were identified for an in-depth interview. Given the small number of HIV seroconverts anticipated, the study adopted the approach suggested by Morse & Niehaus of purposively interviewing less than 30 experienced participants to reach qualitative data saturation for the targeted topic area of HIV seroconversion and mixing of ART and methadone (Morse & Niehaus, 2009). Therefore, all clients who seroconverted to HIV during the study period were purposively selected for the in-depth interview.

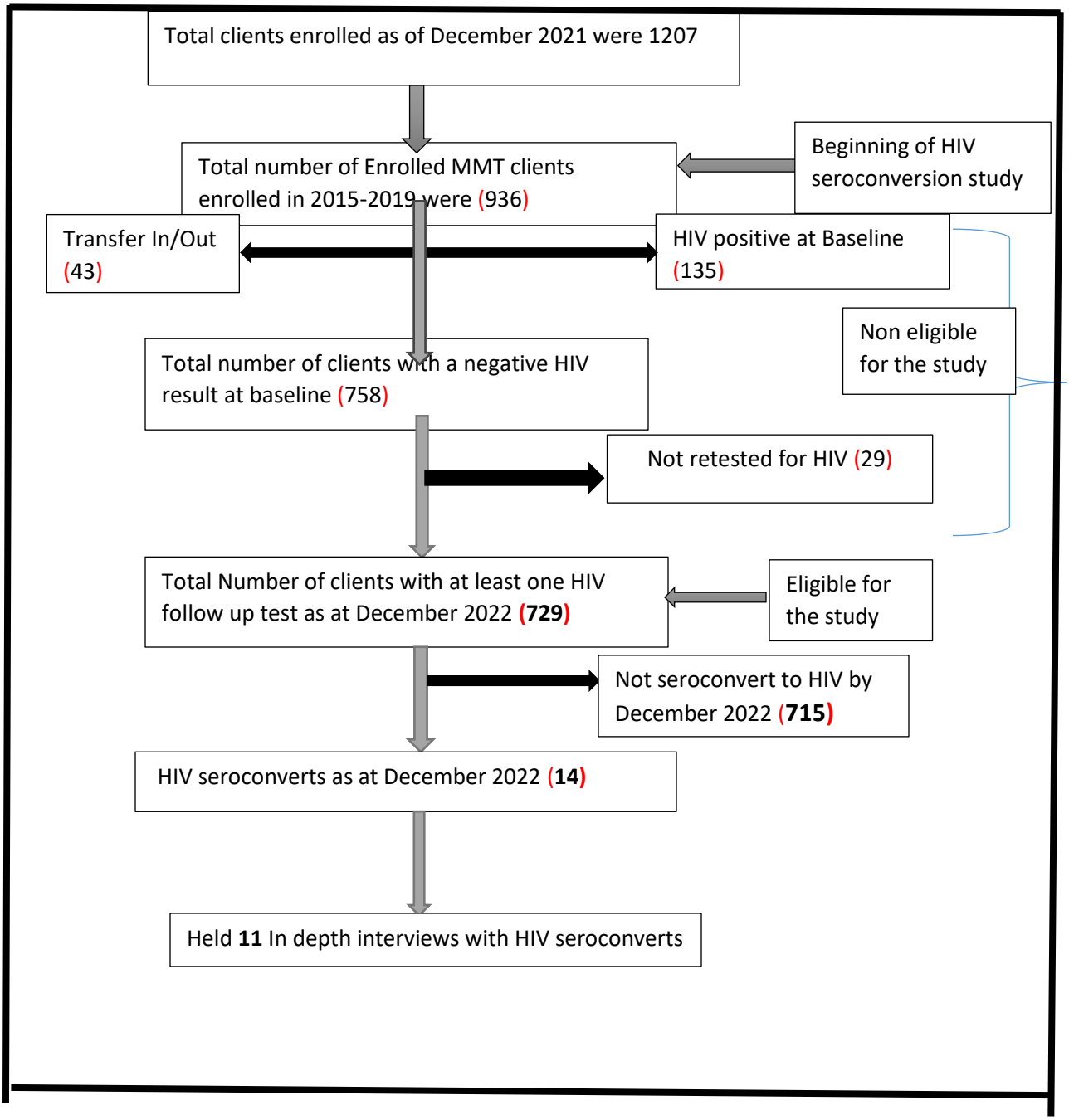
3.8 Sampling Procedure

All the records for clients enrolled from July 2015 to June 2019 were retrieved and their MAT IDs entered in an MS Excel sheet. The MAT IDs were assigned unique numbers and randomly selected using the MS Excel randomization formula. Sampled records found to be ineligible during data abstraction as per the identified exclusion criteria were excluded and replaced with the remaining records. Therefore, after sampling, a total of 936 records were reviewed and 729 records met the inclusion criteria. Of the 207 of the records sampled not meeting the inclusion criteria; 14.4% (135/936) records had a positive HIV test result at baseline, 43 were transfers in and out, and 29 records did not have a follow-up HIV test; thus, were excluded from the study (figure 4).

To integrate the quantitative and qualitative forms of data, quantitative data were linked after the quantitative analysis to identify participants to be interviewed for qualitative data collection (J. Creswell, 2013). The study applied a purposive sampling procedure for the second phase where HIV seroconverts were purposively selected. The participants were

chosen because they had experienced the central phenomenon of seroconverting to HIV and experienced taking both methadone and ART during MMT.

Figure 4: Flow chart for eligible clients and sampling procedure for HIV seroconversion study in Kisauni MMT clinic, 2015–2022



3.9 Data Collection Procedures

Data were collected sequentially, aligning with the sequential explanatory approach. The first phase of data collection was the collection of the quantitative data from the individual patient files. Variables on clients' demographics, enrolment date, clinical, HIV risk factors, outcomes, and laboratory results were extracted. The collected data was cross-checked and supplemented with pharmacy, laboratory, HTC, and psychosocial registers. Data extraction for the variables of interest was carried out from January through February 2023. A standardized data abstraction tool was developed to extract quantitative data including the HIV test results as of December 2022.

The second phase of the study was qualitative data collection. Qualitative data were collected through in-depth interviews using an interview guide. The interview guide was formed after analysis of the quantitative data. This step contributed to the identification of patterns, trends, and associations within the data (J. Creswell, 2013) (Annex 3). The qualitative data aimed at understanding the identified HIV risk factors prior to seroconversion and exploring the experiences of mixing methadone and ART during MMT.

3.10 Data Collection and Variables

Data were collected between December 2022 and February 2023. The study relied on both primary and secondary data sources. Using a developed data abstraction tool, research assistants were used in the data abstraction process under the supervision of the principal investigator. The investigator and the research assistants reviewed individual patient files, pharmacy registers, and laboratory registers. Data were captured in a line list during the records review. The most recent entries for all variables of interest were picked (Annex 2). Variables collected were categorized as:

1) Socio-demographic characteristics, e.g., sex, age, level of education, occupation, marital status
2) Outcome: HIV status by December 2022.
3) Individual factors: current employment status, sexual behaviour, MMT status (Defaulter, Lost to follow, weaned off, active, died), urine toxicology results to identify the type of drug used, Modes of drug use, and period of opioid use before enrolling in the MMT program, etc.

The research assistants were oriented on the data abstraction tool before starting the data abstraction process. Since the data to be collected was sensitive, healthcare workers with experience in attending to key populations were used as the research assistants. The investigator held face-to-face individual in-depth interviews in a private room within the clinic. The researcher took notes and recorded responses using the developed interview guide during the in-depth interviews. Questions were comprised of closed and open-ended questions. The researcher stored the notes taken. The audio recordings were used to ensure a reliable analysis of the participant's responses, review the data collected, and update missed information during note-taking. The interviewer considered the ethical issues and avoided bias by administering the standard questions to the study participants using the developed semi-structured interview questionnaire guide.

From the pre-interview questions, the interviewer asked core questions and more questions related to the topic of reasons for joining the Medically Assisted Therapy program, experience with the MMT program, drug use behaviours, experience with psychosocial counseling, methadone availability and benefits, HIV prevention services, facilitators and barriers to ART and methadone use, and HIV risk behaviours. The study participants were

asked to identify the possible ways that exposed them to HIV infections and describe their experiences and risk perceptions. During the interview, the investigator sought clarification and further elaboration of any discrepancy between the self-reporting information and patient-filed records. At the end of the interview, the interviewer wrote a detailed interview record that mirrored the session's transcription.

3.11 Data Analysis

Before conducting data analysis, data were cleaned and cross-checked for errors. Descriptive and analytical statistics were calculated for the socio-demographic data, outcome, and individual factors using the reviewed records for quantitative data.

3.12 Descriptive Analysis

Descriptive statistics were calculated for both the categorical and continuous variables. For the categorical data, frequencies, proportions, rates, and ratios were calculated, e.g., HIV seroconversion rates, HIV outcomes, and gender. Continuous variables' mean and median and their respective measures of central tendency or dispersion were calculated, e.g., age and period of heroin use were measured using mean and medians respectively. Person-years were calculated by multiplying the number of eligible MMT clients by the time (in years) each client spent in the program, and then summing the total observation time across all clients.

A HIV Seroconversion Rate

Table 1: Table for calculating HIV seroconversion rate

Frequency	Total time duration	Rate
Number of clients turning HIV positive (A)	Total midpoints time contributed by the clients turning HIV+ (B)	(A)/(D) per person-years

Total number of eligible clients in the study (C)	Total time duration contributed by all the eligible clients (D)	

In analytic statistics, a chi-square test was used during bivariate and multivariate analysis. Potential risk factors associated with HIV seroconversion during the bivariate analysis were calculated, e.g., still injecting while on MAT, polydrug use during MAT, condom use, multiple sexual partners, etc. The analysis was performed using either the final behavioural record prior to seroconversion or the study's endpoint. All factors found to have a p-value of ≤0.05 during the bivariate analysis were considered statistically significant.

Table 2: Contingency Table: To compare the risk of HIV among clients enrolled on MAT. (Bivariate analysis)

	Seroconverted to HIV			
Variable	**Yes**	**No**	**Crude Risk Ratio (cRR) (95% CI)**	P-value
Injecting while on MAT)				
Yes	A	B		
No	C	D		
Polydrug use during MAT	**Seroconverted to HIV**			
Yes	A	B		
No	C	D		

Factors with a p-value of ≤0.2 at bivariate analysis were included in the multivariate analysis. A backward regression model to identify independent factors for HIV seroconversion was used. All factors with a p-value of ≤0.2 were selected together and

added to the model. Factors with the highest p-value from the model were removed one after the other. Removal of the factors from the model stopped after the remaining factors were at or below ≤0.05. Independent factors associated with HIV seroconversion, their adjusted Relative Ratios (aRR), 95% confidence intervals (CI), and P-values were reported.

Table 3: Contingency table for the factors with P-value ≤0.2. To identify independent risk factors associated with seroconverting to HIV (Multivariate analysis).

