ACCESSIBILITY OF MEDICINES USED IN THE MANAGEMENT OF SUBSTANCE USE DISORDERS IN TWO HOSPITALS IN NAIROBI

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DEDICATION

I dedicate this thesis to my husband William for his unwavering support, and my lovely children Lyndsey and Kyle.

I also dedicate it to all who are suffering from substance use disorders and have not accessed treatment.

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I thank God almighty for this far I have come.

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Table of Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATONS AND ACRONYMS

ADH	Aldehyde dehydrogenase
AIDS	Acquired immune-deficiency syndrome
AWS	Alcohol withdrawal syndrome
CNS	Central nervous system
ERC	Ethics Review Committee
GABA	Gamma aminobutyric acid
HIV	Human immune-deficiency virus
IDU	Injection drug use
KEML 2010	Kenya Essential Medicines List 2010
KEMSA	Kenya Medical Supplies Agency
KNH	Kenyatta National Hospital
MOH	Ministry Of Health
NACADA	National Authority for the Campaign against Alcohol and Drug Abuse
NASCOP	National Aids and Sexually Transmitted Infections Control Program
NHIF	National Hospital Insurance Fund
NIDA	National institute on drug abuse
NMDA	N-methyl-d-aspartate
NRT	Nicotine replacement therapy
OOP	Out of Pocket Payments
PPB	Pharmacy and Poisons Board

SUD	Substance use disorder
UNODC	United Nations Office On Drugs and Crime
UON	University of Nairobi
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Addiction	Compulsive drug seeking and using behaviour
Dependence	An established syndrome of repetitive substance use with psychological, behavioural and cognitive components
Detoxification	The gradual removal of an abused substance from the body in a controlled environment
Mean stock-out period	Annual number of days on which a drug was not available in the pharmacy
Pharmacotherapy	Treatment of a disease using drugs
Substance use disorder	Disorder in which the use of one or more substances of abuse leads to clinically significant impairment or distress

ABSTRACT

Background

Substance use disorder (SUD) is a complex chronic disease that requires a multidisciplinary approach in treatment. Pharmacotherapy is one of the components in the treatment of this condition. Accessibility to treatment is a universal right and this study sought to assess the accessibility of medicines used in the treatment of substance use disorders in selected hospitals in Nairobi.

Objectives

The main objective of this study was to determine the accessibility of pharmaceutical commodities used in the treatment of patients with substance use disorders in selected hospitals in Nairobi.

Methods

This descriptive cross-sectional study with both qualitative and quantitative components was carried out in April and May 2015 at two hospitals in Nairobi, Mathari Mental hospital and Chiromo Lane Medical Centre, that provide pharmacotherapy. Data on availability and affordability was collected from the two sites and the World Health Organization performance indicators for health facilities were used to assess availability. Affordability was determined using the daily wage of the lowest paid government worker.

Key findings

About 50% of medicines on the Kenya Essential Medicines List (KEML 2010) for management of SUDs were available in Mathari while Chiromo Lane had all of them. The mean stock out duration was 8 months and 0.5 months in Mathari and Chiromo Lane, respectively. About 70% of the medicines required less than a single day's wage to buy a month's supply in Mathari while in Chiromo Lane all the medicines required more than a single day's wage to purchase. The cheapest medicine required 0.3 days wage to purchase while the most expensive required 50 days wage to purchase.

Conclusions

Medicines for the treatment of SUDs had limited availability but were relatively affordable in Mathari while their availability was better in Chiromo Lane but with limited affordability.

Key words: Substance Use Disorders, Pharmacotherapy, Availability, Affordability.

