SUBSTANCE USE AND HEROIN ABSTINENCE RATES AMONG PATIENTS ENROLLED AT MEDICALLY-ASSISTED THERAPY CLINIC AT MATHARI NATIONAL TEACHING AND REFERRAL HOSPITAL.

By

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DECLARATION

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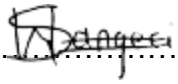
Signed……  ……Date……15-7-2021…..…

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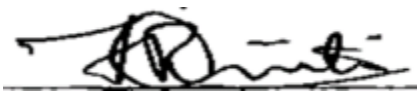
Signed…  ……. Date…15-7-2021……

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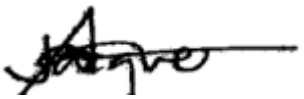
Signed…  …….... Date…15-7-2021……

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LIST OF ABBREVIATIONS

ERC - Ethics and Research Committee
HIV - Human Immunodeficiency Virus
KNH - Kenyatta National Hospital

MAT - Medically Assisted Therapy/Medication-Assisted Treatment
MMT - Methadone Maintenance Treatment

MNTRH - Mathari National Teaching and Referral Hospital
NIDA – National Institute on Drug Abuse

OST - Opioid Substitution Treatment
OUD - Opioid Use Disorder

SAMHSA – Substance Abuse and Mental Health Services Administration
UDS - Urine Drug Screen

UNODC - United Nations Office of Drugs and Crime

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OPERATIONAL DEFINITIONS

Opiates - A group of opioids containing products extracted from opium poppy plant Papaver somniferum. They include opium, heroin, and morphine.

Opioids - Refers to all opiates and their body-synthesized synthetic analogs and compounds. Substances that act on opioid receptors

OUD - A disorder whereby there is a loss of control of opioids use, risky use of opioids, impairment of social functioning, withdrawal, and tolerance. According to Diagnostic Statistical Manual 5, a person experiences at least 2 of the 11 symptoms.

Polysubstance use - Consuming more than one drug at the same time.

MAT - A direct program that offers pharmacotherapy in combination with behavioral treatments to a person who has drug use disorder or mental disorder as a treatment for related symptoms or disabilities.

MMT - A MAT using methadone to assist persons with opioid use disorder to decrease use or abstain from illicit opiates like heroin or non-prescription opioids.

Substance – A chemical in any formulation that when consumed it will cross the blood-brain barrier and alter a person's perception, mood, behavior, and cognition.

NPS – Psychotropic drugs of abuse in a pure form or in preparation that are not regulated by the United Nations drug Convention on Narcotic Drugs of 1961 or 1971, but which may pose a public health danger.

ABSTRACT

Introduction: Several evidence-based assessments have shown that the Methadone Maintenance Treatment (MMT) is beneficial, however, multiple substance use among the patients at the time of enrolment has affected the outcomes of the program. Studies have indicated patients continue to use heroin and other substances while in the program.

Aim: This study aimed to determine substance use and heroin abstinence rates among patients attending the Medically-Assisted Therapy Clinic at Mathari National Teaching and Referral Hospital, Nairobi.

Method: This was a retrospective cohort study of 713 patients who had enrolled in the MAT clinic between December 2014 and February 2018. Data of each participant was collected over a period of 24 months. This study was a census. A researcher-designed socio-demographic form and data collecting form were used to collect data.

Data analysis: Data was entered into MS-Excel and checked for errors before being analyzed with SPSS version 26.0. For discrete variables, frequency tables, pie charts, and bar graphs were provided, while for continuous data, means and standard deviations were provided. Chi-square test was used to analyze the associations between variables at the bivariate level. At the multivariate level, logistic regression analysis was utilized to calculate adjusted odds ratio. The confidence interval was set at 95%, while the statistical significance level was set at $p \leq 0.05$.

Results: There were 713 participants in the study. Most were male 611(85.7%). The mean age was 34.2 years (SD 8.55). The majority had attained primary level of education 333(46.7%), were employed 424(59.47%), and were separated 322(45.1%). All the participants had used at least one other substance apart from heroin. The commonest substances were; tobacco 649(91%), followed by cannabis 591(82.9%) and benzodiazepines 367(51.5%). Tobacco, benzodiazepines, miraa, and benzhexol all had a significant association with various sociodemographic characteristics. At 6, 12, 18, and 24 months, heroin abstinence rates were 61.3%, 76.0%, 73.5%, and 81.4%, respectively. Abstinence rates increased from 61.3% at 6 months to 81.4%at 24 months, which was statistically significant ($p<0.001$).

Conclusion: Majority of the patients attending MAT clinic use more than one substance, therefore, there is a need to scale up the program to also offer free management for other substances. This study replicated the evidence of methadone treatment among heroin users,

however, there is still a need to explore further why some patients continue to use heroin while in the program.

CHAPTER 1: INTRODUCTION AND BACKGROUND INFORMATION

1.1 Introduction

According to the latest United Nations Office on Drugs and Crime report 2020, substance use has increased across the world. It was estimated that 269 million people used drugs at least once in the previous year in 2018, accounting for 5.4 percent of the world's population aged 15 to 64. (UNODC, 2020b). The study also revealed that 58 million people used opioids in 2018. Despite the low number, opioids were responsible for 66 percent of the estimated 167,000 deaths in 2017 attributable to substance use disorders, as well as 21 million years of lost productivity due to drug use-related impairment or premature death(UNODC, 2020a). Around 11.3 million people injected drugs in 2018, a behavior contributing to about 10 percent of the global HIV infections (UNODC, 2020a). Other major drugs reported were; cannabis which had been consumed by 192million people, amphetamines and prescription stimulants by 27 million people, ecstasy by 21 million people, and cocaine by 19 million people (UNODC, 2020a). This drug use has been increasing more rapidly in developing than in developed countries.

The 2019 European Drug Report showed that the most widely used illegal drug in Europe is heroin, which is associated with the most dangerous routes of administration like intravenous use. The report indicated that despite there being some improvements, opioids use disorder has continued to make major contributions to social and health costs. The report further indicated that in most other parts of the world the opioid addiction has continued to increase, resulting in worsening public health costs. (Addiction, 2019).

Opioid Use Disorder's core management includes pharmacological treatment and psychosocial treatment (UNODC, 2020b). The pharmacological management which has been approved by Food and Drug Administration includes methadone, buprenorphine, and naltrexone (McCance-Katz, Johnson, Harding, del Vecchio, & Kade, 2018). However, the majority of rehabilitation centers lack access to these approved medications, therefore they use other medications to mainly relieve withdrawal symptoms with poor efficacy. The psychosocial treatments which are evidence-based include psychoeducation, brief interventions, cognitive behavior therapy, motivational interview, motivational enhancement therapy, and family therapy (Ministry Of

Health, 2017). Most treatment protocols advise a combination of both pharmacotherapy and psychosocial treatment for a better outcome.

The Substance Abuse and Mental Health Services Administration (SAMHSA) located in the United States of America describes Medication-Assisted Treatment (MAT) with methadone as the use of methadone to treat persons with Opioids addiction (Fullerton et al., 2014). Methadone is incorporated in the World Health Organisation list of essential medications (McCance-Katz, Johnson, Harding, del Vecchio, & Kade, 2018). Methadone is considered one of the most popular treatments for opioid use disorder.

Several assessments of evidence from meta-analyses, systematic reviews (Fullerton et al., 2014)(MacNeill, Brunelle, DiTommaso, & Skelding, 2020)(McCance-Katz et al., 2018) have shown a variety of benefits from the Methadone Maintenance Treatment (MMT). MMT worldwide is cost-effective (MacNeill et al., 2020) (Anh Le et al., 2019). The benefits cut across many domains including physical health, psychological, social, financial, and legal issues. Results from research have been consistent showing reduction of HIV and Hepatitis C infection, reductions in premature deaths attributed to overdose, reduction in the use of illicit drugs, and reduction in criminal behaviors (Taylor, 2015)(Proctor et al., 2016) (Nguyen, Nguyen, Nguyen, Tran, & Latkin, 2017)(Michie et al., 2017). MMT during pregnancy is also associated with reduced complications and increased better fetal outcomes (Fullerton et al., 2014). These benefits translate to increased retention in MMT (National Institute on Drug Abuse, 2018).

Multiple studies have shown that higher doses of methadone are associated with better outcomes, such as improved treatment retention and reduced illicit drug use. The recommended dose-ranging is 80-120mg/day. Such high doses will help relieve cravings, block euphoric feelings and suppress the abstinence syndrome that is associated with heroin. (Taylor, 2015)(McCance-Katz et al., 2018).

1.2 Background

Heroin is an illicit psychoactive drug with a high potential for addiction because it produces intense euphoric feelings and has a short half-life. It is processed from morphine which occurs as a natural substance that is derived from the seed pod of certain poppy plants. Heroin is available as a white or brown powder (National Institute on Drug Abuse, 2018). The majority of the global supply of heroin originates from South America and Southeast Asia. (UNODC, 2020c). Routes of heroin administration include intravenous injection, smoking, and snorting.

The most preferred route of administration is intravenous because it has a quicker onset of action compared to the other routes. (National Institute on Drug Abuse, 2018).

Methadone research started as early as the nineteenth century through the early twentieth century (Thomas Payte, 1991). The Germans discovered methadone during the second world war, however, its properties were first published in the United States of America in 1947 (Thomas Payte, 1991). Initially, there was strong resistance from the United States Bureau of Narcotics for the use of methadone. It was until the 1960s that methadone became recognized as a treatment for opioid use disorders after extensive research. (Fareed et al., 2010)(Michie et al., 2017). Methadone in most centers is usually administered orally daily under direct supervision in a government-licensed clinic (Proctor et al., 2016). There is no consensus about the duration of time in an MMT program, SAMHSA and NIDA proposed a minimum of 12 months and lasting up to 24-36 months but some patients prefer lifelong treatment (Ripanda, Srivastava, Vuai, & Nyundo, 2019)(McCance-Katz et al., 2018)

The Global State of Harm Reduction 2018 6th Edition report shows the global coverage of Opioid Substitution Treatment (OST). Africa has been subdivided into two regions; North African countries whereby only one country Morocco (2010) has at least one OST and Sub-Sahara African countries where there are seven countries with at least one OST; Tanzania(2011), South Africa (2013), Kenya (2014), Mauritius (2016), Senegal (2016) and Cote d' Ivoire (2017)(Reduction, 2018)(Kurth et al., 2018).

In Kenya MAT was introduced in December 2014. It is sponsored by the United States President's Emergency Plan for AIDs Relief (PEPFAR) through the Center for Disease Control (CDC) and the United States Agency for International Development (USAID) and implementation support from the University of Maryland and UNODC (Rhodes, 2018). Currently, there are eight operating MAT clinics in Kenya; two in Nairobi County (Mathari and Ngara), two in Mombasa County (Kisauni and Miritini) one in Kisumu County (Jaramogi), one in Kilifi County (Malindi), one in Kisumu County (Jaramogi), one in Kwale County (Kombani) and one in Kiambu County (Karuri). There is also one methadone dispensing site at Shimo la Tewa prison in Mombasa County. The Mathari MAT clinic receives patients referred from various Civil Society Organisations (CSOs) such as Nairobi Outreach Services Trust (NOSET), Support for Addictions Prevention and Treatment in Africa (SAPTA), Medecins du Monde (MdM), and Liverpool Voluntary Counselling and Testing centers

(LVCT). The duration of treatment across all the MAT clinics in Kenya is two years (Ministry Of Health, 2017).

1.3 Problem Statement

According to the Global Burden of Disease Study, Opioid use disorders result in the highest burden of disease in regards to Disability Adjusted Life Years (DALYs) (UNODC, 2020b)(MacNeill et al., 2020). Opioids have the highest death rates among all psychoactive drugs. Opioid Use Disorders have resulted in several negative outcomes (Proctor et al., 2016). The medical complications include those related to injections by sharing needles; are increased transmissions of blood-borne viruses Hepatitis B and C and HIV infections, veins collapsing, bacterial infections of blood vessels, and infective endocarditis (Fullerton et al., 2014) (National Institute on Drug Abuse, 2018). Lung complications resulting from smoking heroin include infections like pneumonia and tuberculosis resulting from its respiratory depressing effects and generally poor quality of health; Snorting heroin results in damaged nasal tissues (National Institute on Drug Abuse, 2018). Women experience menstrual irregularities whereas men get sexual dysfunctions. During pregnancy, heroin results in poor fetal outcomes (National Institute on Drug Abuse, 2018). Other general negative outcomes include premature death, increased criminality, and dysfunctional relationships (McElrath & Joseph, 2018).

The latest UNODC report indicates that there is limited access to treatment for drug use disorders, especially in low or intermediate economy countries. The report further shows that globally only one in eight persons with drug use disorder gets treatment annually (UNODC, 2020a).