	Seroconverted to HIV			
Variable	**Yes**	**No**	**Adjusted Risk Ratio (aRR) (95%CI)**	P-value
Still Injecting while on MAT)				
Yes				
No				
Polydrug use during MAT	**Seroconverted to HIV**			
Yes				
No				

Statistical analysis was performed using EPI Info7 and Statistical Package for the Social Sciences (SPSS) version 26.0. Data were presented using graphs and tables.

Seroconversion was defined as negative results during enrolment in the MMT programs and the first positive test for HIV when on the program.

Qualitative data analysis

The obtained qualitative data explained the data which disagreed or agreed with what was found, explored new findings, and built on the connections between the quantitative and qualitative data. Following the qualitative data collection, the data were analysed separately as the final step before combining the two results (quantitative and qualitative findings) in the discussion section as illustrated by Fetters et al., 2013. A narrative approach and verbatim were adopted to report the results.

The qualitative data were used to obtain supplementary findings, a detailed description, understanding, and explanation of possible related HIV risk factors during MMT and experiences to concurrent use of ART and methadone use. For qualitative data, upon completing the interviews, audio recordings and hand-coded notes were used to analyse the data manually. From the (Maguire & Delahunt, 2017) six-step approach to thematic data analysis was adopted. The steps were as follows:

Step 1: Gathering data and familiarize with it.

The initial stage in the qualitative data analysis was to become acquainted with the complete data collection. It included connected and active reading throughout the field notes gathered during the administration of the semi-structured interviews.

Step 2: Creating preliminary codes from the content.

Following familiarization with the data, notes on prospective data items of interest and preliminary HIV concepts were collected. The codes were created so that each fundamental aspect of the raw data may be thoroughly and meaningfully examined regarding HIV risk

factors. Codes were created that were brief comments or phrases that described the material, e.g., HIV awareness. The Codes were picked from the interviews.

Table 4: Table on how to create codes from qualitative data.

Interview extract	Codes
Personally, I am not sure how I got infected with HIV. I think there was a time I travelled to Eldoret and I missed my methadone dose for 1 week. I met a group of active heroin users and we shared needles and syringes. You know when you enrol on the MMT program, you cannot miss the medication since you become very sick when you miss your medication.	Uncertainty HIV awareness History of travel Missing methadone dose Heroin use Shared Injecting heroin Sickness Very important

The highlighted sentences are associated with various codes. The codes explain the concepts and highlight potential HIV risk factors. New codes were added when the researcher went through the transcriptions looking for anything relevant to HIV seroconversion. The codes addressed the data's identified concerns (Maguire & Delahunt, 2017). In preparation for step 3, the data were arranged by codes after encoding the complete data set. During the coding process, an Excel sheet was used.

Step 3: Look for the themes.

This stage involved reviewing the produced codes and the data extracts for potential themes relevant to the research (Braun & Clarke, 2006). Combination of many codes into single themes, including noting all topics of interest.

Codes:

Uncertainty

HIV awareness

Themes:

Lack of HIV awareness.

Codes

History of travel

Missing methadone dose

Heroin use

Theme: Heroin craving

Codes:

Sickness

Theme: withdrawal effects

Step 4.Reviewing the Themes.

The first stage in this process was to confirm that the codes fit correctly. Specifically, the examination was done to see if the developed themes had enough data and had exhausted the variety of the topics linked to HIV and methadone use (Braun & Clarke, 2006). The retrieved data could be merged, separated, or deleted themes. The second stage was to reread the entire data set, re-examine the themes, and re-code additional data within the generated themes before changing the themes (Braun & Clarke, 2006). Data revision ended if all relevant data to the research topic had been included in the coding schemes and refinement did not reveal new themes.

Step 5.Define and Name the Themes.

The researcher generated definitions and a narrative description of each theme in this stage (Braun & Clarke, 2006). The names were concise and appropriately descriptive before being included in the final report. Each theme's description explains how it relates to HIV seroconversion (Braun & Clarke, 2006; Maguire & Delahunt, 2017), e.g., for the theme of heroin craving and withdrawal effects, a better phrase, "effect of methadone withdrawal" may be used.

Step 6. Reporting.

Verbatims quotes were done for special or interesting quotes derived from the interviews. After establishing and labelling the HIV risk factor themes, the replies were converted into quantitative variables and treated each as a topic. Data triangulation; where combination and merging of findings to discuss the findings using Fetters et al., 2013 principles, was applied.

Coding and analysis were completed in English. The findings from the two forms of data were weaved together in the discussion sections (Driscoll et al., 2007; Morse & Niehaus, 2009).

3.12 Ethical Considerations

The study protocol was approved by Moi University's Institutional Research Ethics Committee (IREC), approval number FAN 004249 (Annex 5). A research permit was obtained from the National Commission for Science, Technology, and Innovation (NACOSTI) license number 667810 (Annex 6). Additional approvals reference numbers: COH/MSA/RSC/2022/(34) were obtained from the Mombasa County Department of Health Services to collect data in the Kisauni MAT Clinic.

Confidentiality was considered by not collecting personal identifiers during data extraction and collection; instead, unique identifiers were used. The study participants were taken through the study risks, benefits and data usage before consenting to participate in the study. During in-depth interviews, the investigator created serial numbers which were only known by the investigator and matching details were kept in a different laptop. Verbal and written consent was sought from the study participants. For ease of understanding and administration of the consent form and the semi-structured questionnaire, the forms were translated into Kiswahili, the common language the locals use.

CHAPTER FOUR

4.0 Results

4.1 Social-Demographic Characteristics

Only 36.9% (269/729) of the 729 eligible clients were injectors at the time of enrolment, with the remaining 63.1% (460) being non-injectors. The median age of the eligible HIV-negative participants was 40 years, with an interquartile range (IQR) of 35–46, and 78.3% (571/729) were aged 35 years and above. Overall, male clients were the majority at 91.4% (666/729). Of the participants, 38.7% (282/729) were married, with non-injectors contributing the majority at 67.3% (191/282). Regarding education level, 10.7% (78/729) had no formal education, and almost half, 48.6% (354/729) of the clients were unemployed. Similarly, the majority of the clients were Muslims at 70.02% (515/729) (Table 5).

Table 5: Social-demographic characteristics for injectors and non-injectors opioid-dependent clients enroled in Kisauni MAT clinic, 2015-2022.

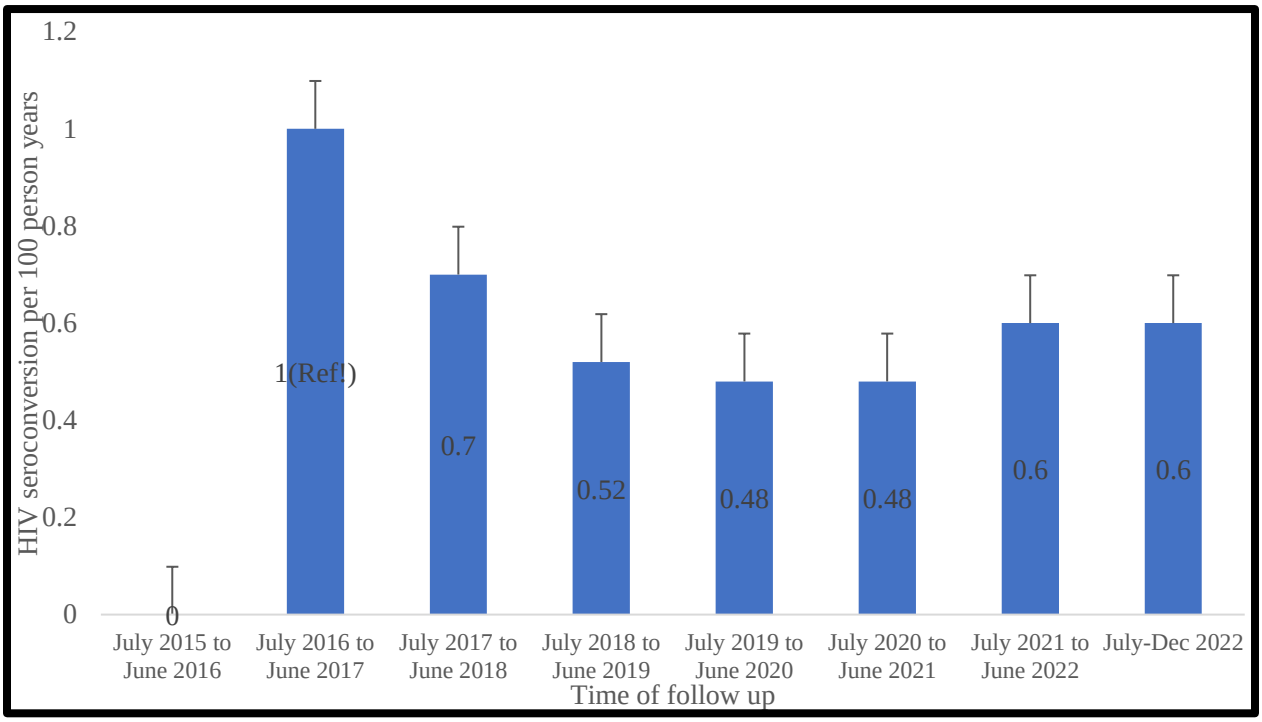
	Injectors (n=269) Frequency (%)	Non-Injectors(n=460) Frequency (%)	Totals (N=729) Frequency (%)
Age Group			
≤24	5 (01.86)	3 (00.65)	8 (01.10)
25−34	59 (21.93)	91 (19.78)	150 (32.61)
≥35	205 (76.21)	366 (79.56)	571 (78.32)
Gender			
Female	27 (10.04)	36 (7.82)	63 (0g8.64)
Male	242 (89.96)	424 (92.18)	666 (91.36)
Marital Status			
Divorced	41 (44.57)	51 (55.43)	92 (12.6)
Married	91 (32.38)	191 (67.26)	282 (38.7)
Separated	23 (30.67)	52 (69.33)	75 (10.3)
Single	111 (41.67)	154 (57.95)	265 (36.3)
Widowed	3 (20.00)	12 (80.00)	15 (02.0)
Occupation			
Employed	72 (26.77)	156 (34.06)	228 (31.28)
Self-Employed	60 (22.30)	68 (14.63)	128 (17.56)
Unemployed	137 (50.93)	236 (51.31)	373 (51.17)
Level Of Education			
None	45 (16.73)	33 (07.21)	78 (10.70)
Post Secondary	12 (04.46)	36 (07.86)	48 (06.58)
Primary	145 (53.90)	251 (54.59)	396 (54.32)
Secondary	67 (24.91)	140 (30.35)	207 (28.40)
Religion			
Christian	79 (29.3)	125 (27.17)	204 (27.98)
Islam	190 (70.63)	335 (72.82)	515 (70.02)

4.2 Findings on HIV Seroconversion

During the study period, 14 clients seroconverted to HIV (turned HIV positive during MMT): eight males and six females. Four clients seroconverted within six months (range from 4 months to 6 years and 4 months) with a median time of 2 years and four months of their enrolment time. Following the calculation of person-years, where multiplication of the number of eligible MMT clients by the time (in years) each client spent in the program, and then summing the total observation time across all clients, the total person-years of

follow-up for the eligible 729 HIV-negative clients were 3,386.9 years, with an average of 4.6 follow-up years. Overall, there were 0.4 (95% CI:0.2–0.7) new HIV infections for every 100 person-years (PY). The highest HIV seroconversion rate was observed in 2017/2018, which was at 0.7 per 100 person-years, while 2015/2016 did not report a positive case (Figure 7).