CHAPTER ONE: INTRODUCTION

1.1 Background

Addiction refers to compulsive drug seeking and using behaviour even in the face of terrible personal and social consequences. It is a result of changes in the brain's structure and function. Addiction is a brain disease that affects multiple brain circuits, including those involved in reward and motivation, learning and memory, and inhibitory control over behaviour. It is a chronic and complex, but treatable disease. Dependence is an adaptive state that occurs after repeated administration of a substance leading to substance use disorder (SUD). It is a chronic condition that is related to the dopamine reinforcement pathway as well as the endogenous opioid system. It develops on the basis of an interaction between several factors that include pharmacological properties of the drug, vulnerability of the person and the environmental influence [1]. However, more often than not, substance abuse is considered an individual's bad habit which can be dropped at will and not as an acquired health condition for which treatment is required. Patients with SUDs are regarded as social misfits or even criminals and do not receive the psychotherapy and pharmacotherapy required. Substance use disorders have not received the attention they deserve from the government and even insurance agencies. Substance abuse treatment has been segregated from the rest of the general healthcare either geographically, financially or both [2].

According to the global status report on alcohol and health 2014, harmful use of alcohol is responsible for 3.3 million deaths annually [3]. This accounts for 5.9% of all the deaths reported. Approximately 5.1 % of the global burden of disease is attributable to alcohol consumption. Heroin (an opioid) and cocaine kill about 0.2 million people each year [4]. The World drug report of 2010 estimated that about 5% of the world's adult population had used an illicit drug at least once in that year which accounts for 230 million people. The problem users were found to be 27 million which is about 0.6 % of the world population [4].

Substance Use Disorders (SUDs) are a common problem globally with extensive public health effects ranging from poor health outcomes, reduced economic productivity, premature death, insecurity among others [5].The delayed burdens for the country due to substance use disorders are social, disease and economic burden. The immediate burdens include crime and violence, risky sexual behaviour leading to contracting sexually transmitted diseases such as Human

Immuno-deficiency Virus/Acquired immunodeficiency Syndrome (HIV/AIDS) and non-productive behaviour. SUDs therefore have negative implications on the health and socio-economic status of an individual, family, community and the country. Illicit drugs also lead to instability and insecurity in the country. Alcohol has a causal relationship with over 200 health conditions by influencing their incidence and clinical outcome.

There has been a steady rise in the spread of injection drug use (IDU) globally. This has presented more implications for the public health sector. Injection drug users are a high risk group for HIV infection since they share needles and syringes as well as having unprotected sex [6]. Other than the physical risk of injection drug use, there is also the impaired judgment leading to dis-inhibition and engaging sexual behaviours and hence HIV infection. In Eastern Europe, sharing of syringes and needles accounts for more than 80 % of all HIV cases. The world's highest rates of HIV infection among IDUs are found in Asia. By 1999, they made up about 77% of HIV infections in Malaysia and 69% in China [7].

According to UNAIDS, injection drug use accounts for around one-third of new HIV infections outside sub-Saharan Africa. Injection drug use is also wide spread in east Africa. A study carried out in Dar-es-salam, the capital city of Tanzania showed that 75% of the multi-drug users were using heroin. About 18% of these were IDUs who were at an increased risk of HIV infection [6]. In Kenya, injection drug users contribute to 3.8 % of new infections, according to the modes of transmission (MOT) survey of 2008. However, the National Aids and Sexually Transmitted Infections Control Program (NASCOP) reports a higher rate, that 17% new HIV infections are attributable to IDUs. Heroin injection is now common in many large towns in Kenya. Out of the 336 heroin users found in Nairobi, 44.9% were or had been injectors and 52.5% of the current injectors were HIV positive.

Access to health care is a fundamental right of all citizens and is included in many international agreements and government policies. This is also enshrined in the Kenyan Constitution Article 43 section 1 [8]. This fundamental right can be fulfilled by ensuring access to essential medicines. There are many factors that affect access to medicines. Examples of these factors include unaffordable medicine prices, poor availability, irrational use of medicines, unfair health financing mechanisms, unreliable medicines supply systems among others [9]. The underlying vision for the health development reforms in Kenya outlines the key areas that are targeted as

sustainable, accessible and affordable quality health care. Governments should invest more in rehabilitation of substance abusers in order to improve outcomes and reduce the impact of SUDs on economic productivity [10].