Several studies have highlighted multiple drug use and continued use of heroin while in the MMT program as a significant problem that negatively impacts retention (Heikman, Muhonen, & Ojanperä, 2017)(Anh Le et al., 2019)(Ripanda et al., 2019). Multiple drug use comprises alcohol, caffeine, cannabis, hallucinogens, opioids, sedatives, hypnotics, anxiolytics, stimulants, tobacco, and others. Despite the success of many MMT programs many patients who attend methadone clinics continue using heroin and other drugs. Some research attributes this continued heroin use to the opiate craving which can lead to lapse and relapse (Fareed et al., 2010). The majority of OST programs have focused on Opioid Use Disorders only rather than a holistic approach inclusive of other substances since a majority of opioid users use multiple substances (Cicero, Ellis, & Kasper, 2020).

This study aimed to determine the patterns of substance use among MAT patients and heroin abstinence rates at Mathari National Teaching and Referral Hospital.

CHAPTER 2: LITERATURE REVIEW

2.1 Sociodemographic characteristics

Several studies have shown different substance use across different sociodemographic categories of people. In terms of age, studies have shown most participants are around 30 to 40 years. Proctor et al found that patients aged 35 years and above at 3 months and 12 months of MMT were less likely to be opioids abstinent, they found that older age was associated with a greater sum number of positive Urine Drug Screen (UDS)(Proctor et al., 2016). Anh Le et al found the mean age of the participants was 40 years (SD 8.9) (Le et al., 2019), Shekarchizadeh et al found the mean age of 40.5 years (SD 11.5)(Shekarchizadeh, Ekhtiari, Khami, & Virtanen, 2012), Michie et al found the mean age of 28.5 years (SD 6.5) (Michie et al., 2017), Lambdin et al found the mean age of 32 years (SD 6)(Lambdin et al., 2014) and Ngarachu found the mean age of 34 years (SD 8.9) (Ngarachu, 2019).

Considering gender, studies have consistently shown males to be more than females. Proctor et al found that male patients were more likely to test positive for opioids than female patients during MMT (Proctor et al., 2016). They found that 27.6% of male patients tested positive at 3 months whereas females were 17.7% (Proctor et al., 2016). Shekarchizadeh et al found 95 % of the participants were males (Shekarchizadeh et al., 2012), Musa et al found 97.2% were males (Musa, Abu Bakar, & Ali Khan, 2012), Michie et al found 91.1% were males (Michie et al., 2017), Lambdin et al found 93% were males (Lambdin et al., 2014), Kisilu et al found 93% were males (Kisilu, Ayuya, & Mwavua, 2016) and Ngarachu found 88.1% were males (Ngarachu, 2019).

In terms of marital status, studies have shown mixed results. Proctor et al found significant associations at 3 months while in MMT 27.3% of patients who were single tested positive for opioids, 19.1% of those who were married tested positive (Proctor et al., 2016). There were no other significant associations at other intervals, finally from bivariate correlation, none of the marital statuses were significantly associated with sum numbers of positive UDS during the 12 months follow-up (Proctor et al., 2016). Anh Le et al found more than two-thirds of the participants lived with a spouse/partner (Le et al., 2019), Shekarchizadeh found 70% were married (Shekarchizadeh et al., 2012), Musa et al found 67.3% were single (Musa et al., 2012), Michie et al found 74.8% were single (Michie et al., 2017), Lambdin et al found 13% were married (Lambdin et al., 2014) and Ngarachu found 72.4 % were single (Ngarachu, 2019).

Considering employment status, studies have shown mixed results. A study done by Anh Le et al found that 35.2% of the participants were self-employed, employed and farmers were 23.3% and unemployed were 10% (Anh Le et al., 2019). Shekarchezadeh found >70% were unemployed (Shekarchizadeh et al., 2012), Musa et al found 70.1 % were employed (Musa et al., 2012), Michie et al found 96.3% were unemployed (Michie et al., 2017) and Ngarachu found 74.3% were unemployed (Ngarachu, 2019).

2.2 Epidemiology of Substance use

The latest UNODC report shows that regions having higher than the global average of Opioid Use Disorder include North America at 3.6%, Australia and New Zealand at 3.3%, Near and the Middle East, and South-West Asia at 2.6%, and South Asia at 2.0% (UNODC, 2020b). Worldwide, women have a lower prevalence of drug use disorders than men, these women are described to be particularly vulnerable (UNODC, 2020c). The UNODC report further indicates that in the USA in 2018 around 800,000 people had used heroin in the previous year (UNODC, 2020b). The main opioid used in Europe and Asia is heroin (UNODC, 2020b).

In Africa, the UNODC report shows a growing trend in terms of Opioids Use Disorders, the common opioids used especially in West and Central Africa being heroin and tramadol. The common source of supply being South-East Asia through the Indian Ocean and South America through the Atlantic Ocean (UNODC, 2020b).

2.3 Patterns of Substance use among opioid users

In Europe, a retrospective study done among 60 opioid-dependent patients at Helsinki University Central Hospital in Finland from November 2015 to January 2016 found that 65% ofthe patients abused multiple substances (Heikman et al., 2017). The substances were grouped into six categories, therefore among the 65%, 48% used benzodiazepines, 42% amphetamines, 30% cannabis, 25% non-prescribed psychotropic medications, 8% new psychoactive medications, and 7% opioids (Heikman et al., 2017).

A retrospective study done among 2,410 patients at 26 MMT facilities in various states in the USA (California, Oregon, Virginia, Louisiana, West Virginia, North Carolina, and Kansas) from January 1 2009 to April 30 2011 found that the patients at intake used multiple substances apart from opioids; benzodiazepines 26.4%, cannabinoids 20.7%, cocaine 10.8%,

amphetamines 9.1 % (Proctor et al., 2016). The study further showed alcohol and barbiturates were found in less than 2.0 % (Proctor et al., 2016). Another retrospective study conducted in an MMT program within the state of Maryland in the USA among 60 patients of the 232 discharged patients from January 2014 to February 2015 found that 68% of the patients used multiple substances (Taylor, 2015). Among the 68%, 47% used opiates, 37% cocaine, 37% benzodiazepines, and 25% marijuana (Taylor, 2015). Of note, no patient in the sample used alcohol though it was known that the patients were drinking alcohol regularly and they used to be monitored daily with breathalyzers (Taylor, 2015).

In Australia, a 36 months prospective cohort Australian Treatment Outcome Study (ATOS) conducted among 429 participants from 19 agencies treating heroin-dependent patients in Sydney from February 2001 to August 2002 showed that the patients used multiple substances (Darke, Ross, Mills, Williamson, & Teesson, 2007). At baseline, 96% used tobacco, cannabis 69%, 51% alcohol, and benzodiazepines 50% (Darke et al., 2007).

In Asia, a cross-sectional study done among 395 participants at 3 MMT clinics at Nam Dinh Province in Vietnam from January to September 2018 showed the patients engaged in multiple drugs (Anh Le et al., 2019). Tobacco was the most used drug at 81%, then alcohol at 54 %, other substances included amphetamine, ecstasy, morphine, methamphetamine, and continued heroin at 6% (Anh Le et al., 2019). Another cross-sectional study conducted among 810 participants in private MMT clinics in Tehran in Iran from January to May 2011 found the patients to be using multiple substances (Shekarchizadeh et al., 2012). The concurrent drugs with heroin included 16% cannabis, 15% amphetamines, and 33% others (Shekarchizadeh et al., 2012).

In Africa, there is a paucity of published data concerning OST. A comparative retrospective study conducted among 135 participants at Sultan Bahu Rehabilitation Centre in Cape Town South Africa from January 1 to December 31 2014 found that 54.8% of all the participants used multiple drugs (Michie et al., 2017). 68 patients were on standard care only while 67 patients were on OST with suboxone (a fixed-dose combination of buprenorphine and naloxone 4:1) (Michie et al., 2017). Among the 54.8% in addition to opioids; 5.4% used cannabis 48.6% methamphetamine, cannabis + any other 33.8%, methamphetamine +any other 41.9%, any two drugs 25.7%, and finally any three drugs 17.6 % (Michie et al., 2017). Another retrospective study conducted among 629 participants at the MMT clinic at Muhimbili National Hospital in Tanzania from February 2011 to January 2013 showed that 34% of the patients used multiple

substances (Lambdin et al., 2014). Other drugs captured from the electronic database included alcohol, cocaine benzodiazepine, and amphetamines, however, the study did not give a breakdown (Lambdin et al., 2014).

In Kenya, a retrospective study done among 388 participants at MAT clinic in Ngara in Nairobi from February 2017 to March 2018 showed most participants used more than one drug (Kisilu et al., 2016). The study aimed to determine the age of onset of using substances and not substance use at enrolment to the MAT program. Most common drug was cannabis at 35.9%, tobacco at 29.1 %, alcohol 12%, heroin 11.3%, khat 5.9%, benzodiazepines 3 %, glue 1.5%, amphetamines 0.3 %, cocaine 0.3 % (Kisilu et al., 2016). Another retrospective study done among 984 participants at MAT clinic in Mathari National Teaching and Referral Hospital from December 2014 to November 2018 to determine the prevalence of cannabis use found that 84.8% of the participants at baseline used cannabis (Ngarachu, 2019).

2.4 Abstinence rates among heroin users in MAT

The above retrospective study done at 26 MMT facilities in various states in the USA followed up 463 patients, it showed an increasing negative opioids tests on a urine drug screen (UDS) conducted at various times during treatment (Proctor et al., 2016). At 3 months 2.8% tested negative, at 6 months 6.9%, at 9 months 16.4% and at 12 months 70.4% (Proctor et al., 2016).

The above Australian Treatment Outcome Study (ATOS) followed up the participants at 12 months, 24 months, and 36 months for heroin abstinence, they had been grouped into four groups; methadone/buprenorphine maintenance (MT), drug-free residential rehabilitation (RR), detoxification (DTX), and no treatment (NT) (Darke et al., 2007). In general among the four groups the proportion of patients who had been abstinent since enrolment reduced from 14% at 12 months to 8% at 36 months. In the MT group at 36months, the abstinent rate was 10% (Darke et al., 2007).

In Asia, a within-group experimental study conducted among 107 participants at The Tengku Ampuan Afzan Hospital in Malaysia from 2007 onwards showed reducing opioid use (Musa et al., 2012). In the first year of follow-up, 2.4% tested positive for opioids while in the second year it was 1.4%(Musa et al., 2012).

In Africa, a cross-sectional study done among 126 participants at MMT in Mwananyamala Hospital Dar es Salaam in Tanzania showed 125 out of the 126 participants were using opioids

both prescription and non-prescription (Ripanda et al., 2019). 50% of all the participants had been in the MMT within 0-12 months, 23.81% within 13-15 months, 11.11% within 26-38 months, and 15.08% over 39 months (Ripanda et al., 2019).

2.5 Significance

Following the above literature review, it is evident that a majority of the patients attending MMT clinics use more than one substance. The mandate of MMT is focussed on opioids (mostly heroin) reduction, however, the use of multiple drugs when enrolling into MMT clinics impacts the opioids abstinence rates, hence the need for holistic management of all substances is unmet.

According to the United Nations Sustainable Development Goals Set in 2015, goal 3.5 is concerned with strengthening the prevention and treatment of substance abuse including narcotic drug abuse and the harmful use of alcohol. However, with a dearth of data especially in developing countries the Ministry of Health, sponsors, and other stakeholders experience challenges mitigating substance use disorder (UNODC, 2020b).

The NACADA 2017 report showed that heroin users are a hidden population and they fear arrests, it recommended a more targeted survey. Heroin is an illicit psychoactive drug hence using it is a crime. Through advocacy this population has now been able to attend MMT, however, the use of multiple substances is still unmet (NACADA, 2017).

There is a paucity of data especially in Kenya about substance use and heroin abstinence rates among MAT patients. The findings of this study will help to inform the Ministry of Health, sponsors and other stakeholders on the need for a holistic management approach among the MAT patients with multiple substances use for better outcomes. The study will also add to the pool of knowledge of literature and inform future studies.

2.6 Research questions

1. What are the substances used during induction among patients enrolled at the MNTRH MAT clinic?
2. What are the heroin abstinence rates of the patients at 6 months, 12 months, 18 months, and 24 months while in the program?
3. What are the socio-demographic characteristics of the patients and their association with substance use at induction?

4. What are the heroin use characteristics of the patients at induction and their association with its abstinence rates at 6 months, 12 months, 18 months, and 24 months while in the program?