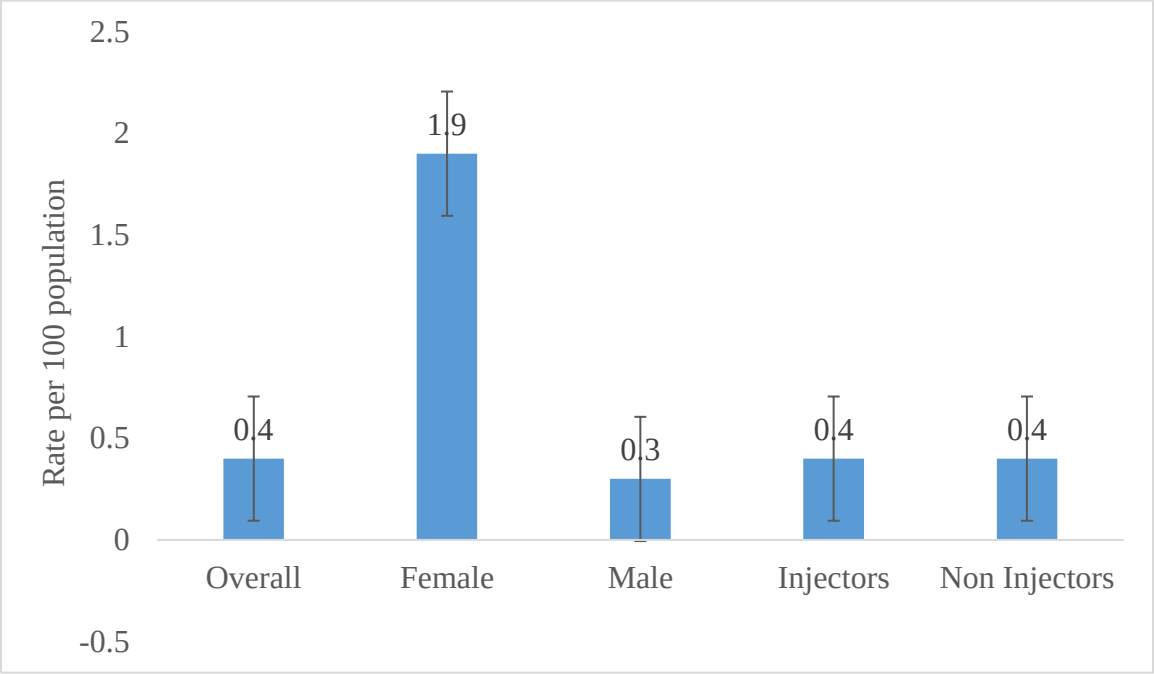
Figure 5: Yearly HIV seroconversion rate among enrolled MMT clients in Kisauni MAT clinic, 2015-2022.



The incidence rate for females was greater than the rate for males, at 1.9/100 (95% CI:0.7–4.2) PY versus 0.3/100 (95% CI:0.1–0.5) PY. The incidence rate for injectors was 0.4/100 (95% CI:0.2–1.0) PY, whereas the incidence rate for those who were non-injecting was 0.4/100 (95% CI:0.2–0.8) PY. After additional analysis injectors' HIV incidence rate ratio was shown to be 1.1 (95% CI:0.3–3.7) higher than that of non-injectors. The HIV

seroconverts were taking their ART medication off-site, thereby data pertaining to their viral loads were not available.

Figure 6: HIV seroconversion rates per gender and modes of drug use among Opioids dependent clients in Kisauni MAT clinic, 2015–2022.



4.3 Outcomes of Medically Assisted Therapy (MAT) treatment status among clients in Kisauni MAT clinic, 2015–2022

This was not part of the study objective; however, it was found that at the end of the follow-up time, 59.4% (433/729) of the clients were active; the proportions were almost equal for both injectors and non-injectors at 62.8% (169/269) and 57.6% (265/460) respectively. Lost to Follow-Up was at 29.5% (215/729) and non-injectors were slightly more at 30.6% (141/460) compared to injectors who were at 27.1% (73/269). Those who died during MMT were 3.2% (23/729); 2.3% (17/729) had defaulted from the MMT program, and only 5.6% (41/729) of the clients were successfully weaned off. Here, a defaulter of MMT was

defined as any client who missed more than 14 consecutive doses of methadone drug (Table 7).

Table 6: Treatment outcomes among enrolled Kisauni MMT clients as of December 2022

MAT Outcomes	Injectors (n=269)	Non-Injectors (n=460)	Total (N=729)
Active	169 (62.8)	265 (57.6)	434 (59.6)
Defaulter	6 (2.2)	11 (2.4)	17 (2.3)
Died	10 (3.7)	13 (2.8)	23 (3.2)
Lost To Follow Up	73 (27.1)	141 (30.6)	214 (29.4)
Weaned Off	11 (4.1)	30 (6.5)	41 (5.6)

4.4 Findings on HIV coinfections among the seroconvert

Hepatitis B positivity for the HIV negative clients was at 4.7% (34/729), Hepatitis C was 10.7% (78/729), and Tuberculosis (TB) was at 3.8% (28/729). The HIV coinfection with Hepatitis B was at 14.2% (2/14), HIV/Hepatitis C was at 21% (3/14), and HIV/Tuberculosis was at 14.2% (2/14) among the seroconverts (Table 8).

Table 7: HIV and other comorbidities among the enrolled MMT clients in the Kisauni MMT clinic, 2015-2022.

	HIV Seroconversion		Total clients enrolled
Variables	No(n=715)	Yes (n=14)%	N=729(%)
Hepatitis B			
Positive	32 (04.4)	2 (14.3)	34 (4.7)
Negative	683 (93.6)	12 (85.7)	695 (95.3)
Hepatitis C			
Positive	75 (10.3)	3 (21.4)	78 (10.7)
Negative	640 (87.8)	11 (78.6)	651 (89.3)
T.B			
Positive	26 (3.5)	2 (14.3)	28 (3.8)
Negative	689 (94.5)	12 (85.7)	701 (96.2)

4.5 Associated with HIV seroconversion

On bivariate analysis, females were 7.9 times more likely to seroconvert to HIV than male clients, Risk Ratio (RR)= 7.9, (CI: 2.84, 22.13), p-value <0.001. Similarly, clients with a history of defaulting from Medically Assisted Therapy were 4.2 times at higher risk of HIV seroconversion than those who did not default, Risk Ratio 4.21 (95% CI = 1.50,11.8) p-value <0.003. Clients who used condoms were 73% less likely to seroconvert to HIV RR 0.27 (95% CI 0.09, 0.89) than those who did not use condoms (Table 8).

Table 8: Factors associated with HIV seroconversion among the enrolled MMT clients in Kisauni MAT clinic, 2015-2022.

Variables	HIV Seroconversion Yes	No	Risk Ratio (Confidence Interval)	P-Value
Social Demographic				
Gender				
Female	6	57	7.92 (2.84,22.13)	<0.001
Male	8	658		
Family Integration				
Yes	8	377	1.19 (0.42,3.40)	0.74
No	6	338		
Marital Status				
Separated/divorced/widowed	4	178	Ref.	
Single	6	259	0.97 (0.28,3.39)	0.96
Married	4	278	1.55 (0.39,6.11)	0.53
Religion				
Islam	7	518	0.39 (0.14,1.09)	0.06
Christian	7	197		
Occupation				
Self-Employed	2	126	Ref.	
Unemployed	9	364	0.65 (0.14,2.96)	0.83
Employed	3	225	1.12 (0.20,7.01)	0.85
Clinical Status				
Hepatitis B				
Positive	2	32	3.41 (0.79,14.62)	0.08
Negative	12	683		
Hepatitis C status				
Positive	3	75	2.27 (0.65,7.98)	0.19
Negative	11	640		
Mode of drug use at enrolment	6	263	1.28 (0.45,3.65)	0.64
Injecting				
Non-Injecting	8	452		
Last Methadone dose (Mg)				
≤30	2	164	2.68 (0.50,14.4)	0.23
31–60	4	213	1.75 (0.45,6.87)	0.42
61–100	4	218	1.79 (0.46,7.03)	0.40
≥101	4	120	Ref.	
Behavioural				
Poly Drug Use During MMT				
Yes	7	282	1.52 (0.54,4.30)	0.42
No	7	433		
Living with a sexual partner				
Yes	2	267	0.29 (0.01,1.26)	0.08
No	12	448		
History Of Incarceration				
Yes	0	26	0.0 (Undefined, Undefined)	0.47
No	14	689		

Variables	HIV Yes	Seroconversion No	Risk Ratio (Confidence Interval)	P-Value
Injecting during MMT				
Yes	2	58	1.85 (0.43,8.11)	0.32
No	12	657		
History of treatment interruption (LTFU)				
Yes	7	133	4.21 (1.50,11.8)	0.003
No	7	582		
Condom Use in the last 30 days	5	484	0.27 (0.09,0.89)	0.01
Yes				
No	9	231		

4.6 Independent factors associated with HIV seroconversion.

Following the analysis at the bivariate analysis, factors with a p-value of ≤0.2 were included in the model for analysis. Using a backward regression model, independent factors for HIV seroconversion were identified. On multivariate analysis, being female adjusted risk ratio (aRR) was 8.01 (95% CI 2.64, 24.3) p-value <0.01, and Hepatitis C positive aRR 3.66 (95% CI 1.08,12.42), p-value of 0.04 were independently increasing the risk for HIV seroconversion. Conversely, condom use during sex reduced the risk of HIV seroconversion by 74% aRR 0.26 (95% CI 0.09,0.8), p-value 0.02 (Table 9).

Table 9: Independent risk factors associated with HIV seroconversion among clients enrolled in Kisauni MAT clinic, 2015-2022

Variables	HIV Seroconversion Yes	No	Crude Risk Ratio (cRR)	P-Value	Adjusted Risk Ratio (aRR)	P-value
Gender						
Female	6	57	7.92 (2.84,22.13)	<0.001	8.01 (2.64,24.3)	<0.01
History of Defaulting to MAT						
Yes	7	133	4.21 (1.50,11.81)	0.003	1.71 (0.47,6.31)	0.41
Condom Use in last 30 days						
Yes	5	484	0.27 (0.09,0.89)	0.01	0.26 (0.09,0.8)	0.02
Religion						
Islam	7	518	0.39 (0.14,1.09)	0.06	0.46 (0.16,1.4)	0.17
Living with a sexual partner						
Yes	2	267	0.29 (0.006,1.26)	0.08	0.37 (0.06,1.76)	0.21
Hepatitis C						
Positive	3	75	2.27 (0.65,7.98)	0.19	3.66 (1.08,12.4)	0.04

4.7 Experiences of Methadone Maintenance Treatment Program for HIV seroconvert

Following the analysis of the quantitative data where 14.3% (2/14) of the HIV seroconverts were Lost to Follow-Up to both ART and methadone, hence the program was missing out on the 2nd and 3rd 95 targets (95% ART adherence and probably 95% reduction in Viral Load suppression), in-depth interview questions were developed. This finding informed the crafting of questions to explore the barriers and facilitators to concurrent use of ART and methadone during MMT. Additionally, at bivariate and multivariable analysis, factors like history of defaulting to MMT and positive HCV results needed to be explored further on how they contributed to HIV seroconversion, thus semi-structured questions on the identification of events that led to HIV acquisition during MMT were developed (Figure 8).