1.2 Problem Statement

The high prevalence rate of substance use disorders in Kenya does not match the available treatment services including pharmacotherapy [5]. Unsubstantiated media reports show that the prevalence of SUDs in Kenya is on the rise [11]. A big gap exists between the need for treatment and the availability of services. Estimates from the National Drug Control Strategy 2001, show that about 5 million drug users needed immediate treatment in 1998 while only 1.2 million received it [12]. In Kenya the availability and affordability of substance abuse treatment is wanting. Patients in the public rehabilitation units are not provided with some or all of the medication indicated for their treatment. Some drugs that have been found to be efficacious are not on the Kenya Essential Medicines List (KEML 2010). Relapse rates are also high which could be due to ineffectiveness of the treatment offered. This could be related to poor availability of medicines that are required in this therapy. Pharmacotherapy needs to be employed together with psychotherapy in order to achieve optimum treatment goals.

1.2 Research Question

What is the accessibility of medicines used in the treatment of substance use disorders?

1.3 Objectives

1.3.1 Main Objective

To carry out an assessment of the accessibility of pharmaceutical commodities used in the treatment of patients with substance use disorders in selected hospitals.

1.3.2 Specific Objectives

i. To determine the availability of essential medicines used in the treatment of SUDs over a period of one year at Mathari hospital and Chiromo Lane medical centre.

ii. To determine the affordability of the essential medicines used in the treatment of SUDs.

iii. To determine factors that influence availability and affordability of the medicines for the management of SUDs.

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of Substance Abuse

The World Drug Report of 2010 shows that the problem of substance abuse affects more than 5 % of the world's population. About 270 million people have ever used illicit drugs in their life. Table 2.1 below shows the prevalence of various illicit drugs in the world.

Table 2.1 Annual prevalence and number of illicit drug users globally, 2010 [4]

Illicit Drugs	Number of illicit drug users n (%)	
	Low	High
Cannabis	119420(2.5)	224490(5.0)
Opioids	380(0.6)	36120(0.8)
Cocaine	13200(0.3)	19510(0.4)
Amphetamines	14340(0.3)	52540(0.4)
Ecstasy	10480(0.2)	28120(0.6)

*low – the lowest prevalence found worldwide

*high – the highest prevalence found worldwide

The WHO's global burden of disease study estimated the impact of alcohol consumption on the burden of disease to be 4.4%. Neuropsychiatric disorders constituted the category linked most to substance abuse. It showed that the health burden is more for men than for women in all the populations surveyed [1].

Substance use disorders fall under the non-communicable diseases whose prevalence is increasing at an alarming rate. This has doubled the burden of disease adding to the burden already caused by the non-communicable diseases such as AIDS, tuberculosis and malaria. The main substances of abuse in Kenya are alcohol, tobacco, cannabis, miraa, heroin, cocaine, psycho-stimulants and prescription medicines. The types of substances abused also vary regionally. For instance, alcohol abuse is more prevalent in central region while Cannabis abuse

is more prevalent in western Kenya. Abuse of opioids and cocaine is more prevalent in the coast region. The age-bracket that is affected is wide covering 15-65 years, ages at which one is most economically productive [5]. There are at least three people who are initiated into drug use every day and that youth between the ages of 12 and 18 years re the most affected while those between 25 and 65 years are the major users [11].

The Kenyan National Authority for the Campaign against Alcohol and Drug Abuse (NACADA) performed a rapid assessment in 2012 to establish the level of alcohol and drug use. Findings from this survey revealed that drug and substance abuse was a major social problem in Kenya. The study confirmed that drug and substance use disorders in Kenya has a complex cause and effect relationship. The survey identified the main direct cause of drug and substance use disorders to be easy availability of cheap drugs and other psychoactive substances [5]. A high level of awareness of cigarettes and bhang among the Kenyan population was reported. The more accessible drugs are relatively cheaper compared to the less accessible ones such as cocaine and heroin. Cocaine is most easily accessible in Nairobi, Coast and North Eastern regions.

In a study conducted on college students, the life time substance use prevalence rate was found to be 69.8 % [2]. The same study found that the prevalence rate of lifetime alcohol use and cigarette smoking was 51.9 % and 42.8 %, respectively. According to a study carried out among patients attending health centresin Nairobi and Murang'a, there are more males who are dependent on substances of abuse than females (12)].