2.7 Research objectives

2.7.1 Broad objective

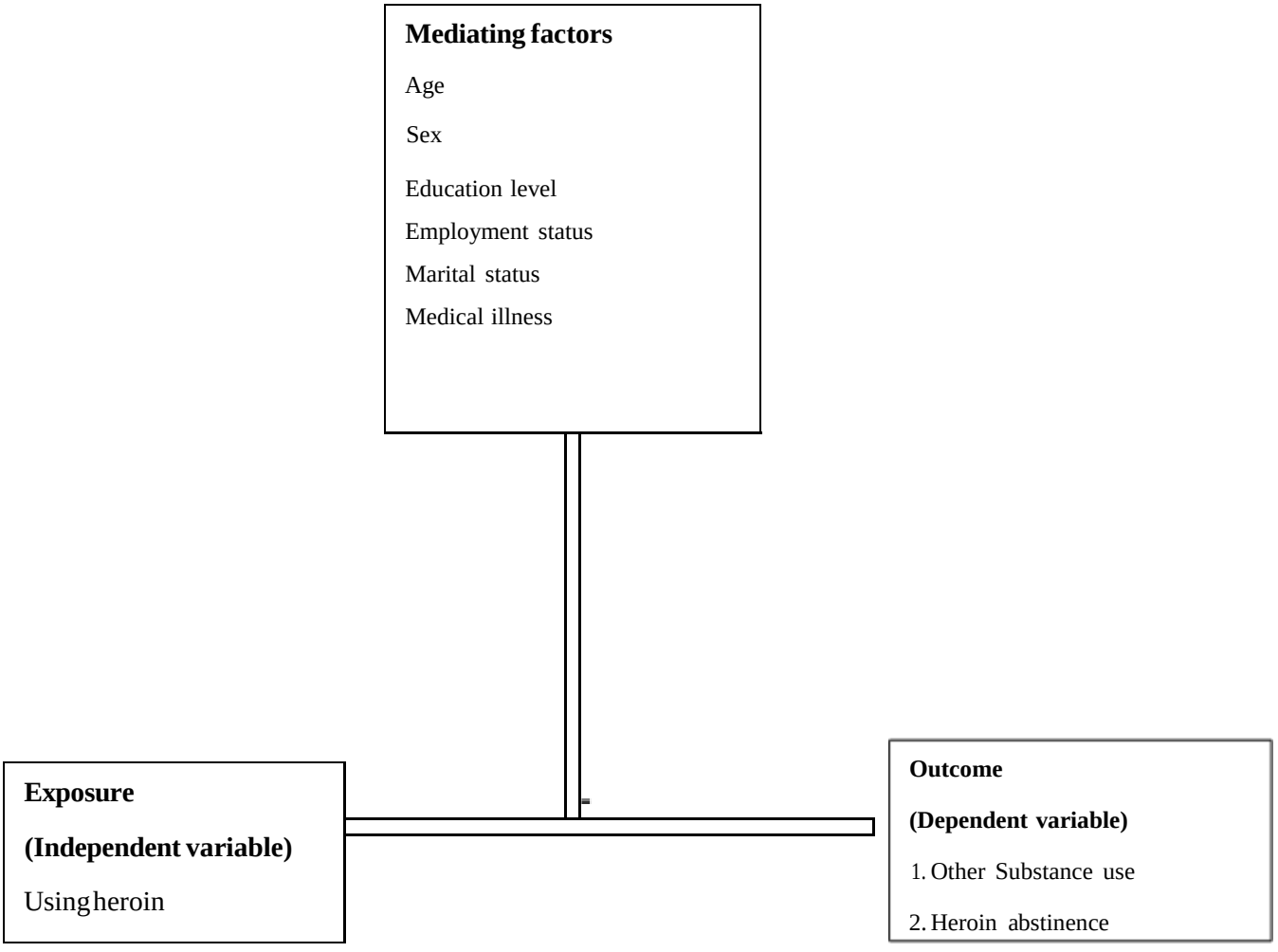
To determine substance use and heroin abstinence rates among patients attending MAT clinic at MNTRH.

2.7.2 Specific objectives

1. To determine substance use during induction among patients enrolled at MNTRH MAT clinic
2. To determine the heroin abstinence rates of the patients at 6 months, 12 months, 18 months, and 24 months.
3. To assess the association between sociodemographic characteristics of the patients with other substances at induction.
4. To assess the association between heroin use characteristics of the patients and heroin abstinence rates at 6 months, 12 months, 18 months, and 24 months.

2.8 Conceptual framework

Figure 1: *Conceptualframework*



CHAPTER 3

3.0 METHODOLOGY

3.1 Study design

This study was a retrospective cohort study from December 2014 to February 2020. Data was collected for a maximum of 24 months since the time the patient was enrolled in the program.

3.2 Study site

The study was conducted at the Medically-Assisted Therapy Clinic located at Mathari National Teaching and Referral Hospital in Nairobi, Kenya. This was the first MAT clinic in Kenya and it became operational in December 2014. The catchment area is most parts of Nairobi City as the facility is located approximately 5 kilometers from Nairobi City Centre. The clinic runs every day of the week from 6 am to 1 pm. All patients are on methadone the oral syrup formulation, most are given daily as a directly observed treatment in the clinic while a few have qualified for taking home dosages. Other services offered in the clinic are Human Immunodeficiency Virus management, Tuberculosis treatment, Sexually transmitted infections treatment, Hepatitis management, Psychiatry treatment in addition to other common minor physical illnesses. The clinic has three Psychiatrists, one Medical Officer, among other health care workers, and support staff. Patients are referred to the facility from drop-in centers where they have undergone psychosocial education and support and educated on other harm reduction practices like not sharing needles nor syringes, no flushing, and safe sex among others.

3.3 Study Population

The number of patients has been increasing annually since the initiation of the clinic. The crude cumulative retention over time from December 2014 up to February 2018 was 727 patients. All the patients are adults aged 18 years and above, no minors are attending the clinic.

3.4 Inclusion criteria

1. All the 727 participants are adult males and females of age 18 years and above.

3.5 Exclusion criteria

1. Files with missing data of the participants were excluded.

3.6 Sampling frame and size determination

The researcher conducted a census of all the 727 patients enrolled from December 2014 to February 2018. The last period of February 2018 was informed by the Covid-19 pandemic because since February 2020 there have been no enrolments of new patients in the clinic nor the random urine drug screen testing. This allowed the patients who were enrolled up to February 2018 for their data to be collected and analyzed to mitigate excess missing data.

3.7 Sampling procedure

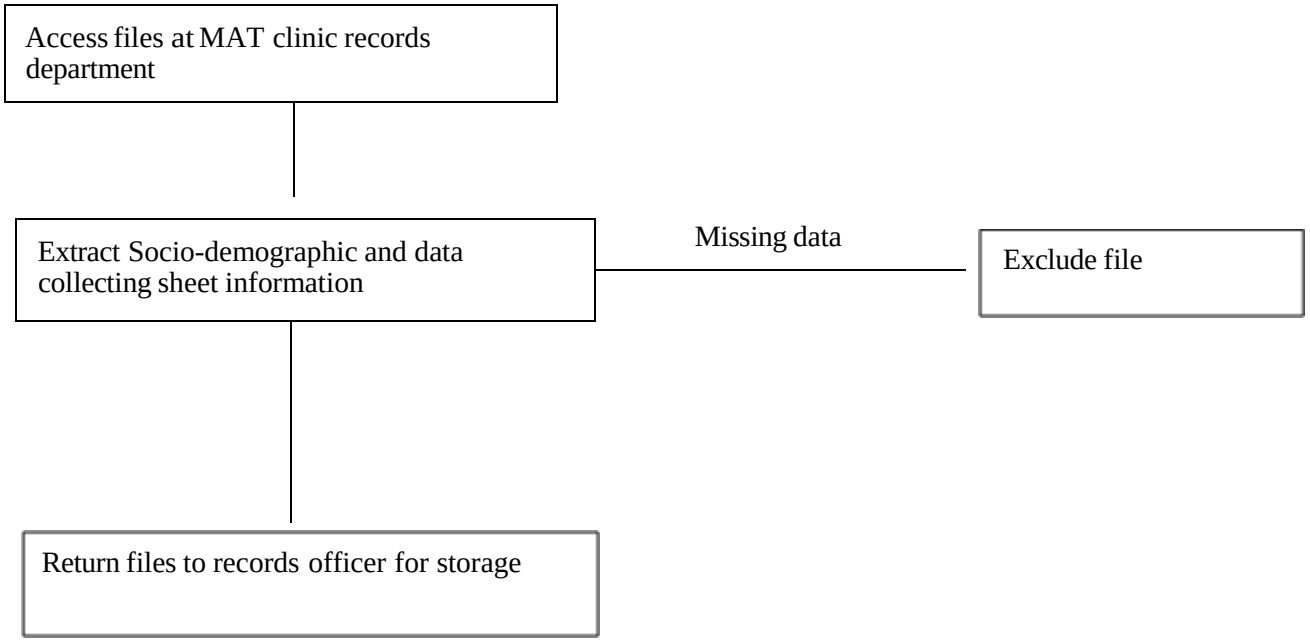
This study was a census of all the 727 patients enrolled from December 2014 to February 2018.

3.8 Recruitment and data collecting procedure

The researcher got to the MAT clinic records department after approval from KNH-UoN ERC and Mathari National Teaching and Referral Hospital Research Committee. Files for patients enrolled from December 2014 to February 2018 were retrieved based on the register. Socio-demographic data and collecting data sheet information were extracted from the files. Files with missing data were excluded. Files were then returned to the records officer for storage.

3.9 Recruitment and data collecting flow chart

Figure 2: *Recruitment and data collectingflow chart*



3.10 Variables

The Independent variable was using heroin by the MAT patients. All the patients attending the MAT clinic must have been using opioids (mostly heroin) before enrolment.

Dependent variables were other substance use among the MAT patients and the heroin abstinence rates. The other substances included alcohol, caffeine, cannabis, hallucinogens, inhalants, sedatives, hypnotics, anxiolytics, stimulants, tobacco, and other substances.

According to Diagnostic and Statistical Manual for Mental Disorders 5 there has been changes in the use of terminologies in regards to Substances related disorder. The use of terms like "Substance Abuse" and "Substance Dependence" have been removed, now they use one terminology "Substance Use Disorder" (Association, 2013.)

The mediating variables were age, sex, education level, employment status, marital status and medical illness.

3.11 Research instruments

The researcher used researcher-designed sociodemographic and data collection forms to collect data. Socio-demographics data collected included age, gender, education level, marital status, occupation, housing status, and legal status. The data collection form included;

1.The age at which the patient first used heroin, duration of years, frequency of use in the last 30 days, and route of administration.

2. Severity of the Opioid Use Disorder

3. Other drugs use apart from heroin; cannabis, tobacco, alcohol, benzodiazepines, cocaine, miraa, glue, phencyclidine, barbiturates, and others.

4. Medical conditions

5. Urine drug screen results at 6 months, 12 months, 18 months, and 24 months.

3.11.1 Pre-testing of the study instrument

The researcher conducted a pilot study at the MAT clinic at MNTRH before the study to ensure the validity and reliability of the study tool. A sample size of 20 files was used. The pre-test assisted with assessing the accuracy, clarity, and feasibility of the main study in terms of costs and other logistics.

3.12 Ethical considerations

The researcher got approval for the study from the Ethics and Research Committee of Kenyatta National Hospital and the University of Nairobi. The researcher got approval to carry out the study at Mathari National Teaching and Referral Hospital from the Medical Superintendent and the institution's Research Committee.

3.12.1 Privacy and Confidentiality

The researcher observed the privacy and confidentiality of patient's information. Patient's names were not be captured in the forms, the researcher used serial numbers instead of names and unique identification numbers that the patients are allocated while attending MAT.

3.12.2 Potential benefits of the study

The results of the study will inform the Ministry of Health, sponsors and other stakeholders on the need for holistic management of MAT patients who also use other substances, this too will benefit the patients who enroll in the program and are using multiple substances.

3.12.3 Potential risks of the study

The research being retrospective there were no invasive questions, no physically invasive procedures nor emotional provoking questions to the participants.

3.13 Data management and analysis

The sociodemographic and data collection forms were kept in a lockable cabinet accessible only to the researcher. The data was coded before being computerized. Soft copies of data were entered and stored in a password-protected computer that was only accessible to the researcher. Microsoft Excel was used to store and manage data. Data analysis was done using SPSS version 26.0.

The univariate analysis was done to describe the patterns and sociodemographic characteristics of the participants. The bivariate analysis was used to describe the association between variables. Multivariate analysis was done to describe the correlates between socio-demographic variables and the outcomes. Associations were expressed using the odds ratio with the corresponding 95% confidence interval and a P-value of significance set at 0.05. The results were presented in narratives, tables, graphs, and pie-charts.

3.14 Quality assurance

The research proposal was reviewed by the Department of Psychiatry before being submitted to the KNH/UoN Ethics and Research Committee which ensured it has passed the quality threshold. The researcher is a Part 2 Resident at the Department of Psychiatry at the University of Nairobi, she worked under the supervision of two lecturers from the Department of Psychiatry and one consultant Psychiatrist working at the MAT clinic at MNTRH. The researcher did not employ research assistants. The researcher involved a qualified Bio-statistician who assisted with analyzing the data.