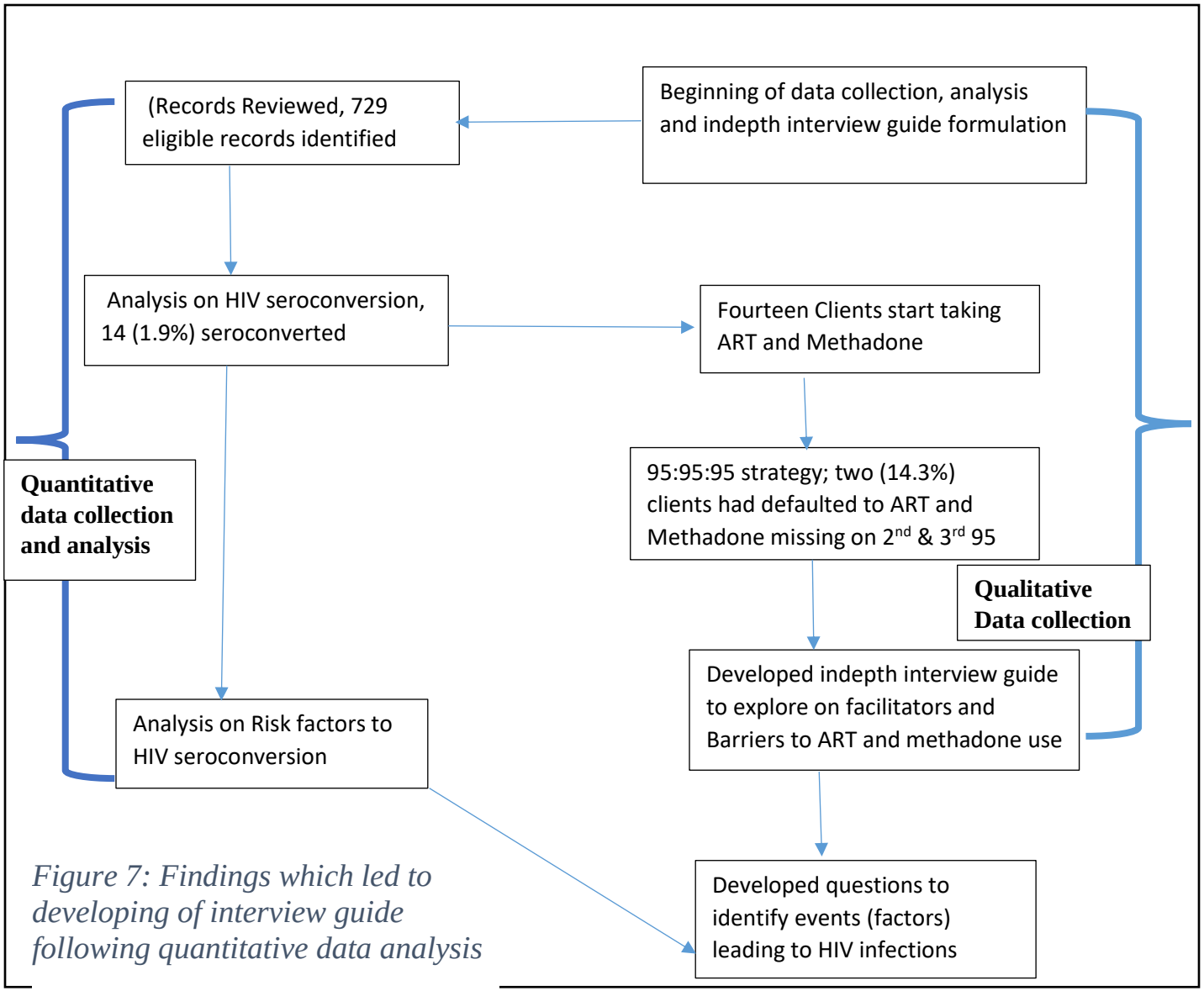


Figure 7: Findings which led to developing of interview guide following quantitative data analysis

4.8 Findings for Qualitative Data

Two participants agreed to be interviewed but not to have their voices recorded. One session was cancelled after the investigator discovered that the client was intoxicated with drugs at the time of the interview. The investigator halted the interview, and the data were not analysed. Therefore, 11 HIV seroconverts were analysed after the interview. There were 11 participants in the in-depth interviews with a median age of 33 years (interquartile range 29–48). Of these, five were male and six were females. A total of six were injectors at baseline, and six had used heroin for more than five years before starting MMT. During MMT, four clients reported mixing methadone with other illicit drugs.

Thematic analysis

After the in-depth interviews, experiences were grouped into two periods; prior to HIV seroconversion and after HIV seroconversion.

Prior to HIV seroconversion.

Here we found out

a. Reasons for joining MMT,

    i. Stop drug use and lifestyle change

Participants joined the program intending to stop opioid use and achieve lifestyle changes. The motivation factors were previous jailing and being tired of being dependent on heroin.

A Client A5.M: . "*I started using drugs when I was a teenager. Over the years I used drugs, and I was jailed because of crimes that were driven by my drug addiction. I reached a point I decided I was done with drug use and that's when I learnt more about MMT."*

b. Experiences prior to HIV seroconversion

i. Counselling.

Clients experienced counselling from their counsellors before and after enrolment to MAT. The major topics covered before seroconverting to HIV were:

1. Polydrug use
2. Family integration
3. Relationship issues
4. Weaning off process

Client C: "*Here at MMT, we are so many and changing is based on individual efforts. As for me, I go and seek counselling from my counsellor when I feel down or I have issues with my family."*

Client L_3F: "*I can go and meet my counsellor at any time I want and talk to her about anything I want but most of the time I met with her it was about the issue of methadone dose and polydrug use."'*

Also, clients participated in psychosocial and Narcotics Anonymous (NA) meetings which help them in maintaining a healthy and drug-free lifestyle.

Client D5. "*I prefer going to seek counselling in the Civil Society Organization (CSO)…there is a male counsellor with whom we can talk about the male issues I'm going through…here I have a counsellor but I prefer to attend the NA meetings we hold with peers and meditation where we talk a lot about how we cannot relapse and how to identify personal triggers to relapsing"*

ii. **Events leading to HIV infection.**

Clients identified having unprotected sex and having multiple sexual partners as the likely way they acquired HIV. Being under the influence of alcohol and seeking favours in exchange for sex were the main themes facilitating unprotected sex or multiple sexual partners, which led to HIV infection. Some of the responses from the clients interviewed.

Client A2 M: "*You know am not married doc…when I am given my packed lunch or supper at home, I go to a nearby street at night and pick a lady beggar where I exchange my food with sex…. Or if I have cash, I go to brothel to pick this particular lady who satisfies my thirst."*

Client L4.F: '*After I joined the MMT program, I changed my partner and had a sexual relationship with this guy who had been on MMT before me…. I didn't know that he was positive so I moved with him and we had sex without protection…."*

Client L1F: "*If you drink alcohol you forget all the HIV prevention measures and decide to do what you want to do without thinking…. I will never forgive myself for not using protection…"*

Table 10: Counselling topics during MMT among opioid dependent clients enrolled in Kisauni MMT clinic, 2015-2022.

Time of assessment	**Theme**	Sub-theme	Key quotes
Prior to HIV seroconversion	**Counselling**	Poly drug use	*I met with her it was about the issue of methadone dose and polydrug use*
		Family integration & Relationship Issues	*I go and seek counselling to my counsellor when I feel down or I have issues with my family.*
		Weaning off	***we talk a lot on how we cannot relapse and how to identify personal triggers to relapsing***
	Likely Modes of HIV transmission	unprotected sex	***I didn't know that he was positive so I moved with him and we had sex without protection***
		Multiple sexual partners	***I go to a nearby street at night and pick a lady beggar where I exchange my food with sex***

ii. Experiences after HIV seroconversion

i. Factors contributing to MMT adherence

Clients identified program areas facilitating the concurrent use of Methadone and HIV treatment.

a. Alternate times for Intake of Methadone and ART use

Clients reported alternate flexible times of taking their methadone dose before the clinic is closed and taking ART at night as a reason for adherence.

Client L_5F: "*I use my ART drugs at night while I take methadone anytime during the day…".*

Client A_4M: "*The Civil Society Organization (CSO) supplies me with ART drugs and I take them at home when I am in my house."*

b. Religious Practices and Healthcare fulfilments

Muslim clients identified access to methadone during Ramadhan after breaking their fast (Moonlight methadone dispensing) which fulfils their spiritual obligations as motivation to adhere to treatment.

Client A_3M: "I am not worried about missing my methadone dose during Ramadhan when fasting…the clinic provides methadone in the evening for those who fast."

Client A_5.M: "During Ramadhan, the clinic offers methadone in the morning and evening to accommodate Muslims fasting....fasting during Ramadhan is among the five Muslim commandments"

c. Family support

Other clients attributed the importance of family support to their level of adherence. They described support from their close family members, including spouses and parents, where they are reminded to take their ART medication and constantly follow up on the progress with MMT medication.

Client A_6M: "*My wife knows that I am taking ART drugs but she is not aware of my methadone use. She is very supportive and reminds me about my drugs….she never knew that I was a heroin user…."*

Client A_2M: "*My family supports my drug use recovery by facilitating my transport to MAT……mum asks if I am still using my treatment."*

Patient Well-being and Support

Most clients identified the availability of client-friendly services and providers at the MMT clinic as a motivation for them to adhere to MMT and ART treatment.

Client L_4F: "*Here we can be treated and counselled any day*."

Client L_2F: "*I can get treated here for free… if they miss any drug, I can buy or they get them from a nearby facility."*

Barriers to methadone adherence

a. The proximity of the MMT clinic and operating hours

Clients staying far from the clinic could miss some days due to a lack of cash for transport, and some identified the daily routine of going to the clinic as tiresome.

Client A_6M. "*The distance from MMT to where I am staying is far, sometimes I miss my daily methadone dose because I do not have cash for transport…. like now I only had one-way cash so I have to trek back home."*

Client L_3F: "*I have been on MMT for a long time…to tell you, it's not possible to get your daily MMT dose without missing a day..."*

Also, the challenges of taking the methadone dose at different times within the clinic operating hours due to engagements at work or other competing tasks were the other reasons for non-adherence.