According to the assessment done in 2012 by NACADA the prevalence of the different substance use disorders in Kenya were as shown in Table 2-2

Table 2.2: Level of use of various substances of abuse in the general population in Kenya [5]

Substance	Moderate Users (%)	Abusers (%)	Dependent Persons (%)	General Annual Prevalence (%)
Alcohol	4.7	5.8	5.5	16
Tobacco	1.7	3.7	4.5	9.9
Miraa	0.9	1.6	1.5	4.0
Bhang	0.5	0.4	0.4	1.3
Heroin	0.2	-	-	0.2

There are high rates of prevalence for alcohol and tobacco abuse. This is due to their social acceptability, easy availability and due to uncontrolled promotions and advertisements.

The assessment of drug abuse done in 2012 showed that use of hard drugs is not yet widespread in the Kenyan population because they are not readily available and are more expensive. For instance, heroin and cocaine cost about Kshs. 1000 and 16,000 per kilogram respectively. The prevalence rate of heroin and cocaine use in Kenya is less than 1%. The prevalence is however higher in the coastal region. The rates are higher among urban dwellers than rural dwellers [5].

Cannabis is the most widely abused illicit drug globally whose estimated annual prevalence in 2010 was at about 4 % of the adult population. This means that there are about 220 million users aged 15- 64years. Asia has the highest number of users at between 26 million and 92 million [13]. Prevalence of cannabis abuse in Kenya is at 1.3% [5]. The use of Cathaedulis (Miraa) was at 4.2 % in 2012 and was higher in urban dwellers and in males as compared to the rates in rural dwellers and in females. The rate was highest in North eastern province.

2.2 Complications of Substance Dependence

Prolonged use of substances of abuse leads to dependence, an adaptive state in which the physiological functions of the body are altered. Abrupt stopping of the substance use leads to withdrawal symptoms. Substances of abuse affect a wide array of body organs and systems.

Some effects are detrimental to health, even leading to death. It is estimated that 1 in every 100 deaths is associated with substance abuse [4]. Substance use is associated with increased morbidity and mortality. The effects of the various substances on the body are discussed below.

Alcohol dependence leads to an array of medical and social complications. Alcohol has a causal relationship with more than 200 diseases. The medical complications include alcoholic liver diseases (cirrhosis, hepatitis, fatty-liver), cardiovascular diseases (cardiomyopathy, hypertension), hematological disorders (anaemia, thrombocytopenia), CNS and neuropsychiatric complications (Wernicke's encephalopathy, Korsakoffs syndrome).

Alcohol withdrawal syndrome (AWS) occurs when the patient abruptly stops or reduces the amount of alcohol intake. It presents with an array of symptoms; both physical and emotional. They include restlessness, irritability, anxiety, agitation, anorexia, nausea, vomiting, tremor, elevated heart rate, increased blood pressure, insomnia, intense dreaming, nightmares, poor concentration, impaired memory and judgment, increased sensitivity to sound, light, and tactile sensations. Hallucinations usually occur and they could be auditory, visual, or tactile. Patients could also get delusions, usually of paranoid or persecutory varieties. Convulsions may also occur usually the grand mal type of seizures. The AWS usually presents with disorientation with regard to time, place, person, and situation and with fluctuation in level of consciousness [1] . This is a potentially serious medical condition that can lead to death if not attended to promptly.

The most common form of nicotine dependence is cigarette smoking which accounts for approximately 450,000 deaths/year globally; these are more deaths than those caused by AIDS, alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fire combined [13]. Smoking is a well known risk factor for lung cancer, aero- digestive (respiratory tract and upper digestive tract) and other cancers, emphysema, chronic obstructive lung disease, chronic bronchitis, myocardial infarction, coronary artery diseases, hypertension, stroke, and peripheral vascular disease [1].