CHAPTER 4: RESULTS

Out of the 727 files intended for the study, the researcher found 717 files; 10 files were missing, translating to a response rate of 98.62%. Among the 717 files, patients using heroin were 713(99.4%), pethidine 3(0.42%), and tramadol 1(0.14%). The files of the patients using pethidine and tramadol were then excluded. Therefore, the researcher analyzed 713 files. The results are presented below according to the study objectives.

4.1 Socio-demographic characteristics of study participants

The socio-demographic characteristics of the study participants are presented in Table 1 below. Most were male 611(85.7%), females were 102(14.2%). The mean age was 34.2years, with a standard deviation of 8.55, the minimum age was 18 years while the maximum age was 78 years. A majority had attained primary level of education 333(46.7%). The majority were separated 322(45.1%) and had mostly informal employment 424(59.47%). In terms of housing status over the past 12 months, the majority were living in a rental house. Unstable housing status means the patient reported more than one status. A majority had a positive lifetime legal history of arrest 548(64.24%).

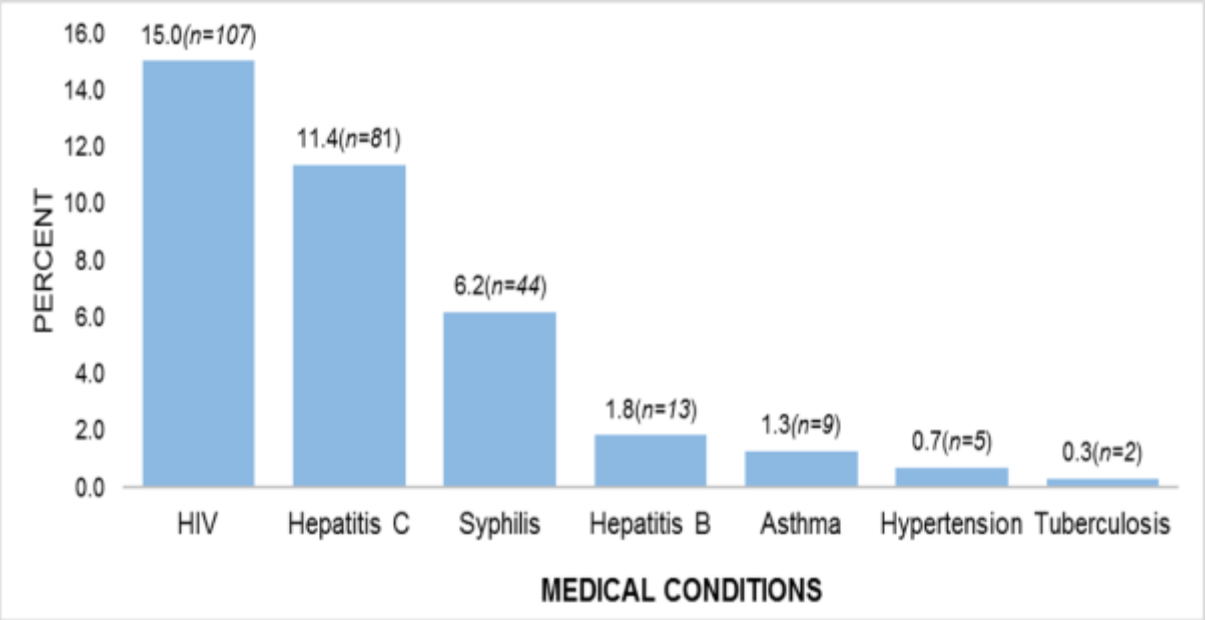
Table 1: Socio-demographic characteristics of study the participants

Variable	Category	Frequency (*n*=713)	Percent (%)
Gender	*Male*	611	85.7
	Female	102	14.3
Age	*≤ 20yrs*	19	2.7
	21-30	227	31.8
	31-40	310	43.5
	41-50	178	18
	51-60	25	3.5
	61-70	3	0.4
	> 70	1	0.1
Education level	*Primary*	333	46.7
	Secondary	290	40.67
	Tertiary	75	10.52
	None	15	2.1
Marital status	*Separated*	322	45.1
	Single	225	31.6
	Married	154	21.6
	Widowed	12	1.7
Occupation	*Unemployed*	195	27.35
	Employed	424	59.47
	Self-employed	94	13.18
Housing status	*Rental*	234	32.82
	Unstable	196	27.49
	Homeless	120	16.83
	Friends	104	14.59
	Relatives	55	7.71
	Own house	4	0.56
Legal history	*Yes*	548	64.24
	No	255	36.76

4.2 Medical conditions of the study participants

The leading medical condition affecting the participants was Human Immunodeficiency Virus 107(15.0%), followed by Hepatitis C 81(11.4%) and syphilis 44(6.2%) as shown below in Figure 3.

Figure 3: Medical conditions of the study participants



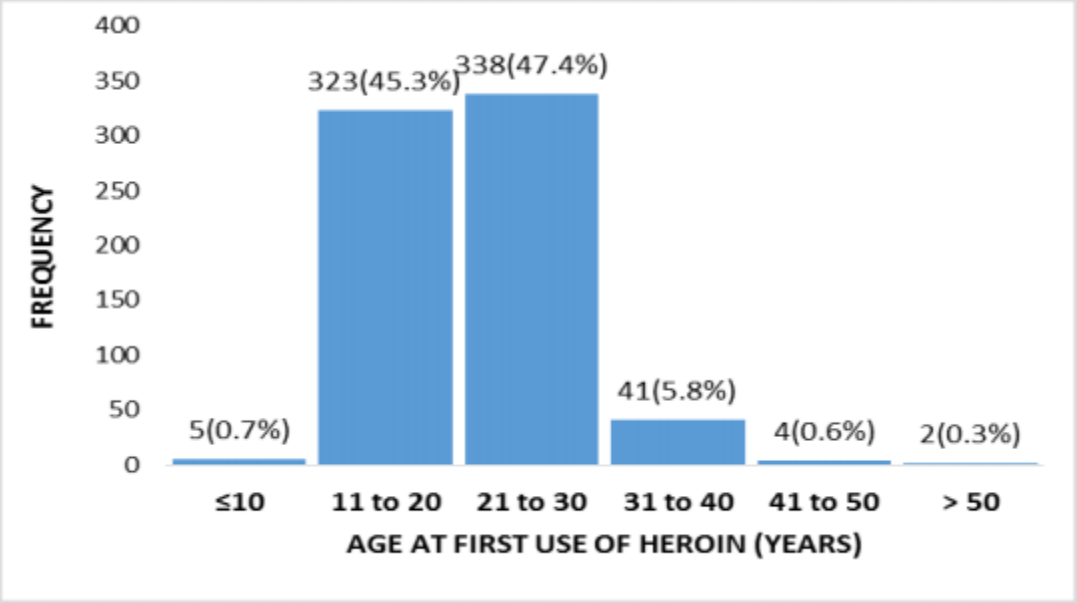
4.3 Substance use among study participants

4.3.1 Heroin use disorder

4.3.1.1Age at first use of heroin

The mean age at first use of heroin was 22.21 years (standard deviation 6.14, range 8-77 years). Majority 338(47.4%) of the participants were in the age group 21-30years followed by 11-20 years 323(45.3%) as shown below in Figure 4.

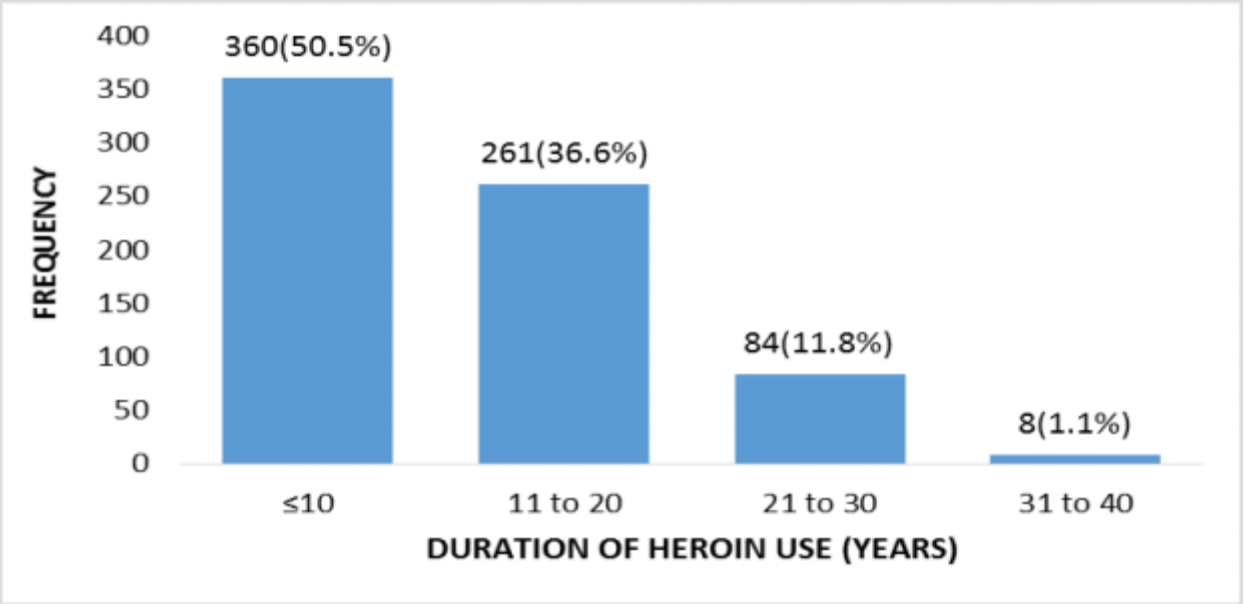
Figure 4: Age at first use of heroin



4.3.1.2Duration of use of heroin

The mean duration of use of heroin before enrolling in MAT was 11.87 years (standard deviation 7.28 years, range 1 to 40 years). Most patients 360(50.5%) had used heroin for less than 11 years, followed by 11-20 years 261(36.6%) as shown below in Figure 5.

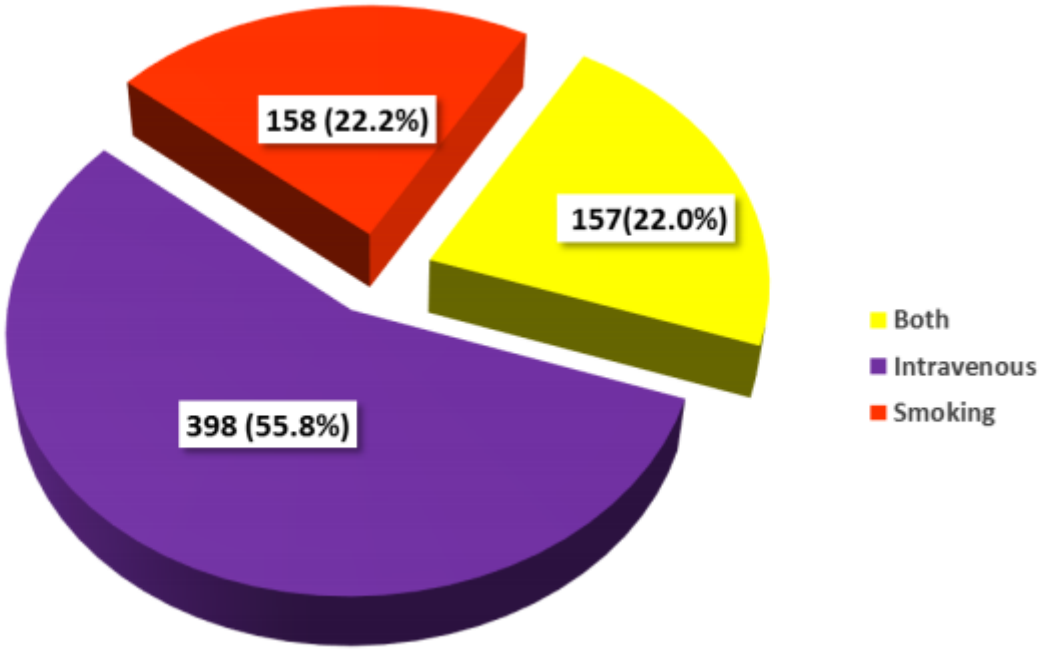
Figure 5: Duration of use of heroin



4.3.1.3 Route of administration of heroin

The most recent route of administration was intravenous 398(55.8%), followed by smoking 158(22.2%). Those who had both injected and smoked were 157(22.0%) as shown in Figure 6.

Figure 6: Route of administration of heroin



4.3.1.4 Frequency of use of heroin

All the participants were using heroin daily in the last month before enrolment.