Client A_2M: "*I have to go to work before getting my methadone dose, it's a big challenge for me to balance the two when you compare the distance from home to MMT and MMT to work…. sometimes I miss my dose."*

Client A_5M: "*When using the HIV drugs, you need to follow up on the time of taking your drugs, unlike methadone which you can take any time…with changing times of taking methadone depending on circumstances."*

Barriers to ART and MMT adherence

a. Stigma and discrimination

HIV seroconverts identified double stigma; from peers and the community as one of the barriers to ART and MMT adherence. The protracted opioid dependence treatment duration gives community members a misperception that the MMT program is not effective for clients. Therefore, they treat clients as other active persons with opioid use disorder. In addition, the community members and some family members don't like being associated with HIV-positive people, more so those with a history of drug use. The participants also

revealed having experienced exclusion from their peers after learning that someone is HIV positive.

Client A_6M. "…*When you walk past a group of clients you can hear them pointing fingers at you referring to your HIV status…initially, I used to feel so low after experiencing people talking about my HIV behind my back."*

Client A_1M.. *"….I still hear my neighbour talking about my drug use experience and MMT treatment as just a waste of time….after he learned that I was HIV positive he distanced from me when talking to our family……"*

b. Pill burden and side effects during the initial period of ART use

As with all drugs, clients experienced side effects when they initiated concurrent intake of ARTs and methadone. Some of the side effects identified included dizziness, headache, and body pains. The side effects were some of the reasons clients did not adhere to ART and MMT during the initial months of their ART initiation.

ClientA M: "*In the early days of my ART use, I felt dizziness and headache….I used to skip days for taking the drugs…but now, my dose was adjusted and I am good."*

Client: "*I almost defaulted from methadone. I felt sick after I was told to use methadone, HCV drugs and HIV drugs. The drugs were too much for me."*

c. HIV disclosure

Most of the clients were uncomfortable sharing their HIV status with their peers and sexual partners. There was significantly lower inhibition in disclosing HIV status to healthcare workers (HCWs) compared to peers and partners. Reasons for the discrepancy in the level of comfort for the disclosure were pegged on fear of being left by the sexual partner and peer stigmatization.

Client A_1M. "*I am comfortable disclosing my HIV status to only a few doctors who provide me with counselling and treatment……I can't share my status with any of my peers……they won't treat me as one of their own."*

Client L_1F:--- *"I don't want to infect my husband but I fear if I tell him about "this" he will leave me"*

d. Daily Transportation cost and fatigue

Clients staying far from the clinic could miss some days due to a lack of cash for transport, and some identified the daily routine of going to the clinic as tiresome.

Client A_6M. "*The distance from MMT to where I am staying is far, sometimes I miss my daily methadone dose because I did not have cash for transport…. like now I only had one-way cash so I have to trek back home."*

Client L_3F: "*I have been on MMT for a long time…to tell you, it's not possible to get your daily MMT dose without missing a day..."*

Work restriction

Also, the challenges of taking the methadone dose at different times within the clinic operating hours due to engagements at work or other competing tasks were the other reasons for non-adherence.

Client A_2M: "*I have to go to work before getting my methadone dose, it's a big challenge for me to balance the two when you compare the distance from home to MMT and MMT to work…. sometimes I miss my dose."*

Client A_5M: "*When using the HIV drugs, you need to follow up the time of taking your drugs, unlike methadone which you can take any time…with changing times of taking methadone depending on circumstances."*

Table 11: Facilitators and barriers on ART and methadone concurrent use among opioid clients enrolled in Kisauni MMT clinic, 2015–2022.

Time of assessment	**Theme**	Sub-theme	Key quotes
After HIV seroconversion	**HIV disclosure**	Not comfortable sharing status	Client F--- ***"I don't want to infect my husband but I fear if I tell him about this "disease' he will leave me"***
	Facilitators of ART and MMT adherence	Availability of counselling	***"Here we can be treated and counselled any day"***
		Religious Practices and Healthcare fulfilments	***I am not worried about missing my methadone dose during Ramadhan when fasting…the clinic provides methadone in the evening for those who fast."***
		Patient Well-being and Support	***"I can get treated here for free… if they miss any drug, I can buy or they get them from a nearby facility."***
		Family support	***My wife…….is very supportive and reminds me about my drug.***
	Barriers to ART and MMT adherence	Double Stigma	***initially, I used to feel so low after I heard people talking about my HIV status behind my back***
		Transport costs, work restrictions	***it's a big challenge for me to balance the two when you compare the distance from home to MMT and MMT to work….Sometimes I miss my dose because of work.***
		Treatment Fatigue	***the daily back and forth for methadone pickup with little or no psychosocial support***
		Pill burden and Side effects at concurrent treatment initiation	***I felt sick after I was told to use methadone, HCV drugs and HIV drugs. The drugs were too much for me.***

CHAPTER FIVE

5.0 Discussion

5.1 Summary on the Findings

There was a low HIV seroconversion rate of 0.4 per 100 (95% CI: 0.2–0.7) person-years (PY) among people with opioid use disorder, with no statistically significant difference between injectors and non-injectors with an incidence rate ratio of 1.1 (95% CI:0.3–3.7) when on MMT. Being female and Hepatitis C (HCV) positive status were independent risk predictors of HIV seroconversion, while condom usage was associated with protection against contracting HIV. The study findings further revealed that HIV seroconverts experienced stigma at the institutional and community levels, pill burden, daily transport fatigue, discomfort in disclosing HIV status, and limited knowledge about the adverse effects of the concurrent use of ART and methadone treatment, which may influence treatment adherence.

The study included both injectors and non-injectors regardless of the mode of opioid drug use, which was contrary to what Huang et al., 2014 studied. At baseline, people who injected drugs constituted slightly more than a third (269/729) of all clients enrolled in the clinic, despite the program's proactiveness in prioritizing injectors during the initial years of launching the MMT program in the county. Due to the low percentage of injectors enrolled in MMT, a large number of the estimated 2,000 injectors residing in the county (Health, 2019), 18% of whom are estimated to be HIV positive (MOH & NASCOP, 2020), do not have access to MMT services. Since MMT services include HIV testing and treatment, which are linked to improving HIV risk reduction and treatment adherence, the lack of MMT enrolment among people with opioid use disorders (PWOUDs) in Mombasa

could increase the risk of disease transmission among both opioid users and the general population.

It was found that few women people with opioid use disorders were enrolled in the MMT program at the study site with the ratio of female to male at 1:9. This proportion is low given that a meta-analysis study found that women accounted for 20% of the 156 million (95% CI 10.2–23.7 million) people who inject drugs globally. Largely, the proportion of women who inject drugs differs between locations, with North America reporting the highest proportion of women injecting drugs at 30·0% (95% CI 28·5–31·5) (Degenhardt et al., 2017). To sustain their Opioid Use Disorder (OUD), women outside MMT have been linked to participating in sex work, which can place them at risk of exposure to increased violence, and sexually transmitted diseases like HIV and HCV (A. Kurth et al., 2018). Existing literature shows that women are more likely than men to become drug addicts and are far more inclined to pursue treatment promptly due to biological, clinical, and sociodemographic reasons (McHugh et al., 2018). Contrary to the documented factors, this study found fewer female opioid-dependent clients utilizing MMT services. A plausible explanation for this finding may be in part due to emerging evidence that women who use drugs (WWUD) seldom congregate in outdoor locations compared to their male counterparts in coastal areas (Zamudio-Haas et al., 2016). This renders it challenging for drug prevention programs to reach them. Subsequently, women who use drugs (WWUD) are less likely to enrol in drug treatment programs, which is probably why there were few female participants in this study. Consequently, an additional factor sustaining gender discrepancies in access to harm reduction programs could be the high levels of stigma that

WWUD may experience from both communities and healthcare providers (Tasnim et al., 2015).

Slightly more than half of the MMT clients were reintegrated with their families. Family reintegration helps individuals recovering from drug addiction feel more connected to their families and allows them to experience more family support (Liu et al., 2020). Overall, family integration has been linked to a decrease in drug use and risky sexual activities and hence should be addressed (Lin et al., 2011). Recognizing the importance of family support in drug use treatment, Civil Society Organizations working with the MMT clinic identify eligible opioid-dependent clients and their immediate family members before program registration. The majority of the clinic's opioid-dependent patients, however, live distant from their homes and relatives because they are drawn from different parts of the country. This makes tracing and identifying clients' family members difficult for Civil Society Organizations. The inaccessibility of the families may be one reason leading to the small proportion of clients successfully reintegrating with their families.

Previous studies showed that the extent of family reintegration also correlates with the employment status of recovering addicts (Liu et al., 2020). As per the finding, only a small proportion of the MMT clients were employed, similar to a study in Dar es Salaam, Tanzania, which reported an employment proportion of 49 (17%) for enrolled MMT clients (Ubuguyu et al., 2016). In this setting, the low level of employed MMT clients could be linked to their low education level, lack of direct employable skill sets, and the country's unemployment status. In Kenya, the unemployment status rate among the citizens stood at between 4.9% and 10.4% between 2019 and 2021 (Natalie, 2023). The higher levels of unemployment among the clients might put pressure on these clients to join the social

networks of current persons with opioid use disorder and peddlers. Reviving these networks may expose the clients to unlawful means of earning a living and initiate consuming illicit substances while on methadone treatment (Rosen, 2004) negating the benefits of being in the MMT program.

In comparison to the number of clients receiving their daily methadone dose, the number of professionals working in the psychosocial department is insufficient to meet the need for services. Section 3.9 of the World Health Organization guidelines recommends psychosocial therapies as a key treatment strategy for opioid dependence. These therapies are intended to reduce or stop opioid use, reduce the potential negative long-term effects of opioid use, and improve the patient's quality of life (World Health Organization, 2009). However, the lack of necessary human resources to support this important aspect may also have an impact on the proportion of clients receiving psychosocial support due to their large numbers. Nevertheless, the study did not establish any association between the lack of counselling and the risk of HIV seroconversion.

5.1.1 Objective one: HIV seroconversion rate among injectors and non-injectors with opioid use disorder enrolled in Methadone Maintenance Treatment (MMT) program.

The HIV seroconversion rate found in this study was lower than what the Stone et al. model predicted for MMT clients in the country. An HIV seroconversion rate of 0.4 per100 person-years was reported. Contrary to our findings, the model estimated an HIV incidence of between 1.8 (95% CI: 1.3–2.3) per 100 person-years with an Opioid Substitution Therapy (OST) coverage of 13.4% (95% CI: 8.8–16.6) (Stone et al., 2022). The

discrepancy in HIV seroconversion could be due to the fact that the model used data from Europe, Australia, and North America during the systematic review to parameterize the effectiveness of OST in the country (Stone et al., 2022). Additionally, the study findings further illustrated that clients receiving MMT registered a greater decrease in the HIV seroconversion rate compared to the active persons with opioid use disorder in the country, who had a rate of 3.8 new HIV infections per 100 person-years (Rhodes et al., 2015). Unlike the Zou et al., 2015 study, which showed a consistent drop in HIV seroconversion to 0.00 per 100 person-years at the end of seven years of follow-up, this study found that clients seroconverted to HIV at varied rates, with a gradual decline in the last 2.5 years of follow-up. The fluctuation in the number of new HIV cases may be related to the time it takes for clients to stabilize in the program and adhere to the methadone program in the first few months after enrolment. The median time of seroconversion was 2.1 years and was consistent with Wang's findings in his qualitative research of newly diagnosed MMT patients (Wang et al., 2016). Despite the similarity in time of seroconversion, in this study, some new HIV infections were detected within six months of their program enrolment.