Withdrawal symptoms associated with nicotine include dysphoric or depressed mood, insomnia, irritability, frustration, or anger, anxiety (difficulty concentrating, restlessness), decrease heart rate, increased appetite or weight gain.

Cannabis is the most commonly used illicit drug in the world. Approximately 4% of the world's population use the drug. Use is common in young people ages 16- 24 years, an age when the brain is still developing and vulnerable to deleterious effects. Cannabis dependence can cause various medical complications including depression, delirium, paranoia, cognitive impairment and psychosis (usually referred to as cannabis psychosis). Social complications include impaired performance at school/work, criminal activity, family and relationship problems.

Opioid dependence can lead to medical complications such as infections through injections (HIV, hepatitis). Sharing of contaminated needles and other drug paraphernalia facilitates the transmission of the HIV virus via exchange of blood from infected to uninfected users.

Opioid withdrawal symptoms include sweating, anorexia, generalized body aches, diarrhoea insomnia among others. They also cause psychological symptoms such as depression and anxiety. Social complications include imprisonment, marginalization, family and relationship problems.

Psycho-stimulant use may lead to complications such as restlessness, hyperactivity, sleep disorders, depression, panic attacks, stimulant induced psychosis, enhanced libido and engaging in risky sexual behaviours which may lead to HIV infection. Alcohol and cocaine together can result in cardiac arrest due to changes in QT interval [14].

All substances of abuse are associated with poor health care service-seeking behaviours. This leads to worsening of other medical conditions not associated with the substance. Prognosis of many curable diseases is usually poorer among substance abuse patients [15].

2.3 Treatment of Substance use disorders

The history of SUDs dates back to the 18th century where Christians regarded alcoholism as sin and abstinence was preached. The drunkard was expected to repent and cease the habit. However it was later realized this 'disease' was much more complex and required management by qualified medical personnel. In 1804, Thomas Trotter wrote an article in which he indicated that 'drunkenness was not sin to be prayed for but a disease of the mind' [15].

Many types of treatments have been put to test thus far including patients being injected with their own serum to which whisky had been added, subcutaneous injections of carbon dioxide or

oxygen to cure inebriety, electroconvulsive therapy and brain surgery. The most hilarious suggestion for treating alcoholism was ‘a treatment regime involving the consumption of precisely 231 lemons over exactly 29 days’ [16].

Towards the end of the 20th century, more conventional modes of treatment had been conceived and were undergoing trials. Those that were found to be effective were approved for use in the treatment of SUDs. It is now known that the treatment of substance abuse is multidimensional and may consist of biophysical, pharmacological, psychological and socio-cultural components as outlined in Figure 2.1 below.