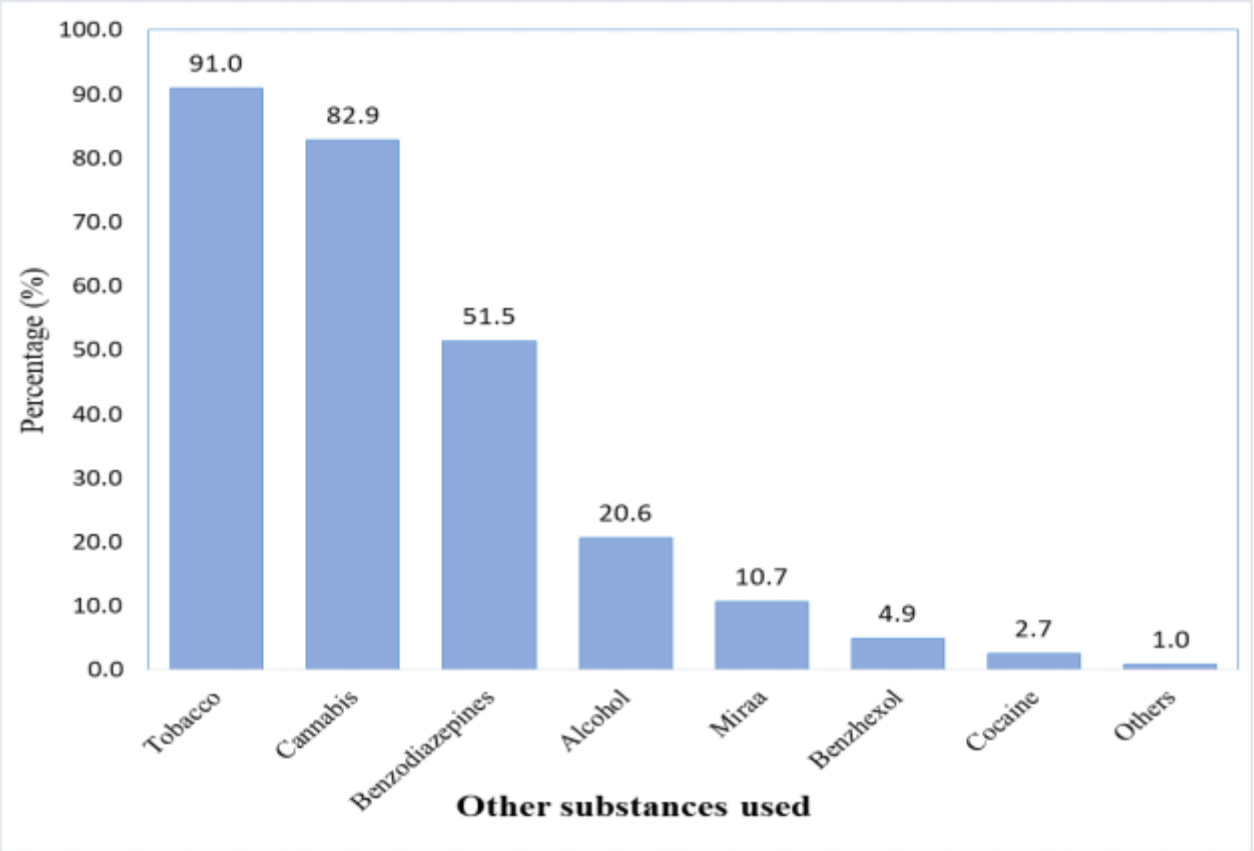
4.3.1.5 Severity of use of heroin

The severity of heroin use disorder was determined using the Diagnostic Statistical Manual of Mental Disorders 5 diagnostic criteria. Almost all the patients had severe heroin use disorder 712(99.9%), only 1(0.1%) patient had moderate heroin use disorder. None had mild heroin use disorder.

4.3.2 Other substances use at induction

All the participants used at least one other substance apart from heroin. The commonest substances used were tobacco 649(91.0%), cannabis 591(82.9%) and benzodiazepines 367(51.5%) as shown in Figure 7. The benzodiazepines commonly used were diazepam,clonazepam and flunitrazepam. Others in figure 7 included barbiturates, glue, and chlorpromazine.

Figure 7: Other substances use at induction



4.3.3 Number of other substances per participant

Regarding the total number of substances used per participant apart from heroin, the majority were using three 248(34.8%), followed by two 245(34.4%) and four 97(13.6%) as shown below in Table 2.

Table 2: Number of other substances used per participant

	Frequency (N)	Percent (%)
Number of substances		
0	1	0.1
1	88	12.2
2	245	34.4
3	248	34.8
4	97	13.6
5	29	4.1
6	5	0.7
7	1	0.1
	Total	.713	100.0

4.4 Association between sociodemographic characteristics & other substance use

4.4.1 Association between sociodemographic characteristics and Tobacco use

During bivariate analysis between the sociodemographic characteristics of the participants who were all using heroin in association with tobacco use, the researcher found a significant association with gender, housing, and legal status. Upon further multivariate logistic regression analysis, gender and legal status were significant. Males were two times more likely to use tobacco compared to females (aOR 2.008, 95% CI 1.077-3.744, P-value 0.028). Participants with a positive legal history were three times more likely to use tobacco than those with a negative history (aOR 3.234, 95% CI 1.847-5.660, P-value <0.001). These results are shown in tables 3 and 4 below.

Table 3: Association between sociodemographic characteristics and Tobacco use

Variable	Category	Use of heroin with tobacco		χ^2	df	P-value
		Yes	No			
Gender	Male	564(92.33%)	47(7.67%)	8.616	1	***0.003***
	Female	85(83.33%)	17(16.67%)			
Age groups (yrs)	≤20	17(89.47%)	2(10.53%)	4.865	6	0.561
	21 to 30	202(88.98%	25(11.02%)			
	31 to 40	286(92.26%)	24(7.74%)			
	41 to 50	115(89.84%)	13(10.16%)			
	51 to 60	25(100%)	0			
	61 to 70	3(100%)	0			
	> 70	1(100%)	0			
Level of education	None	15(100%)	0	5.916	3	0.116
	Primary		23(6.91%)			
	Secondary	256(88.28%)	34(11.72%)			
	Tertiary	68(90.67%)	7(9.33%)			
Marital status	Separated	295(91.61%)	27(8.39%)	1.195	3	0.754
	Widowed	11(91.67%)	)			
Occupation	Self employed	96(95.74%)	4(4.26%)	3.833	2	0.147
	Employed					
Housing status	Homeless	114(95.0%)	6(5.0%)	15.057	5	***0.010***
	Own house	3(75.0%)	1(25.0%)	21.877	***1***	***<0.001***
	Unstable	178(90.82%)	18(9.18%)			
Legal history	≤10	5(100%)	0	2.096	5	0.836
Age at first use of heroin (yrs)	11 to 20	292(90.04%)	31(9.60%)			
	21 to 30	30790.83%)	31(9.17%)			
	31 to 40	39(95.12%)	2(4.88%)			
	41 to 50	4(100%)	0			
	> 50	2(100%)	0			
Duration of heroin use (yrs)	≤10	327(90.83%)	33(9.17%)	1.266	3	0.737
	11 to 20	236(90.42%)	25(9.58%)			
	21 to 30	78(92.86%)	6(7.14%)			
	31 to 40	8(100%)	0			

Table 4: Multivariate logistic regression analysis of Tobacco use

Variable	Category	aOR	95% C.I.		P-value
			Lower	Upper	
Housing status	Homeless	2.301	0.868	6.100	0.094
	Friends	0.788	0.369	1.680	0.537
	Relatives	0.749	0.305	1.842	0.530
	Rental	2.057	0.966	4.381	0.061
	Own house	0.479	0.045	5.152	0.544
	Unstable	*Ref*			
Legal history	Yes	3.234	1.847	5.660	**<0.001**
	No	*Ref*			
Gender	Male	2.008	1.077	3.744	***0.028***
	Female	*Ref*			

4.4.2 Association between sociodemographic characteristics and Cannabis use

There was a significant association between cannabis use and age (p=0.031), age at first use of heroin (p=0.034), and duration of heroin use (p= 0.030). However, at the multivariate level, there was no association between sociodemographic characteristics and cannabis use. These results are shown below in Table 5 and 6.

Table 5: Association between sociodemographic characteristics and Cannabis use

Variable	Category	Use of heroin with cannabis		χ^2	df	P-value
		Yes	No			
Gender	Male	508(83.1%)	103(16.9%)	0.193	1	.660
	Female	83 (81.4%)	19(18.6%)			
Age groups (yrs)	≤20	16(84.2%)	3(15.8%)	13.903	6	**0.031**
	21 to 30	197(86.8%)	30(13.2%)			
	31 to 40	259(83.5%)	51(16.5%)			
	41 to 50	100(78.1%)	28(21.9%)			
	51 to 60	17(68.0%)	8(32.0%)			
	61 to 70	2(66.7%)	1(33.3%)			
Level of education	None	14(93.3%)	1(6.7%)	1.956	3	.582
	Primary		56(16.8%)			
	Secondary	236(81.4%)	54(18.6%)			
	Tertiary	64(85.3%)	11(14.7%)			
Marital status	Separated	262(81.4%)	60(18.6%)	1.502	3	.682
	Widowed	11(91.7%)	1(8.3%)			
	Self employed					
Occupation	Employed					
	Homeless	102(85.0%)	18(15.0%)	1.110	2	0.574
Housing status	Own house	4(100.0%)	0(.0%)	2.286	5	.808
	Unstable	159(81.1%)	37(18.9%)			
Legal history	≤10	5(100.0%)	0(.0%)	1.894	1	.169
Age at first use of heroin (yrs)	11 to 20	270(83.6%)	53(16.4%)	12.045	5	**0.034**
	21 to 30	277(82.0%)	61(18.0%)			
	31 to 40	35(85.4%)	6(14.6%)			
	41 to 50	4(100.0%)	0(.0%)			
Duration of heroin use (yrs)	≤10	312(86.7%)	48(13.3%)	8.950	3	**0.030**
	11 to 20	208(79.7%)	53(20.3%)			
	21 to 30	66(78.6%)	18(21.4%)			
	31 to 40	5(62.5%)	3(37.5%)			

Table 6: Multivariate logistic regression analysis of cannabis use

Variables	aOR	95% C.I.		P-value
		Lower	Upper	
Age (yrs)	1.055	0.937	1.187	0.380
Age at 1st use of heroin (yrs)	0.924	0.820	1.041	0.196
Duration of use (yrs)	0.915	0.813	1.030	0.141

4.4.3 Association between sociodemographic characteristics and Benzodiazepine use

There was a significant association between age at first use of heroin and benzodiazepines use at bivariate analysis (Table 7). Upon multivariate analysis, there was still a significant association between age at first use of heroin and benzodiazepines use with adjusted Odds ratio of 0.955 (95% C.I 0.931-0.98, p <0.001). This means for every unit increase in age there was a 4.5% reduction in benzodiazepine use.

Table 7: Association between sociodemographic characteristics and Benzodiazepines use

Variable	Category	Use of heroin with benzodiazepines		χ^2	Df	P-value
		No	Yes			
Gender	Male	294(48.12%)	317(51.88%)	0.287	1	0.592
	Female					
Age groups (yrs)	≤20	11(57.89%)	8(42.11%)	9.486	6	0.148
	21 to 30	100(44.05%)	127(55.95%)			
	31 to 40	151(48.71%)	159(51.29%)			
	41 to 50	63(49.22%)	65(50.78%)			
	51 to 60	18(72.0%)	7(28.0%)			
	61 to 70	2(66.67%)	1(33.33%)			
	> 70	1(100%)	0			
Level of education	None	7(46.67%)	8(53.33%)	1.785	3	0.618
	Primary	165(49.55%)	168(50.45%)			
	Secondary	143(49.31%)	147(50.69%)			
	Tertiary	31(41.33%)	4458.67%)			
Marital status	Single	99(44.0%)	126(56.0%)	6.565	3	0.087
	Married	88(57.14%)				
Occupation	Unemployed	88(45.13%)	107(54.87%)	1.276	2	0.528
	Self-employed	46(48.94%)				
Housing status	Homeless	62(51.67%)	58(48.33%)	7.946	5	0.159
	Friends	43(41.35%)	61(58.65%)			
	Relatives	25(45.45%)	30(54.55%)			
	Rental	126(53.85%)	108(46.15%			
	Own house	3(75.0%)	) 1(25.0%)			
	Unstable	87(44.39%)				
Legal history	Yes	224(48.91%)	234(51.09%)	0.074	1	0.785
	No					
Age at first use of heroin (yrs)	≤10	1(20.0%)	4(25.5%)	12.190	5	***0.032****
	11 to 20	139(43.03%)	184(56.97%)			
	21 to 30	181(53.55%)	157(46.45%)			
	31 to 40	20(48.78%)	21(51.22%)			
	41 to 50	3(75.0%)	1(25.5%)			
	> 50	2(100%)	0			
Duration of heroin use (yrs)	≤10	177(49.17%)	183(50.83%)	2.351	3	0.503
	11 to 20	129(49.43%)	132(50.57%)			
	21 to 30	35(41.67%)	49(58.33%)			
	31 to 40	5(62.5%)	3(37.5%)			

Logistic regression benzodiazepines

		95% C.I.)		Pvalue
	aOR	Lower	Upper	
Age at 1st use of heroin (yrs)	0.955	0.931	0.980	0.001

4.4.4 Association between sociodemographic characteristics and Alcohol use.

There was no significant association between the sociodemographic characteristics of the participants and alcohol use as shown below in Table 8.