As earlier noted, this study uniquely included both injectors and those who do not inject drugs at enrolment. Following the analysis of HIV seroconversion rates, there was a minimal difference in HIV seroconversion rates between injectors and non-injectors. These findings demonstrate that methadone can mitigate opioid dependence among heroin addicts in many settings, irrespective of whether they are categorized as people who inject drugs or not injecting drugs. Overall, this study adds to the repository of evidence on the effectiveness of Medically Assisted Therapy (MAT) programs in the treatment of opioid dependence and HIV prevention. Several other studies from diverse cultural backgrounds,

such as Tanzania, China, and South Africa (Zou et al., 2015) have demonstrated the same. However, it is notable that patients on MMT may still contract HIV infections through other routes of transmission such as unsafe or unprotected sexual activities, particularly among persons who have several partners (Chen et al., 2013). As a result, clients stabilized on MMT and who have reduced their opioid dependence, should still be provided with other services focused on reducing sexual risky behaviours in both injectors and non-injectors.

5.1.2 Objective two: Proportion of HIV, HCV, HBV and T.B and their co-infections among the enrolled Methadone Maintenance Treatment (MMT) clients in the Kisauni MAT clinic

The proportion of Hepatitis C Virus (HCV) among the recruited MMT clients was consistent with prior research among opioid substitution therapy clients (Leyna et al., 2019). When this finding is compared to the general population, which has a prevalence of 1% (0.0-1.0), it is found to be tenfold higher HCV prevalence among opioid substitution therapy clients (Karoney & Siika, 2013). This could be attributable to the high-risk behaviour of people with opioid use disorders prior to starting opioid substitution therapy treatment. On further comparisons to active people who inject drugs and still actively using opioids, this study's findings differed with another study in Kenya, which showed a higher prevalence of 22% among active injecting drug users on the Coast (Akiyama et al., 2018). The gap could be owed to the effectiveness of MMT in reducing the risky injecting behaviour among the recovering people with opioid use disorders on the program. These findings contribute to the scientific community's understanding of the effectiveness of opioid substitution therapy in lowering Hepatitis C infection.

It was further demonstrated that the prevalence of Hepatitis B infection among this population was within the national prevalence among Kenyan blood donors, who had a pooled prevalence of 3.4% (95% CI 2.7–4.2%) (Downs et al., 2023). Nevertheless, the study discovered that there was a lower prevalence of Hepatitis B in MMT users than what was reported by (Leyna et al., 2019) in developed countries. The low prevalence could possibly be connected to Kenya's low national HBV prevalence. While analysing HIV coinfections, it was noticed that the HIV/HCV co-infection was far more prevalent than the Hepatitis B/HIV and Tuberculosis/HIV coinfections. The parallel ways for the acquisition of HIV and HCV infections could partially explain the significant prevalence of HIV/HCV coinfection (Cainelli, 2013).

5.1.3 Objective three: To identify risk factors associated with HIV seroconversion among clients enrolled in the Methadone Maintenance Treatment (MMT) program in the Kisauni MAT clinic

A pool of studies recommends patients with Hepatitis C infections be provided with specific care including “test and treat” emphasizing the importance of medically assisted therapy programs to monitor the behaviours of these patients (Stone et al., 2022). Yet, during analysis, it was discovered that HCV is an independent predictor of HIV seroconversion. These findings concurred with a similar study in Madrid where they found an association between HCV and being an HIV seroconvert while on MMT (Zou et al., 2015). Further studies to specifically elucidate this finding are needed.

Gender differences have been identified as an HIV risk factor for the general population, active persons with opioid use disorder, and clients in MMT programs worldwide. Studies

have reported that females with opioid use disorder are at a greater risk of contracting HIV than their male counterparts due to their risky behaviours (Lister et al., 2019). For instance, 22% of females with opioid use disorder in Uganda had started injecting heroin by the age of 17 compared to 13% of male people who inject drugs (Baluku et al., 2019). This study also demonstrated that female clients had a ten-fold higher significant risk of seroconversion than male clients when on MAT. Plausible explanations may include unsafe sexual conduct (such as sex work and the exchange of sex for favours) to alleviate economic hardships, and alcohol use (Kumar et al., 2018). These findings were also substantiated by the qualitative findings of our study, in which female MMT clients reported changing sexual partners and having unsafe intercourse while under the influence of alcohol as reasons they likely became infected with HIV.

Condom usage was independently linked to a reduction in HIV seroconversion in this study. Nevertheless, before they got HIV infected, a few of the seroconverts engaged in unprotected sexual contact, with their sexual partners while unaware of their HIV status. This demonstrates changes to the routes of HIV transmission for the enrolled MMT clients. These findings concurred with a prior study in New York that reported 68% of clients did not use a condom during sex in the last 30 days (Magura et al., 1990). Seroconversion to HIV via unprotected sex indicates that clients were unaware of the benefits of utilizing condoms, Post-Exposure Prophylaxis (PEP), and Pre-Exposure Prophylaxis (PrEP) in HIV prevention. Understanding factors for not using condoms among the opioid clients in the MMT program will have an impact on the development of HIV messages targeting this group. As reported by (Bryan et al., 2000), skills in condom use, availability of condoms at the clinic, and possession of condoms were factors contributing to condom use for

Methadone Maintenance Treatment (MMT) clients (Bryan et al., 2000). Therefore, to reduce HIV seroconversion in the MMT sites, condoms should be offered at the clinic, and condom usage should be promoted by raising understanding about condom acceptability and partner readiness to use them.

On the other hand, MMT defaulters were at a greater risk of seroconverting to HIV. This result was comparable to that of Williams et al, which showed that clients who continued to receive methadone therapy had lower HIV seroconversion rates than those whose treatments were interrupted (Williams et al., 1992). Existing literature has identified reasons for defaulting from MMT to include; the availability of heroin, lack of family support, having a partner or friend who is an active drug user, abrupt dose reduction, and homelessness (Hayashi et al., 2017). On top of that, the failure to recognize opioid addiction as a disorder, as well as a lack of understanding regarding the duration and doses of methadone treatment, were found to be contributing to defaulting (Khazaee-Pool et al., 2018). Concurrently, chronic defaulters may continue to use heroin or change their addiction to other substances while on MMT and so may continue injecting. This was similarly hypothesized by Khalid in Iran that MMT defaulters may continue to use heroin and relapse into injecting habits (Khalid et al., 2022). In the literature review, it was discovered that clients who stopped MMT increased their chances of drug injection by 1.5 times after every 3 months (Serpelloni et al., 1994). In Mombasa County, where the HIV prevalence among PWIDs is 18%, therefore, defaulters are more likely to share an injection with a positive active drug user or engage in sex with an injector or a female sexual partner (Health, 2019; A. E. Kurth et al., 2015b). Throughout the qualitative interviews, however,

none of the individuals mentioned reverting to injecting drugs as a potential mechanism of HIV infection.

Globally, the purpose of the Opioid Substitution Therapy Program is to prevent HIV infection among drug addicts through the reduction of risky injection behaviours (Bertschy, 1995; World Health Organization, 2005). Contrary to the goal of the program, the study found that heroin addicts were more concerned with changes in the social consequences of drug use as the motivation for joining the OST program. According to the qualitative findings, the key topics discussed after enrolment to MMT were family integration, relationship concerns, polydrug usage, and the weaning-off process. Given that the Opioid Substitution Treatment (OST) program seeks to limit HIV transmission and halt injection habits, clients should receive counselling on a range of themes with an emphasis on HIV prevention as a way to bridge motivational gaps. Introducing HIV prevention education through one-on-one counselling, partner counselling, group counselling, and psychosocial education may increase HIV awareness among MMT clients, allowing them to make informed choices and reduction in unsafe sexual behaviours. However, from our findings, it's important that counselling and support should encompass the greater social issues around substance use, not narrowly focus on HIV prevention alone.

5.1.4 Objective four: To explore the facilitator and barriers to concurrent methadone and Anti Retroviral Therapy (ART) use for HIV seroconverts in a Medical Assisted Therapy Program in the Kisauni MAT Clinic

While HIV seroconverts must take both methadone and ART, switching up the time at which they take the two medications facilitates a level of adherence to the two treatments. These findings, however, contradict previous findings in Kenya and Taiwan, which

revealed that MMT clients on ART adhered better when ART and methadone were dispensed together over the window than those who took their ART offsite (Guise et al., 2019). The disparity in our findings might be related to differences in question structure, since we solely focused on factors for improved adherence at a certain moment in time, whereas Guise et al. tracked clients over time to assess their adherence level (Guise et al., 2019).

Comparable to other HIV patients, MMT patients also face stigma from the community as barriers to treatment adherence (Shrestha et al., 2019). Due to gender differences and being recovering people with opioid use disorders, female HIV seroconverts experienced double stigmatization; stigma from peers and the community. This finding concurs with (Ndimbii et al., 2021) findings on the same cohort of participants. In addition to that, HIV seroconverts on MMT experienced fatigue owed to the daily travel expenses to access their medication at the clinic. This finding concurred with studies among MMT clients (Shrestha et al., 2019). The likely reason could be that the majority of the clients in our study were unemployed and the daily commutes to the MMT clinic to receive their methadone dosage could have an effect on adherence. Other studies have also demonstrated that disclosure of health status to an intimate partner or spouse while on MMT was linked to treatment non-adherence (Tran et al., 2018). Similarly, to our findings, HIV seroconverts were not ready to disclose their status to their sexual partners, which may have influenced their level of adherence. Reasons for failure of disclosure were linked to stigma and fear of being left by the spouse.

In this research, it was also identified that inadequate knowledge of the adverse effects of concurrent ART and methadone usage is a barrier to treatment adherence. Existing

literature has documented that, poor methadone adherence is associated with switching back to opioid use, which amplifies the probability of contracting HIV and experiencing social dysfunction for opioid recovery users (Tran et al., 2018). Moreover, studies conducted for HIV patients in various settings and cohorts have demonstrated that discontinuing antiretroviral treatment causes unsuppressed viral load, increases patient mortality, and increases opportunistic infections (Arrivillaga et al., 2013). The most probable explanation is that methadone has severe adverse effects, therefore when clients begin ART treatment, their dosages are not adjusted to account for the changes in medication for the body to perform optimally (NIAID, 2021).

The Moonlight Methadone Dispensing during Ramadhan, which aligned with patients' spiritual needs while fasting, health access, family support, and attainment of patients' emotional and psychological well-being during the course of ART and methadone treatment, significantly enhanced treatment adherence. Rhodes *et. al* hypothesized social and psychological settings could provide a risk environment for drug use-related harms (Rhodes et al., 2003); our study explained how these factors in the clinic–healthcare workers' adjustments to service offerings during Ramadhan, healthcare access, and respecting cultural and religious practices–had positively impacted adherence to both methadone and ART.