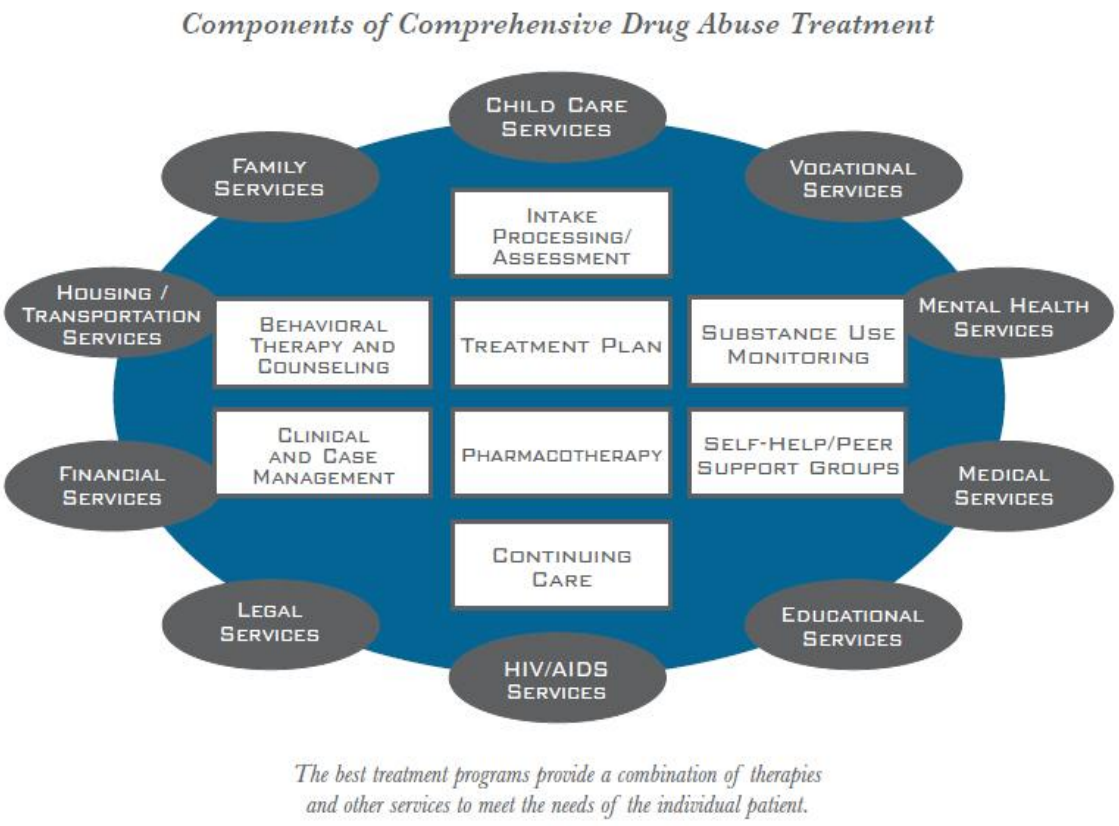

Figure 2.1 Components of comprehensive substance abuse treatment

Adapted from Principles of addiction treatment (NIDA) [17]

Many programmes have been employed across the world in rehabilitating substance abusers. Heroin abusers may be rehabilitated using detoxification, imprisonment, civil commitment or methadone maintenance. The cost-effectiveness of such programmes should be considered

before they are embraced by governments. For instance, the cost of methadone for a year in the US is $4000 while that of HIV management for the same period is $157, 811 were the patient to get infected via sharing of syringes.

Methadone maintenance has a higher net benefit than other approaches. Benefits are derived from an increase in employment income following rehabilitation and reduction in the opportunity loss of addict crime.

The net benefit of different modes of rehabilitation for heroin users in USA was compared to methadone in the Table 2.3 below [18].

Table 2.3 Net benefit of the different modes of rehabilitation for heroin users in USA

PROGRAM	NET BENEFIT ($)
Methadone maintenance	10639
Imprisonment and parole	8271
Civil commitment	4030
Detoxification	1387

The findings above support the importance of pharmacotherapy as one of the components in the treatment of substance use disorders. In a study on the patterns of drug use among patients attending primary health care facilities in Nairobi and Murang'a, it was shown that the prevalence of substance abuse was about 18%. This shows that there is need for availing substance abuse treatment services at all levels of healthcare services [12].

Health professionals have an important role in reducing the harmful use of alcohol by monitoring alcohol consumption in their patients and providing brief interventions, counseling and pharmacotherapy, as appropriate, in all cases of identified hazardous drinking or alcohol use disorders.

Pharmacological treatment is emerging as another means to enhance abstinence and prevent relapse, complementing psychosocial interventions that have been in use for many years. This is

usually done at two levels, that is, for detoxification and as medication assisted treatment (MAT). Detoxification involves the treatment of withdrawal symptoms usually in patients with severe dependence [18].

The type of pharmacotherapy employed varies depending on the substance of abuse. Many pharmaceutical ingredients have undergone trials to prove their effectiveness in treating dependence. Some components are still under trial such as acamprosate for the treatment of alcohol use disorders, while some are used off-label such as topiramate. There is substantial evidence supporting the role of pharmacotherapy in the management of substance abuse disorders [17]. The new evidence-based modes of treatment are however not widely used because they have not been disseminated and health care workers have not embraced them due to various factors [19].