Table 8: Association between sociodemographic characteristics and Alcohol use

	Category	Use of alcohol		χ^2	df	P-value
		No				
Variable	Male	490(80.2%)	121(19.8%)	1.727	1	0.189
Gender	≤20	16(84.21%)	3(15.79%)	5.776	6	0.449
Age groups (yrs)						
	21 to 30	186(81.94%)	41(18.06%)			
	31 to 40	247(79.68%)	63(20.32%)			
	41 to 50	93(72.66%)	35(27.34%)			
	51 to 60	20(80.0%)	5(20.0%)			
	61 to 70	3(100%)	0			
	None	15(100.0%)	0	5.347	3	0.148
	> 70	1(100%)	0			
Level of education						
	Primary	262(78.68%)	71(21.32%)			
	Secondary	226(77.93%)	64(22.07%)	1.000	3	0.801
	Tertiary	63(84.0%)	12(16.0%)			
Marital status	Separated	251(77.95%)	71(22.05%)			
	Widowed	9(75.0%)	3(25.0%)			
	Unemployed	159(81.54%)	36(18.46%)	1.943	2	0.378
	Self-employed	70(74.47%)	24(25.53%)			
Occupation	Employed		87(20.52%)			
	Homeless	96(80.0%)	24(20.0%)	3.228	5	0.665
	Friends	87(83.65%)	17(16.35%)			
Housing status						
	Relatives	44(80.0%)	11(20.0%)			
	Rental	185(79.06%)	49(20.94%)			
	Own house	4(100%)	0	0.438	1	0.508
	Unstable	150(76.53%)	46(23.47%)			
Legal history	≤10	4(80.0%)	1(20.0%)	5.793	5	0.327
	11 to 20					
Age at first use of heroin (yrs)						
	21 to 30	276(81.66%)	62(18.34%)			
	31 to 40	29(70.73%)	12(29.27%)			
	41 to 50	2(50.0%)	2(50.0%)			
	≤10	286(79.44%)	74(20.56%)	1.421	3	0.701
	> 50	2(100%)	0			
	11 to 20	214(80.84%)	50(19.16%)			
Duration of heroin use (yrs)	21 to 30	63(75.0%)	21(25.0%)			
	31 to 40	6(75.0%)	2(25.0%)			

4.4.5 Association between sociodemographic characteristics and Miraa use.

There was a significant association between miraa use and gender and legal status of the participants at bivariate analysis. During multivariate analysis, there was still a significant association between gender and legal status. Gender had aOR of 0.487 (95% C.I 0.274-0.866, p= 0.014). This means there was a 51.3% chance for males to use miraa compared to women. Those who had positive legal history had aOR of 0.487 (95% C.I 0.302-0.786, p= 0.003). This means there was a 51.3% chance for those who had positive legal history compared to those without miraa use. These results are shown below in tables 9 and 10.

Table 9: Association between sociodemographic characteristics and Miraa use

Variable	Category	Use of miraa No		χ^2	df	P-value
Gender	Male	554(90.67%)	57(9.33%)	7.936	1	***0.005****
	Female	83(81.37%)	19(18.63%)			
Age groups (yrs)	≤20	18(94.74%)	1(5.26%)	3.431	6	0.753
	21 to 30	198(87.22%)	29(12.78%)			
	31 to 40	276(89.03%)	34(10.97%)			
	41 to 50	118(92.19%)	10(10.97%)			
	51 to 60	23(92.0%)	2(8.0%)			
	61 to 70	3(100%)	0			
Level of education	None	14(93.33%)	1(6.67%)	3.443	3	0.328
	Primary	296(88.89%)	37(11.11%)			
	Secondary	264(91.03%)	26(8.97%)			
	Tertiary	63(84.0%)	12(16.0%)			
Marital status	Separated	294(91.3%)	28(8.7%)	6.591	3	0.086
	Widowed	9(75.0%)	3(25.0%)			
	Self employed	81(88.04%)	11(11.96%)			
	Employed	140(96.91%)	4(3.09%)			
Occupation	Homeless	108(90.0%)	12(10.0%)	2.137	5	0.830
	Friends	91(87.5%)	13(12.5%)			
	Relatives	49(89.09%	6(10.91%)			
	Rental	206(88.03%)	28(11.97%)			
	Own house	4(100%)	0	8.955	1	***0.003****
	Unstable	179(91.33%)	17(8.67%)			
Housing status	≤10	5(100%)	0	5.785	5	0.328
	11 to 20	282(87.31%)	41(12.69%)			
	21 to 30	310(91.72%)	28(8.28%)			
	31 to 40	35(85.37%)	6(14.63%)			
	41 to 50	3(75.0%)	1(25.0%)			
	> 50	2(100%)	0			
Legal history	≤10	318(88.33%)	42(11.67%)	1.585	3	0.663
	11 to 20	235(90.04%)				
	21 to 30	76(90.48%)	8(9.52%)			
	31 to 40	8(100.0%)	0			
Age at first use of heroin (yrs)						
Duration of heroin use (yrs)						

Table 10: Multivariate logistic regression analysis of miraa use

			95% C.I.		p-value
Variable		**aOR**	Lower	Upper	
Gender	Male	0.487	0.274	0.866	***0.014***
	Female	Ref			
Legal history	Yes	0.487	0.302	0.786	***0.003***
	No	Ref.			

4.4.6 Association between sociodemographic characteristics and Benzhexol use.

There was a significant association between occupation and benzhexol use at bivariate analysis (Table 11). Upon multivariate analysis, there was a significant association between the unemployed and benzhexol use. The aOR was 2.14, 95% C. I 1.057-4.331 and a P-value of 0.034 (Table 12). This means those who were unemployed were 2.14 times more likely to use benzhexol than the self-employed and employed.

Table 11: Association between sociodemographic characteristics and Benzhexol use

Variable	Category	Use of benzhexol		χ^2	df	P-value
		No				
Gender	Male	578(94.6%)	33(5.4%)	2.216	1	0.137
Age groups (yrs)	≤20	19(100%)	0	2.823	6	0.831
	21 to 30	213(93.83%)	14(6.17%)			
	31 to 40	297(95.81%)	13(4.19%)			
	41 to 50	122(95.31%)	6(4.69%)			
	51 to 60	2392.0%)	2(8.0%)			
	61 to 70	3(100%)	0			
Level of education	None	14(93.33%)	1(6.67%)	2.372	3	0.499
	[illegible]	315(94.59%)	18(5.41%)			
	Secondary	275(94.83%)	15(5.17%)			
	Tertiary	74(98.67%)	19(1.33%)			
Marital status	Married	[illegible]	[illegible]	3.724	3	0.293
	Separated	301(93.48%)	21(6.52%)			
	Widowed	12(100%)	0			
Occupation	Self employed	[illegible]		6.831	2	***0.033****
Housing status	Homeless	113(94.17%)	7(5.83%)	6.301	5	0.278
	Friends	97(93.27%)	7(6.73%)			
	Relatives	52(94.55%)	3(5.45%)			
	Rental	229(97.86%)	5(2.14%)			
	Own house	4(100%)	0			
	[illegible]	[illegible]	[illegible]	0.301	1	0.583
	Unstable	183(93.37%)	13(6.63%)			
Legal history	≤10	5(100%)	0	1.650	5	0.895
Age at first use of heroin (yrs)	11 to 20	304(94.12%)	19(5.88%)			
	21 to 30	324(95.86%)	14(4.14%)			
	31 to 40	39(95.12%)	2(4.88%)			
	41 to 50	4(100%)	0			
	> 50	2(100%)	0			
Duration of heroin use (yrs)	≤10	34495.56%)	16(4.44%)	1.480	3	0.687
	11 to 20	248(95.02%)	13(4.98%)			
	21 to 30	78(92.86%)	6(7.14%)			
	31 to 40	8(100%)	0			

Table 12: Multivariate logistic regression analysis for Benzhexol use

			95% C.I.		P-value
Variable		**aOR**	**Lower**	**Upper**	
Occupation	Unemployed	2.140	1.057	4.331	***0.034***
	Self-employed	0.520	0.118	2.292	0.388
	Employed	Ref.			

4.4.7 Association between sociodemographic characteristics and Cocaine use

There was no significant association between the sociodemographic characteristics of the participants and cocaine use as shown in Table 13 below.

Table 13: Association between sociodemographic characteristics and Cocaine use

Variable	Category	Use of cocaine		χ^2	df	P-value
		No				
Gender	Male	596(97.55%)	15(2.45%)	0.725	1	0.395
Age groups (yrs)	≤20	19(100%)	0	6.045	6	0.418
	21 to 30					
	31 to 40	297(95.81%)	13(4.19%)			
	41 to 50	127(99.22%)	1(0.78%)			
	51 to 60	25(100%)	0			
	61 to 70	3(100%)	0		3	0.303
	> 70	1(100%)	0			
Level of education	None			15(100%)	0	3.641
	Primary	327(98.2%)	6(1.8%)			
	Secondary	281(96.9%)	9(3.1%)		3	0.202
	Tertiary	71(94.67%)	4(5.33%			
Marital status	Single			215(95.56%)	10(4.44%)	4.614
	Married	150(97.4%)	4(2.6%)			
	Separated	317(98.45%)	5(1.55%)	1.915	2	0.384
	Widowed	12(100%)	0			
Occupation						
Housing status	Homeless	118(98.33%)	2(1.67%)	.918	5	0.969
	Employed	412997.17%)	12(2.83%)			
	Friends					
	Relatives	53(96.36%)				
	Own house	4(100%)	0			
	Unstable	190(96.94%)	6(3.06%)	) .149	1	0.700
	NO	249(97.65%)				
Legal history					5	0.818
Age at first use of heroin (yrs)	11 to 20	312(96.59%)	11(3.41%)			
	21 to 30	330(97.65%)	8(2.37%)			
	≤10			5(100%)	0	2.223
	31 to 40	41(100%)	0			
	41 to 50	4(100%)	0			
Duration of heroin use (yrs)	≤10	354(98.33%)	6(1.67%)	4.045	3	0.257
	> 50	2(100%)	0			
	11 to 20	250(95.79%)	11(4.21%)			
	21 to 30	82(97.62%)	2(2.38%)			
	31 to 40	8(100%)	0			

4.5 Heroin abstinence rates

At the sixth month while in the MAT program, among the 437 participants who had a urine drug screen (UDS) done, a majority had abstained from heroin 268(61.3%) while 169(38.7%) were still using heroin. At the twelfth month, among the 387 participants who had a UDS done majority had abstained from heroin 294(76.0%) while 93(24.0%) were still using heroin. At eighteen months, among the 321 participants who had a UDS done majority had abstained from heroin 236(73.5%) while 85(26.5%) were still using heroin. At twenty-fourth, among the 354 participants who had a UDS done, a majority had abstained from heroin 288(81.4%) while 66(18.6%) were still using heroin. The abstinence rate increased from 61.3% at 6 months to 81.4% at 24 months, this was statistically significant ($p<0.001$). These results are shown in Figure 8 below. These abstinence rates were found to be statistically significant as shown in Table 14 below.