Additionally, antiretroviral therapy and methadone adherence were also facilitated by family support and flexibility in taking methadone and ART separately, as highlighted during the interviews. These findings concurred with other studies that have documented similar findings. Nevertheless, additional facilitators were the availability of counselling

and integration of health services “one-stop shop” at the clinic. These findings were also discovered by other researchers in developing countries (Kumar et al., 2018).

5.2 Study Limitations

Data from a single MMT site were analysed. Despite this, the facility is located in an area with a high people with opioid use disorder population and is one of the clinics with the highest number of MMT patients in the country. Further, the study was conducted over a much shorter duration within six years of data available. This may attenuate our finding on seroconversion numbers. Finally, the HIV status of the MMT sexual partners was not established owing to the unavailability of their records at the clinic.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The study found a low rate of HIV infection among enrolled clients and no significant difference in infection rates between injectors and non-injectors when on MMT. This suggests that the MMT program in Mombasa is effective in lowering HIV infections. The findings indicate that the adaptation of MMT programs in low-resource settings can decrease HIV seroconversion in both injectors and non-injectors, likely due to the cessation of opioid use and reduced risky sexual behaviours among clients. Importantly, the study shows that Opioid Substitution Therapy (OST) can be successfully applied to both injecting and non-injecting drug users with opioid use disorder, supporting the expansion of MMT programs in similar contexts.

Additionally, HIV co-infections among the enrolled clients were lower compared to people who are actively using drugs in the country. Hepatitis C positivity, history of treatment default, and being female were associated with HIV seroconversion, while condom use reduced the risk. These findings indicate that ongoing HIV risk behaviours and defaulting from treatment can increase the risk of acquiring HIV infection among people with opioid use disorder, even when they are enrolled in MMT programs.

Furthermore, the study found multifaceted barriers to treatment adherence among HIV seroconverts on MMT, which include double stigma from both MMT clients and the community, pill burden, transport fatigue, and the side effects of taking methadone and ART concurrently. Conversely, family support and the availability of counselling services as a one-stop shop facilitated adherence. These findings indicate that HIV seroconverts

experienced structural, economic, and societal barriers in accessing treatments, thereby affecting their adherence.

6.2 Recommendations

To further the goals of the program and achieve UNAID's HIV targets, we suggest that the MMT program adapt and implement the following recommendations.

1. To scale up the program by enrolling more people with opioid use disorder (both IDUs and non-injecting drug users) in the MMT clinic.
2. Clinicians and other healthcare workers at the Kisauni MAT clinic should closely monitor clients with positive HCV test results for HIV risky behaviours since the two infections share similar routes of transmission.
3. Given that females are vulnerable to HIV infections and were few in the MMT program, there is a need for the Department of Health to conduct studies to explore the root causes of low MMT uptake by women with OUDs and understand how to attract and retain them in MMT programs.
4. Reintegration of MMT clients with their families and community is critical to long-term success. The Kisauni MMT clinic, through the Department of Health in the county, should develop and deploy specific strategies towards the reintegration programs.
5. Understanding the advantages of methadone and the use of ART are important factors in MMT effectiveness. As a result, the medical staff at the Kisauni MAT clinic should modify and monitor the methadone dosage given to HIV-positive patients during the initiation of ART and strengthen post-HIV counselling by raising awareness of the negative effects of concurrent use of methadone and ART for HIV seroconverts.

6. Following a retrospective study and a short follow-up time, there is a need for a longer follow-up study to fully document the magnitude of HIV infections and the benefits of MMT to people with opioid use disorder in the county.

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Appendices

Appendix 1: Informed Consent Form

Information sheet

I am Nassoro Juma Mwanyalu, a student from Moi university undertaking an Msc Field Epidemiology course. I am doing research on ***"HIV seroconversion rate and risk factors among Medically Assisted Therapy clients in Kisauni MAT clinic".*** I am going to give you information and invite you to participate in this research.

Purpose the research

Several HIV prevention measures including the MMT program, have been put in place to lower the number of new HIV infections in the country to zero new cases. This study aims to find out what are the factors/reasons for getting HIV infection when on the MMT program to find ways to stop the further spread of the disease. We believe that you can tell us more about all the possible reasons how one can possibly get HIV during MAT. Some of the questions might be very personal and confidential, and you may feel uncomfortable talking about some of the topics. You do not have to answer the question if you don't wish to do so.

Study Confidentiality.

Your participation in this research is entirely voluntary. The research involve participation in a face-to-face interview and it take about one hour. During the interview, I or another interviewer sit down with you in a comfortable place within the clinic. No one else but the interviewer was present unless you like someone else there. The entire interview was audio-recorded and note-taking, but no one was identified by name on the audio record or the document. The audio recorder was kept by the researcher with password protection. The information recorded is confidential, and no one else except the researcher, the two supervisors, and the university have access to it. The audio records was destroyed one year after analysis.

If you have any questions, you can ask them now or you can contact any of the following:

1. Principal Investigator	2. Supervisor	3. Supervisor
Nassoro Juma Mwanyalu	Dr. Davies Kimanga	Dr. Kivwanga Mwaniki
Mob: 0729543039	Mob: 0722218088	Mob: 0723285719

The consent certificate.

Participant serial number for the study: _____

Title of Study: __***"HIV seroconversion rate and risk factors among Medically Assisted Therapy clients in Kisauni MAT clinic".***

Name of Principal Investigator:_____Tel. No.(s)_____

I have read/ it has been explained to me in detail in a language that I comprehend. I have understood the contents. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I agree to take part in the above study I have agree☐ or not a☐d audio-recorded.

……. Date:

(Signature/Left Thumb Impression) Place:

Name of the Participant: _____

This is to certify that the above consent has been obtained in my presence.

…….. Date:

Signatures of the Principal Investigator's Place:

Appendix 2: Table for variables extracted from records review

Social demographic variables							
Age	Date enrolled on MAT	Gender	Literacy Level	Name of 1st MMT clinic inducted	Current employment status	Marital status	Reunited with family
Individual variables							
number of times re-inducted	number of times incarcerated	period of heroin use	Mode of drug use(Injecting/ Not Injecting)	Type of drug abused during MMT		Urine toxicology results	Sex Behavior(Use A Condom)
Clinical variables							
Current MMT status	HIV Status during enrolment	Hepatitis B status	Hepatitis C Status	HIV status during MAT	Date seroconverted to HIV	Counseled in the past 3 months	Current Methadone DOSE

Appendix 3: Semi-structured Questionnaire Guide.
HIV seroconversion and risk factors among MMT clients in Kisauni MMT clinic:

a. Age ( )years b. Gender: Male/Female c. Period on MAT…….

1. **Prior to joining the MMT program:** Let us talk about your life before you joined the MMT program.
    a. What were you doing for a living(occupation)?

    b. Where were you staying?.....
    c. Who did you spend most of your time with before MAT?
    d. Drug use history:
    Age of drug use debut
    types and duration of drug use
    injecting history
    e. Please, describe to me what motivated you to engage in the program……

2. Perceptions and Experiences with HTS and HIV Prevention
    a. Have you had any experience with a counsellor? Yes/No.
    b. If yes, how has your experience been with counselling?
    c. Probe on the frequency of counselling
    d. What's your opinion on HIV risk reduction counselling?

Probe on HIV prevention services suggested/provided
probe on Uptake of risk reduction strategies, HTS and HIV prevention options, including NSP, PrEP, condoms,

    e. Probe on reasons for use, non-use and discontinuation of HIV prevention interventions

3. Thoughts about the current treatment situation: Let's discuss your current methadone dose
a. In your opinion, is the prescribed methadone dose always adequate? Yes/NoProbe. The effect/impact of methadone treatment on your opioid dependency behaviour
Have you been interrupted from accessing MMT services?----**Yes No** Probe on reasons for interruption from MMT services, retention pattern and withdrawal effects
b. In your opinion, has MMT changed your life? Yes/No
    a. Probe. on concurrent drug use (mixing Methadone and other drugs) and social life

3. **Circumstances leading to HIV infection:** Let us look at the possible ways you became HIV-infected.

A. Can you identify Any steps taken to prevent HIV infection..
B. what are your thoughts on why these methods did not work
C. Can you please explain the possible routes of exposure for your HIV infection during MAT
D. Incarceration, Injecting, sharing of needle, sexual behaviours,

Lets talk a little more about your sex life before you were HIV-infected.

a. Please explain your sex life and behaviours before you were infected with HIV. i. Probe. Condom use, sex partner

Facilitators and Barriers to HIV Treatment and MMT

HIV Disclosure

Question: How comfortable are you discussing your HIV status with different people, such as healthcare workers, family members, or peers? What factors make it easier or harder for you to disclose?

Health-seeking Behavior for HIV Care and Treatment:

Question: Can you share your experience of starting ART? What influenced your decision to begin treatment, and how did you choose the site where you receive your ART care?

Experiences with HIV Care and Treatment:

Question: In your opinion, what aspects of your HIV care during MAT are most beneficial to you? Are there any challenges or issues with your current treatment that you think should be improved?

Perceptions of Methadone-Assisted Treatment (MAT):

Question: What are your thoughts on the methadone treatment program? Which parts of the program do you find helpful in your recovery from drug use, and what do you think could be improved?

Impact of Methadone on HIV Care Access:
Question: How does being on methadone treatment affect your ability to access and stick with your HIV care and treatment? Have there been times when methadone treatment made it easier or harder to manage your HIV?

Improving Support for HIV-Positive MMT Clients:
Question: What additional support do you think could help people on methadone treatment who are also living with HIV to better adhere to their ART regimen and improve their health outcomes?

<u>Probing questions:</u>

a. Can you elaborate more on that?
b. What do you think could help in that situation?"
c. How did you feel when this happened?"
d. What kind of changes would improve your experience?

Thank you for your time

Appendix 4: Semi-structured Questionnaire Guide.

Serokonivesheni ya VVU na Sababu za Hatari miongoni mwa Wateja wa MMT katika Kliniki ya Kisauni MMT

a. Umri: ( ) miaka

b. Jinsia: Mwanaume/Mwanamke

c. Muda wa Matumizi ya MAT: …….

1. Kabla ya kujiunga na programu ya MMT: Hebu tuzungumze kuhusu maisha yako kabla ya kujiunga na programu ya MMT.

a. Ulikuwa unafanya kazi gani (ajira)?

b. Ulikuwa unaishi wapi? .....

c. Ulikuwa unatumia muda mwingi na nani kabla ya kujiunga na MAT?

d. Historia ya matumizi ya dawa za kulevya:

Umri ulipoanza kutumia dawa za kulevya

Aina za dawa na muda wa matumizi ya dawa za kulevya

Historia ya kudunga sindano

e. Tafadhali elezea kilichokuhamasisha kujiunga na programu hii……

2. Maoni na Uzoefu na HTS na Kinga ya VVU

a. Je, umewahi kuwa na uzoefu na mshauri? Ndiyo/Hapana.

b. Ikiwa ndiyo, uzoefu wako na ushauri nasaha umekuwa vipi?

c. Ulipokea ushauri nasaha mara ngapi?

d. Maoni yako kuhusu ushauri nasaha wa kupunguza hatari ya VVU ni yapi?