2.4 Pharmacotherapy of Substance use Disorders

2.4.1 Management of Alcohol Use Disorder

Treating alcoholism involves several stages. The initial stage deals with the management of alcohol withdrawal syndrome (AWS) and detoxification. The stages that follow are aimed at managing dependence [21]. It is an attempt to maintain patients in remission and develop a lifestyle compatible with long-term abstinence. This latter aspect of patient management has traditionally involved psychosocial interventions, pharmacological modalities and combinations of both [1]. Several medicines have been used in this effort.

Benzodiazepines remain the medication of choice in treating withdrawal from alcohol. The early recognition of alcohol withdrawal and prompt administration of a suitable benzodiazepine prevents further withdrawal reaction from proceeding to serious consequences. Benzodiazepines have been shown to reduce withdrawal symptoms, and prevent complications such as seizures and delirium tremens. The dose is dependent on the severity of the symptoms and is titrated according to the individual patient's response [1].

Chronic alcoholism causes a condition known as Wernicke's encephalopathy. It is characterized by mental confusion, abnormal eye movements and unsteady gait. This condition results from thiamine deficiency and thiamine supplementation is recommended for its treatment [22].

Pharmacotherapy of alcoholism took a new turn in 1940 with the introduction of the anti-abuse drug-disulfiram. Disulfiram acts by inhibiting aldehyde dehydrogenase (ADH), the enzyme responsible for the degradation of acetaldehyde, resulting in its accumulation. The accumulation produces a very unpleasant reaction that includes flushing, nausea and palpitations. It is more effective in highly motivated patients who are well supported.

Naltrexone is another drug used in management of alcohol dependence. It blocks opioid receptors that are involved in the rewarding effects of drinking and the craving for alcohol. It has been shown to reduce relapse to problem drinking in some patients. An extended release version, Vivitrol® that is administered as a once a month by injection is FDA-approved for treating alcoholism, and may offer benefits regarding compliance [17].

Acamprosate (calcium acetylhomotaurinate) is an organic compound containing a sulfonic acid derivative. It reduces craving by antagonizing the excitatory glutamate at N-methyl-D-aspartate (NMDA) receptors and by stimulating inhibitory gamma-aminobutyric acid (GABA) transmission [23]. This is thought to reduce symptoms of protracted withdrawal, such as insomnia, anxiety, restlessness, and dysphoria [1]. Acamprosate has been shown to help dependent drinkers maintain abstinence for several weeks to months, and it may be more effective in patients with severe dependence [24]. Naltrexone and acamprosate have comparable efficacy in terms of reducing the relapse rates in already detoxified patients [25].

Topiramate is thought to work in a similar way to acamprosate by increasing inhibitory (GABA) neurotransmission and reducing stimulatory (glutamate) neurotransmission. However, its precise mechanism of action is not known. It has not yet been approved by FDA for treating alcohol addiction. It is used off-label for this purpose [17].

2.4.2 Management of Opioid Use Disorder

Pharmacotherapy of opioid addiction involves use of other opioids. This is the most effective way of treating opioid dependence. The opioids used are long-acting and provide relief from craving and withdrawal symptoms and allow the patient to be free from domination of illicit opioids [1]. Methadone is a long-acting orally active synthetic opioid agonist that can prevent withdrawal symptoms and reduce craving in opioid-addicted individuals. It can also block the

effects of illicit opioids such as heroin. It is usually given for maintenance therapy over a long period of time (at least two years).

Buprenorphine is also a synthetic opioid medication that acts as a partial agonist at opioid receptors that does not produce the euphoria and sedation caused by heroin or other opioids but is able to reduce or eliminate withdrawal symptoms associated with opioid dependence and carries a low risk of overdose [1]. Buprenorphine is taken sublingually and is currently available in two formulations, the pure form of the drug and a combination of the drug with naloxone (an opioid antagonist) called suboxone. Naloxone has no effect when suboxone is taken as prescribed, but if an addicted individual attempts to inject suboxone, the naloxone will produce severe withdrawal symptoms. Thus, this formulation lessens the likelihood that the drug will be abused or diverted to others [24].