Figure 8: Heroin abstinence rates

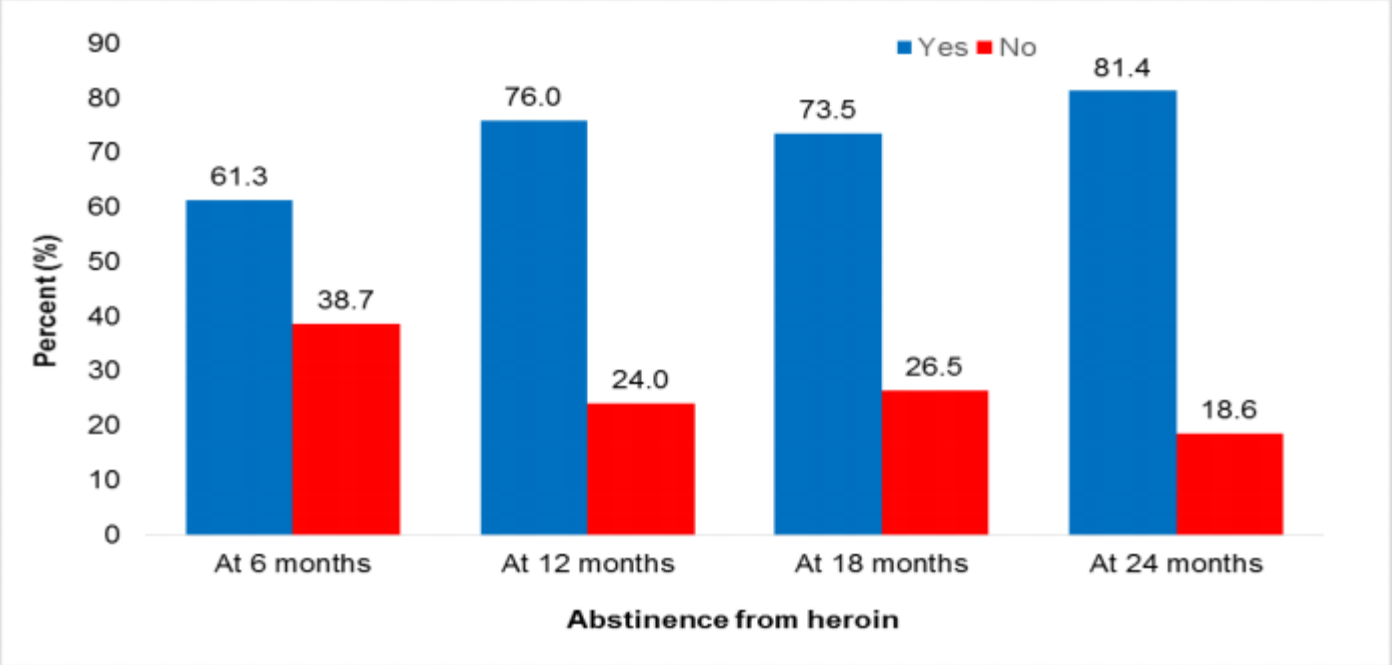


Table 14: Abstinence rates at 6, 12, 18, and 24 months

	Heroin abstinence		**Chi-Square**	**df**	**P-value.**
	Yes	***No***			
6 Months	268(61.33%)	169(38.67%)	22.428	1	**<0.001**
12 Months	294(75.97%)	93(24.03%)	104.395	1	**<0.001**
18 Months	236(73.52%)	85(26.48%)	71.031	1	**<0.001**
24 months	288(81.36%)	66(18.64%)	139.22	1	**<0.001**

4.5.1 Association between heroin use characteristics, number of other substances used and heroin abstinence rate at 6 months

There was a statistically significant association between the number of use of other substances and heroin abstinence rate at 6 months at bivariate analysis (p=0.03). However, at multivariate analysis, there was no association as shown below in Tables 15 and 16.

Table 15: Association between heroin use characteristics and heroin abstinence rate at 6 months

Variable	Abstinence	N	Mean±SD	P-value
Age (yrs)	No	169	34.0±9.1	0.452
	Yes	268	35.0±8.7	
Age at 1st use of heroin (yrs)	No	169	22.3±6.1	0.889
	Yes	268	22.4±6.7	
Duration of use (yrs)	No	169	11.5±7.2	0.718
	Yes	268	12.6±7.2	
Number of substances	No	169	2.6±1.1	***0.030***
	Yes	268	2.7±1.0	

Table 16: Logistic regression analysis of heroin abstinence rate at 6 months

	aOR	95% C.I.		
		Lower	Upper	P-value
Number of substances	1.140	0.944	1.375	0.173

4.5.2 Association between heroin use characteristics, number of other substances used and heroin abstinence rate at 12 months

There was a significant association between the duration of use of heroin before enrolment with heroin abstinence rates at 12 months (Table 17). Further logistic regression analysis showed still a significant association between duration of use of heroin and heroin abstinence rates (Table 18). The adjusted odds ratio was 0.965 (95% C.I 0.932-0.998, P-value 0.037). This means with every unit increase in the duration of use there is a 3.5% chance of heroin abstinence.

Table 17: Association between heroin use characteristics and heroin abstinence rate at 12 months

Variable	Abstinence	N	Mean±SD	P-value
Age (yrs)	No	93	35.6±8.6	0.765
	Yes	294	32.3±8.3	
Age at 1st use of heroin (yrs)	No	93	23.0±6.8	0.795
	Yes	294	21.2±6.2	
Duration of use (yrs)	No	93	12.5±7.4	***0.047***
	Yes	294	10.1±5.6	
Number of substances	No	93	2.7±1.0	0.506
	Yes	294	2.6±1.1	

Table 18: Logistic regression analysis of heroin abstinence rate at 12 months

	aOR	**95% C.I.**		P-value
		Lower	Upper	
Duration of heroin use (yrs)	0.965	0.932	0.998	***0.037***

4.5.3 Association between heroin use characteristics, number of other substances used and heroin abstinence rate at 18 months

There was a statistically significant association between duration of use of heroin and heroin abstinence rates at 18 months (Table 19). The aOR was 0.946, 95% C.I 0.913-0.980 and P-value 0.002 (Table 20). This means for every unit increase in the duration of use there was a 5.4% chance of heroin abstinence.

Table 19: Association between heroin use characteristics and heroin abstinence rate at 18 months

Variable	Abstinence	N	Mean±SD	P-value
Age (yrs)	Yes	236	36.0±8.8	0.422
	No	85	32.6±8.1	
Age at 1st use of heroin (yrs)	Yes	236	22.8±6.5	0.765
	No	85	21.9±5.5	
Duration of use (yrs)	Yes	236	13.2±7.8	***0.020***
	No	85	10.2±6.4	
Number of substances	Yes	236	2.6±1.1	0.714
	No	85	2.7±1.2	

Table 20: Logistic regression analysis of heroin abstinence rate at 18 months

	aOR	95% C.I.		Pvalue
		Lower	Upper	
Duration of heroin use (yrs)	0.946	0.913	0.980	***0.002***

4.5.4 Association between heroin use characteristics, number of other substances used and heroin abstinence rate at 24 months

There was a statistically significant association of duration of heroin use and heroin abstinence rate at 24 months at both bivariate analysis and logistic regression analysis. The aOR was 0.952, 95% C.I 0.914-0.992 and P value of 0.018. This means for every unit increase in the duration of heroin use, there was a 4.8% chance of heroin abstinence. These results are shown below in tables 21 and 22.

Table 21: Association between heroin use characteristics and heroin abstinence rate at 24 months

Variable	Abstinence	N	Mean±SD	P value
Age (yrs)	Yes	288	35.5±8.6	0.300
	No	66	31.7±7.3	
Age at 1st use of heroin (yrs)	Yes	288	22.9±6.6	0.267
	No	66	21.3±5.1	
Duration of use (yrs)	Yes	288	12.6±7.4	***0.006***
	No	66	10.2±5.6	
Number of substances	Yes	288	2.6±1.0	0.323
	No	66	2.7±1.2	
Maximum dose of methadone	Yes	288	129.1±37.7	0.787
	No	66	126.8±39.5	

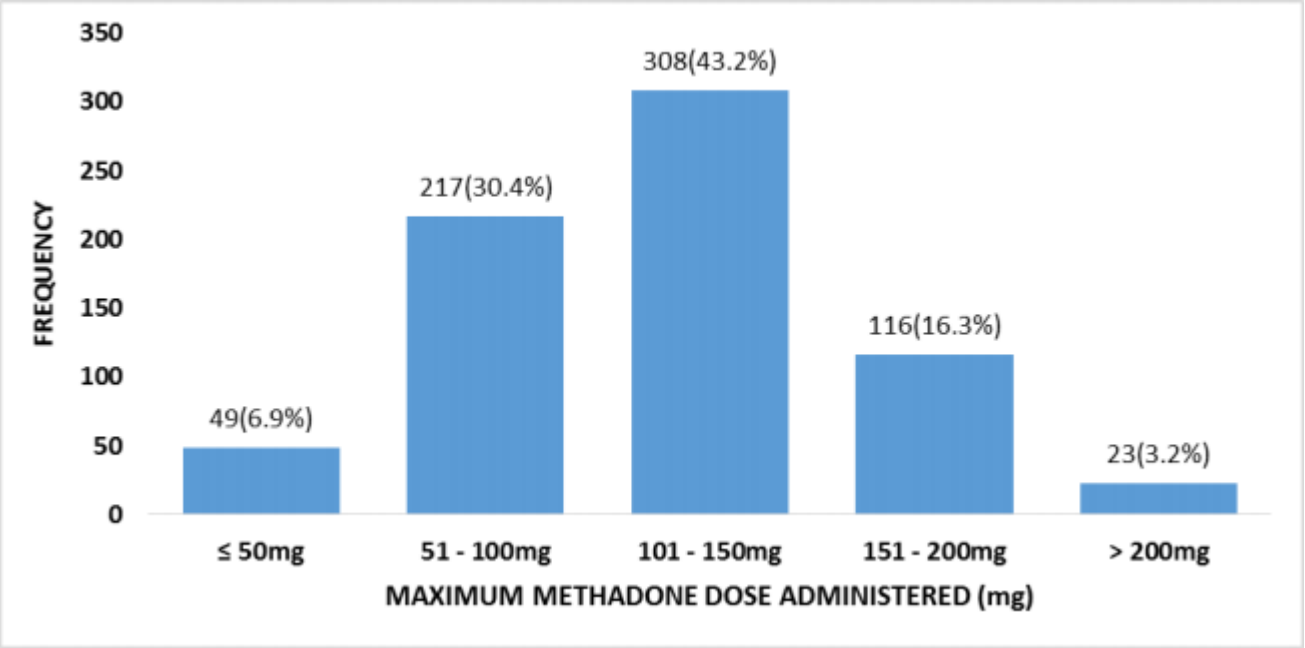
Table 22: Logistic regression analysis of heroin abstinence rate at 24 months

	aOR	95% C.I.		
		Lower	Upper	P value
Duration of heroin use (yrs)	0.952	0.914	0.992	***0.018***

4.6 Maximum methadone dose

The mean maximum methadone dose administered to the participants while in the program was 118.24mg (standard deviation 43.36mg, range 10mg - 240mg). Majority 308(43.2%) of the participants received 101-150mgs, followed by 51-100mgs in 217(30.4%) as shown in Figure 9 below.

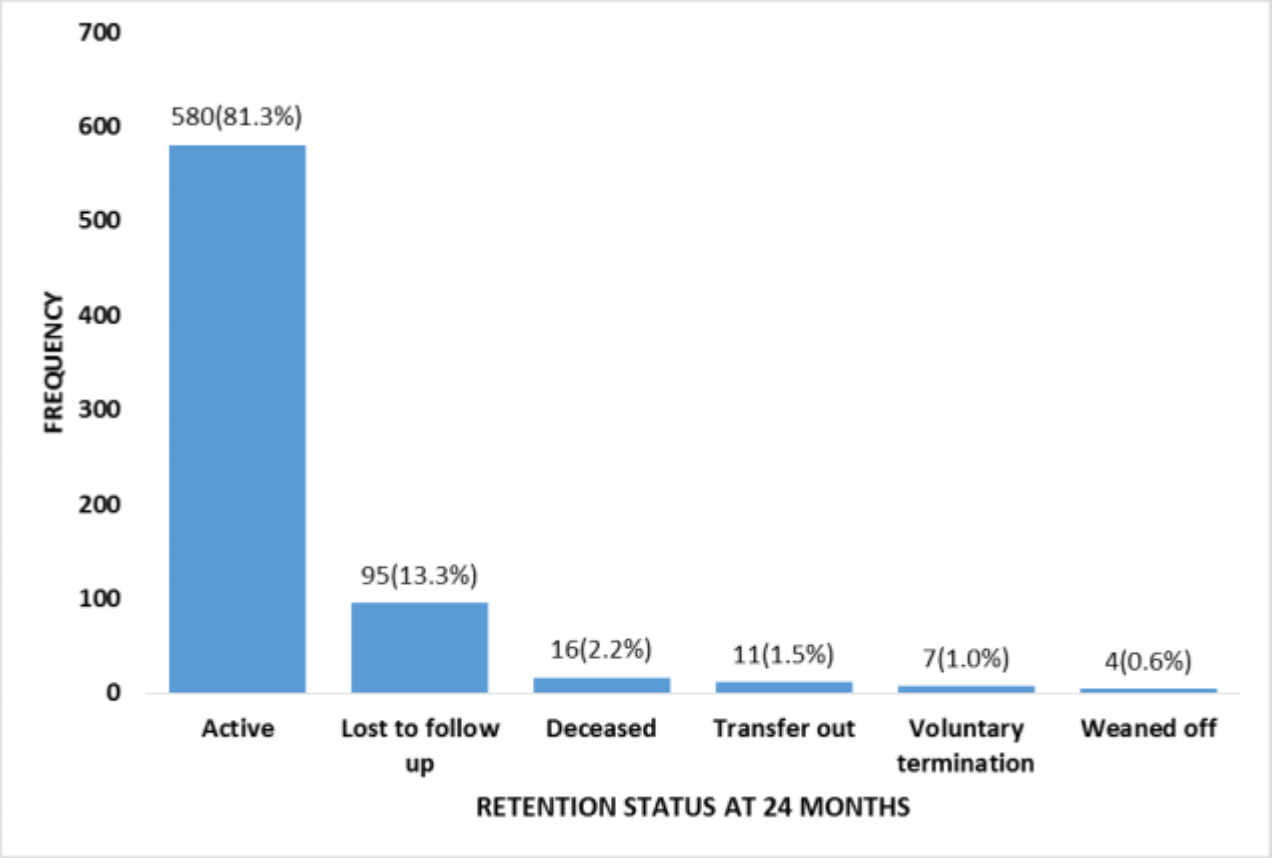
Figure 9: Maximum dose of methadone administered



4.7 Retention status at 24 months since induction into MAT

At 24 months of being in the program, only 4(0.6%) of the patients were successfully weaned off methadone having undergone successfully the four stages of induction, stabilization, maintenance and cessation. The rest, those who were still active were 580(81.3%), lost to follow up 95(13.3%), deceased 16(2.2%) as shown in Figure 10.