Eleza huduma za kinga ya VVU zilizopendekezwa/kutolewa

Eleza kuhusu matumizi ya mikakati ya kupunguza hatari, HTS na chaguo za kinga ya VVU, ikijumuisha NSP, PrEP, mipira ya kondomu

e. Eleza sababu za kutumia, kutotumia au kuacha kutumia njia za kinga ya VVU

3. Mawazo Kuhusu Hali ya Sasa ya Matibabu: Hebu tujadili kuhusu kipimo chako cha sasa cha methadone

a. Kwa maoni yako, je, kipimo cha methadone kilichopendekezwa kimekuwa cha kutosha kila wakati? Ndiyo/Hapana

Eleza athari ya matibabu ya methadone kwenye tabia yako ya utegemezi wa opioid

Je, umewahi kukosa huduma za MMT?—Ndiyo/Hapana

Eleza sababu za kusitishwa kwa huduma za MMT, muundo wa kuhudhuria na athari za kuacha

b. Kwa maoni yako, je, MMT imebadilisha maisha yako? Ndiyo/Hapana

Eleza kuhusu matumizi ya dawa mchanganyiko (methadone na dawa nyingine) na maisha ya kijamii

4. Hali Zilizochangia Maambukizi ya VVU: Hebu tuangalie njia zinazoweza kuwa zilikusababisha kuambukizwa VVU.

a. Je, kuna hatua zozote ulizochukua ili kuzuia maambukizi ya VVU?

b. Kwa maoni yako, kwa nini hatua hizo hazikufanikiwa?

c. Tafadhali eleza njia zinazowezekana za kuambukizwa VVU wakati wa MAT

d. Kufungwa, kudunga sindano, kushirikisha sindano, tabia za ngono

Hebu tuzungumze zaidi kuhusu maisha yako ya ngono kabla ya kuambukizwa VVU.

Tafadhali elezea maisha yako ya ngono na tabia kabla ya kuambukizwa VVU.

Eleza: Matumizi ya kondomu, mwenza wa ngono

Vipengele Vinavyowezesha na Vikwazo vya Matibabu ya VVU na MMT

Ufunuo wa Hali ya VVU (HIV Disclosure)

Swali: Unajisikiaje ukiwafahamisha wengine kuhusu hali yako ya VVU kama vile wahudumu wa afya, wanafamilia, au marafiki? Ni mambo gani yanayokufanya uweze au ushindwe kufichua hali yako?

Tabia za Kutafuta Huduma za Afya kwa Matibabu ya VVU (Health-seeking Behavior for HIV Care and Treatment)

Swali: Tafadhali shirikisha uzoefu wako wa kuanza matibabu ya ART. Ni nini kilikuchochea kuanza matibabu, na ni nini kilikufanya uchague kituo cha kupata matibabu ya ART?

Uzoefu na Matibabu ya VVU (Experiences with HIV Care and Treatment)

Swali: Kwa maoni yako, ni vipengele gani vya matibabu yako ya VVU ambavyo vinakufaidi zaidi? Je, kuna changamoto au masuala yoyote kuhusu matibabu yako ya sasa unayohisi yanahitaji kuboreshwa?

Maoni Kuhusu Matibabu ya Methadone (MAT)

Swali: Maoni yako kuhusu programu ya matibabu ya methadone ni yapi? Ni sehemu zipi za programu unazoziona kuwa muhimu katika kupona kwako kutokana na matumizi ya dawa za kulevya, na unadhani ni nini kingeweza kuboreshwa?

Athari za Methadone kwenye Upatikanaji wa Matibabu ya VVU (Impact of Methadone on HIV Care Access)

Swali: Je, kuwa kwenye matibabu ya methadone kumekuwa na athari gani kwenye uwezo wako wa kupata na kuendelea na matibabu ya VVU? Je, kuna nyakati ambapo matibabu ya methadone yamefanya iwe rahisi au ngumu kudhibiti matibabu yako ya VVU?

Kuboresha Usaidizi kwa Wateja wa MMT Wanaoishi na VVU (Improving Support for HIV-Positive MMT Clients)

Swali: Je, unafikiri msaada gani wa ziada ungeweza kuwasaidia watu wanaotumia methadone na pia wanaoishi na VVU kuboresha utegemezi wao wa ART na matokeo ya afya?

Maswali ya Ufuatiliaji (Probing Questions)

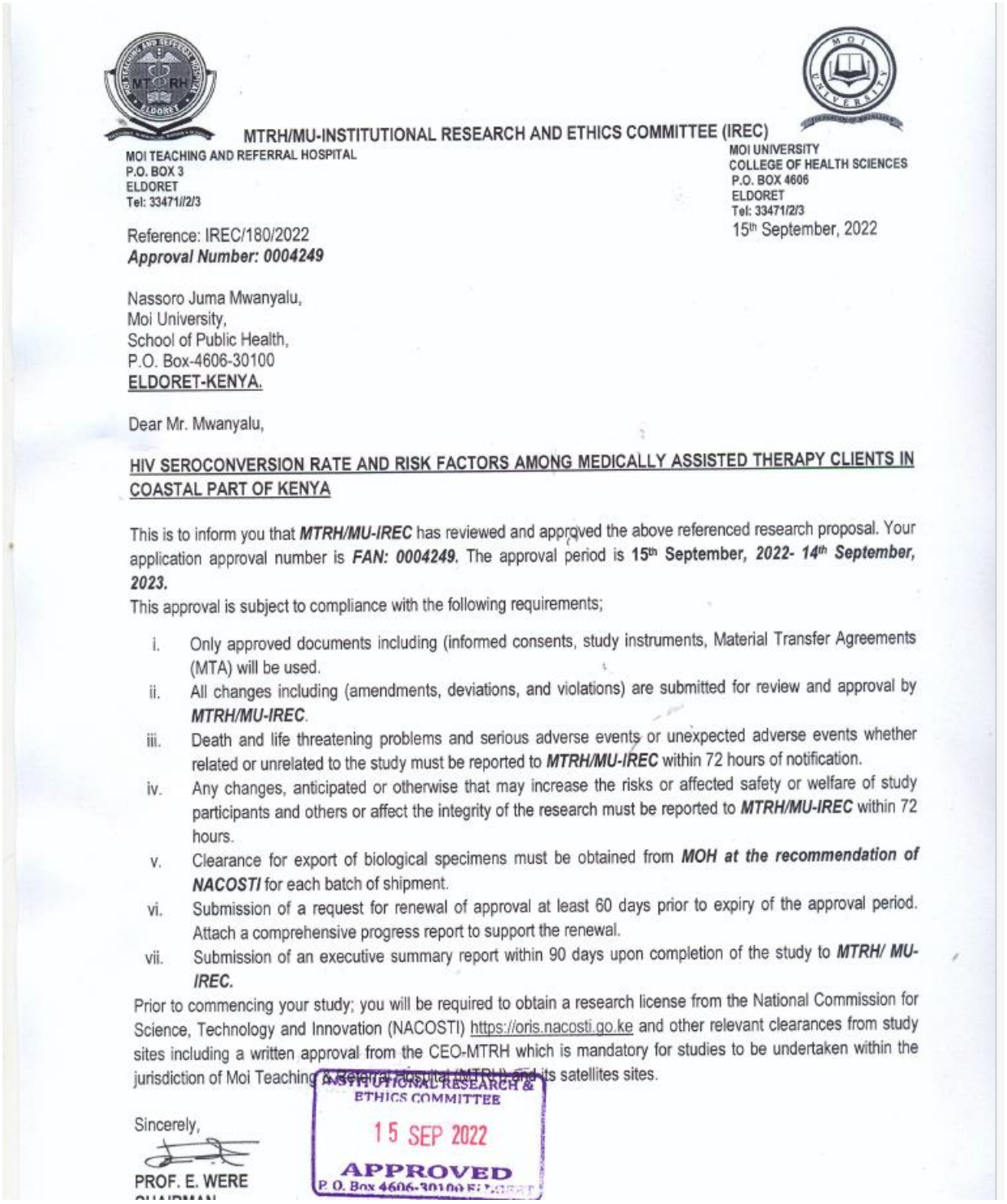
a. Unaweza kuelezea zaidi kuhusu hilo?

b. Unafikiri ni nini kingesaidia katika hali hiyo?

c. Ulijisikiaje wakati hayo yalipotokea?

d. Unadhani ni aina gani ya mabadiliko ambayo yangeboresha uzoefu wako?

Appendix 5: IREC Letter



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/180/2022
Approval Number: 0004249

15th September, 2022

Nassoro Juma Mwanyalu,
Moi University,
School of Public Health,
P.O. Box-4606-30100
ELDORET-KENYA.

Dear Mr. Mwanyalu,

HIV SEROCONVERSION RATE AND RISK FACTORS AMONG MEDICALLY ASSISTED THERAPY CLIENTS IN COASTAL PART OF KENYA

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved the above referenced research proposal. Your application approval number is ***FAN: 0004249***. The approval period is **15th September, *2022- 14th September, 2023.***
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
15 SEP 2022
APPROVED
P. O. Box 4606-30100 ELDORET

Sincerely,

PROF. E. WERE
CHAIRMAN

Appendix 6: NACOSTI License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 667810

Date of Issue: 19/October/2022

RESEARCH LICENSE

This is to Certify that Mr.. Nassoro Juma Mwanyalu of Moi University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Mombasa on the topic: HIV seroconversion rate and risk factors among Medically Assisted Therapy clients in Coastal part of Kenya. for the period ending : 19/October/2023.

License No: NACOSTI/P/22/20832

667810

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 7: Work Plan.

Work Plan	June-July, 2021	August/September 2021	November/December 2021	January/Feb 2022	March/April 2022	May/June/2022	July/August 2022	September 2022
Development of concept note								
Defence/ Approval of study topic								
Allocation of Research supervisors								
Development of protocol								
Review of the protocol by the supervisors								
Submitting of Protocol to IREC, reviews, and Approval								

Data collection								
Data cleaning								
Data analysis								
Report writing								
Submitting of research findings/ mock defence								
Updating comments and submitting a final report to the university.								

Appendix 8: Budget.

s/n	Item	Unit	No. of days	Cost per item	Total
1	Project protocol development Printing, binding, currier services)	1	30	20,000	20,000
2	Training of research assistants	6	1	1000	6,000
3	Data collection(Study personnel) Research assistant(quantitative) Experienced qualitative data collectors Supervisors visit	 4 2 2	 30 10 2	 1,000 5,000 15,000	 120,000 100,000 30,000
4	Supplies and equipment Notebook Biro pen Questionnaire Files Sanitizers Masks	 5 pieces 1 box 1000 5 pieces 15 pieces 10 boxes	 - - - - - -	 250 500 10 300 450 400	 1,250 500 10,000 1,500 6,750 4,000
5	Travel and accommodation Investigator	1 person	32 days	8,000	256,000
	Travel	1 person	2	3,000	6,000
6	Data analysis, report writing, and binding	1	-	50,000	50,000
7	Miscellaneous	1	-	60,000	60,000
	Grand total				722,000