Figure 10: Retention status at 24 months since induction into MAT



CHAPTER 5

5.0 DISCUSSION

5.1 Sociodemographic characteristics

This study found the mean age of the participants was 34.22 years (SD 8.55). This was comparable with other studies which have also shown that most participants were around 30-40 years. A cross-sectional study done in three private MMT facilities in Vietnam found the mean age of the participants was 40 years (SD 8.9)(Anh Le et al., 2019). Another cross-sectional study done in private MMT clinics in the North, Center and South regions in the city of Iran found the mean age of 40.5 years (SD 11.5)(Shekarchizadeh et al., 2012). A comparative retrospective study done in Sultan Bahu Rehabilitation Centre in Cape Town South Africa found a mean age of 28.5 years (SD 6.5)(Michie et al., 2017). A retrospective study done at Mihimbili National Hospital in Tanzania found a mean age of 32 years (SD 6)(Lambdin et al., 2014). All these studies done in different geographical locations with different study designs have common findings. This is a worrying trend as this age group is expected to be the most productive in society but they are using their time, energy and resources in using substances.

Most of the participants in this study were males 611(85.7%). This finding is consistent with most findings of other studies. A cross-sectional study done in private MMT clinics in the North, Center and South regions in the city of Iran found 95 % of the participants were males (Shekarchizadeh et al., 2012). A within-group experimental study conducted in The Tengku Ampuan Afzan Hospital in Malaysia found 97.2% were males(Musa et al., 2012). A comparative retrospective study done in Sultan Bahu Rehabilitation Centre in Cape Town South Africa found 91.1% were males (Michie et al., 2017). A retrospective study done at Mihimbili National Hospital in Tanzania found 93% were males(Lambdin et al., 2014). All these studies showed males were more than females. The reasons could be that culturally males are less condemned than women when they use substances. Women are vulnerable, those using

substances might have undergone trauma, domestic violence or are suffering from depression, hence this needs to be explored further.

In terms of marital status, this study found a majority of the participants were separated 322(45/1%). Similar studies showed mixed results. A cross-sectional study done in three private MMT facilities in Vietnam found more than two-thirds of the participants lived with a spouse/partner(Le et al., 2019). A cross sectional study done in private MMT clinics in the North, Center and South regions in the city of Iran found 70% were married (Shekarchizadeh et al., 2012). A within-group experimental study conducted in The Tengku Ampuan Afzan Hospital in Malaysia found 67.3% were single (Musa et al., 2012). A comparative retrospective study done in Sultan Bahu Rehabilitation Centre in Cape Town South Africa found 74.8% were single (Michie et al., 2017). The results in this study could be possibly due to the negative impacts of substance use disorders which causes disintegration of the family unit. The different results in other studies could be due to differences in culture and impairments in interpersonal relationships.

5.2 Other substance use

This study found that all the participants using heroin at induction were also using at least one other substance. The commonest other substance used was tobacco 649(91.0%), followed by cannabis 591(82.9%), benzodiazepines 367(51.5%), alcohol 147(20.6%), miraa 76(10.7%), benzhexol 35(4.9%), cocaine 19(2.7%) and others (barbiturates, glue and chlorpromazine) 7(1.0%). Other similar studies have shown mixed results.

Studies that have shown comparable findings to this study include a 36 months prospective cohort study done at 19 agencies treating heroin-dependent patients in Australia which showed most participants at baseline used tobacco 96% followed by cannabis 69%, alcohol 51% and benzodiazepines 50% (Darke et al., 2007). A cross sectional study done in three private MMT facilities in Vietnam found most participants were using tobacco 81%, followed by alcohol 54%, and others 6% (Anh Le et al., 2019). These studies showed the most commonly used

other substance by MMT patients was tobacco. There is evidence that nicotine binds nicotinic acetylcholine receptors in the central nervous system and stimulates realise of dopamine in the nucleus accumbens potentiating the euphoria that heroin causes. Nicotine has also been found to relieve the withdrawal symptoms of heroin including irritability, restlessness and depression. Cannabis and tobacco are also regarded as gateway drugs into heroin use with patients continuing to use even after having started using heroin.

Most of the other similar studies have shown different findings from this study. A retrospective study done at Helsinki University Central Hospital in Finland found that the commonest substances to be benzodiazepines 48%, followed by amphetamines 42%, cannabis 30%, non-prescribed psychotropic drugs 25% and new psychoactive medications 8%(Heikman et al., 2017). This could be due to differences in geographical location, socioeconomic status and accessibility to the drugs. A retrospective study done among patients at 26 MMT facilities in various states in the USA found most participants used benzodiazepines 26.4%, followed by cannabinoids 20.7%, cocaine 10.8%, amphetamines 9.1 %, alcohol and barbiturates were <2.0% (Proctor et al., 2016). The difference could be the study was conducted at multiple facilities whereas this study was only at one facility. Also there could be preferential differences among the participants in the studies and differences in accessibility of the drugs. A cross sectional study done in private MMT clinics in the North, Center and South regions in the city of Iran found that the commonest substance was cannabis 16%, followed by amphetamines 15% and others 33% (Shekarchizadeh et al., 2012). The difference could be due to study designs, the study was a cross sectional study while this was a retrospective study. Also the study was done in private MMT clinics while this study was done in a public MAT clinic hence there could be socio-economic differences that influence choices of substance use. A comparative retrospective study done in Sultan Bahu Rehabilitation Centre in Cape Town South Africa found the commonest substance used at baseline was methamphetamine 48.6%,

followed by cannabis 5.4%, methamphetamine + any other 41.9%, cannabis + any other 33.8%, any two drugs 25.7% and any three drugs 17.6% (Michie et al., 2017). This could be due to the difference in availability of the drugs in the two geographical locations. A retrospective study done at Mihimbili National Hospital in Tanzania found that 34% of the participants were also using alcohol, cocaine, benzodiazepine, and amphetamines, however, the study did not give a breakdown (Lambdin et al., 2014). The study and this study were done in countries which are neighbours that share a common transit route of drugs from Asia through the Indian Ocean, hence the patterns were expected to be similar, however, the study did not break down the percentages for each substance.

5.3 Abstinence rates among heroin users attending MAT

This study found the heroin abstinence rates at 6months, 12 months ,18 months and 24 months to be 268(61.3%), 294(76.0%), 236(73.5%) and 288(81.4%) respectively. Other similar studies done at different periods of the patients being in the program showed mixed results. A retrospective study done at 26 MMT facilities in various states in the USA found the heroin abstinence rate at 12 months was 89.8%. Proctor had done 4 intervals of UDS at 3months, 6 months, 9 months and 12 months. Across the 4 intervals categorized into 4, 3, 2 and 1 the heroin abstinent rate was 70.4%,16.4%,6.9% and 2.8% respectively (Proctor et al., 2016). The difference could be due to the study was done in 26 facilities while this study was done in one facility. Also, the study was done at a shorter duration of 12 months while this study was done over 24 months. The study was reported as comparisons of intervals while this study reported specific time points. A 36 months prospective cohort study done at 19 agencies treating heroin-dependent patients in Australia found the heroin abstinence rate at 36 months was 10% (Darke et al., 2007). The study was a prospective study whereas this study was a retrospective study. The study only took the participants put in four different groups and urine drug screens were done for all the participants at 12 months, 24 months and 36 months. However, it only reported

separately the group that was treated with methadone/buprenorphine at 36months only. The study also noted that the people who reported current abstinence at different follow up may not have been the same. The study also did hair sampling only at 3 months instead of UDS, subsequently it relied on self-report. In another within-group experimental study conducted by Musa et al., in 2012 in Malaysia the opioids abstinence rate at 12 months and 24 months was 97.6% and 98.6% respectively. A cross-sectional study done at MMT in Mwananyamala Hospital Dar es Salaam in Tanzania showed 125 out of the 126 participants were using opioids both prescription and non-prescription. 50% of all the participants had been in the MMT within 0-12 months, 23.81% within 13-15 months, 11.11% within 26-38 months, and 15.08% over 39 months (Ripanda et al., 2019). The study was a cross-sectional study while this was a retrospective study. In general, cross-sectional studies that use self-reported tools have been found that participants tend to minimize their substance use.

CHAPTER 6

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

In conclusion, this study found that all the patients attending the MAT program used at least one other drug apart from heroin during enrolment. The commonest drugs used were tobacco, cannabis, benzodiazepines and alcohol. Majority of the participants used at least three other drugs. Some of these drugs when combined in high doses can lead to severe central nervous system depression. This calls for the inclusion of free management of these other substances in the MAT program.

This study showed encouraging evidence for the use of methadone in the management of heroin use disorder. It has replicated the findings of other studies on the efficacy of methadone.

6.2 Recommendations

1. The Ministry of Health together with other stakeholders in the MAT program should scale up the provisions of the free services to include management of other substances commonly used by heroin users. This can include smoking cessation services, alcohol detoxification among others.
2. The Ministry of Health and the Ministry of Education in collaboration with other stakeholders to conduct community and school-based education programs targeting the school children and youths on the harmful effects of substances.
3. The health care workers in the MAT program to utilize software that identifies patients due for a UDS on a specific day on a random interval schedule.
4. The Ministry of health to increase the supply of UDS kits to facilitate better interventions and improve the quality of research conducted at the site.
5. Development of a standardized tool to collect data on heroin abstinence rates
6. Further prospective studies to assess other outcome measures such as relapse rates, mortality, criminality and generally patient's quality of life.

6.3 Strengths

1. This was a census study, therefore there was no selection bias.
2. As far as the literature search conducted, this is the first study in Kenya among the MAT patients, this will add to the global pool of literature and inform policy makers.

6.4 Limitations

1. This study was conducted in a hospital setting among a special category of patients (heroin users), therefore the results cannot be generalized to the general population.
2. The UDS being done at random time points in the course of the program and lack of UDS kits affected the abstinence rates results.
3. This being a retrospective cohort, some participants were lost to follow-up, others died, transferred out or terminated voluntarily.
4. Covid-19 pandemic limited the duration of the study to February 2020, because since March 2020 no UDS was being done

APPENDICES

Appendix 1: Socio-demographics form

Unique Identification Number: …….. **Age** (Years): ……

Sex: ○ Male ○ Female

Education level:

○ None ○ Primary ○ Secondary ○ Tertiary

Marital status:

○ Single ○ Married ○ Separated/ Divorced ○ Widowed

Occupational status:

○ Employed ○ Self-employed ○ Un-employed

Housing status:

○ Rental house ○ Own house ○ Homeless ○ Housed by relatives

Legal status:

○ No arrest history ○ Arrest history

Medical condition:

○ None ○ HIV ○ STI ○ Tuberculosis

○ Hepatitis B ○ Hepatitis C ○ Other ……

Appendix 2: Data collection form

Unique Identification Number ……. Age…… Sex……..

Age at first use ……..

Duration of use in years ……

Frequency of use in the last 30 days …….

Route of administration

○ Intravenous only ○ Smoking only ○ Snorting only

○ Intravenous +any other routes ○ Intravenous +smoking+ snorting

Degree of opioid use severity

○ Mild ○ Moderate ○ Severe

Substance use at induction

Substance	**Use**
Heroin	
Cannabis	
Tobacco	
Alcohol	
Cocaine	
Benzodiazepines	
Miraa	
Glue	
Barbiturates	
Phencyclidine	
Any other	

Random drug screens

Drug	At 6 months	At 12 months	At 18 months	At 24 months
Heroin				
Cannabis				
Tobacco				
Alcohol				
Cocaine				
Benzodiazepines				
Miraa				
Glue				
Barbiturates				
Phencyclidine				
Any other				

Maximum dose of Methadone