Naltrexone is a synthetic opioid antagonist that blocks opioids from binding to their receptors and thereby prevents their euphoric and other effects. It has been used for many years to reverse opioid overdose and is also approved for treating opioid addiction [26]. The theory behind this treatment is that the repeated absence of the desired effects and the perceived futility of abusing opioids will gradually diminish craving and addiction. Naltrexone itself has no subjective effects following detoxification (that is, a person does not perceive any particular drug effect), has no potential for abuse and it is not addictive [27].

Other than opioids, clonidine (Catapres®) is the most commonly used medication for treatment of opioid withdrawal symptoms. It reduces anxiety, agitation, muscle aches, sweating and cramping [26]. There are several advantages to treating opioid withdrawal using clonidine rather than methadone. These include the fact that clonidine does not produce opioid intoxification and is not reinforcing, and that no special licensing is required for the dispensing of this medication. Although clonidine alleviates some symptoms of opioid withdrawal, it usually is relatively ineffective for insomnia, muscle aches, and drug craving [1].

2.4.3 Management of Psycho-stimulants Use Disorders

Psychostimulants such as amphetamines, cocaine and miraa are drugs that increase the central nervous system arousal and are sympathomimetics that act like noradrenaline to increase cardiovascular tone and activity.

Drugs used in the management of opioid and alcohol dependence (such as naltrexone and buprenorphine) could also be important in the management of cocaine dependence. This is because the endogenous opioid systems in the brain may also be involved in the reinforcing effects of other abused substances, including cocaine and alcohol [27].

Disulfiram can also be used to reduce cocaine use. It acts by inhibiting dopamine beta hydrolase leading to an increase in dopamine and a decrease in noradrenaline. This diminishes the 'high' caused by cocaine [29].

Modafinil is a central nervous system stimulant. It is used to treat narcolepsy. It is currently under investigation for use in the treatment of psychostimulant abuse. It has low abuse potential [29].

Antidepressants can also be prescribed for the depression that often accompanies methamphetamine or other amphetamine withdrawal. Desipramine, an antidepressant, has been used for both cocaine detoxification and the maintenance of abstinence. A 1984 report that this drug was safe and effective in treating cocaine abuse led to a placebo-controlled, double-blind assessment of its relative efficacy in 72 cocaine-dependent persons treated at an outpatient clinical facility. The results indicated that Desipramine was beneficial [29].

Bromocriptine, a dopamimetic drug used to treat hyperprolactinemia, has been evaluated in both open and placebo-controlled trials. Bromocriptine was reported to decrease the craving for cocaine during detoxification and to reduce dysphoria during both detoxification and abstinence [24].

2.4.4 Management of Nicotine Use Disorder

Nicotine replacement therapy is one of the most effective and commonly available pharmacotherapies for treating nicotine dependence. It doubles the chance of achieving stable remission from smoking compared to an unmedicated attempt to quit [30]. It is formulated in various dosage forms such as gum, patch, nasal spray, inhaler or lozenge. These dosage forms contain low levels of nicotine, 2 or 4 milligrams.

After the acute withdrawal period, patients are weaned off the medication until they become nicotine free. Research has shown that constituents of tobacco other than nicotine are responsible for causing cancer, and no ill effects have been attributed to long-term use of nicotine replacement therapy.

Bupropion is another pharmacological agent used to treat nicotine dependence. It increases the release of dopamine and noradrenaline which are neurotransmitters in the brain. It can promote up to 30% smoking cessation rates [23].

Clonidine is an α-2 agonist used as an antihypertensive. It is a pre-synaptic agonist which reduces sympathetic activity and mimics the nicotine effect.

Oral dextrose tablets are given during the withdrawal phase, smokers have been known to have an increased demand for sweet substances. It is suspected to work via dampening the desire to smoke due to the satiation effects or via direct effects on neuronal systems involved with nicotine dependence [28].

2.4.5 Management of Cannabis Use Disorder

Currently, there is no specific drug that can be used for management of cannabis dependence. However, for withdrawal symptoms, certain drugs may be used: [1] Benzodiazepines such as diazepam are used to relieve insomnia, irritability and restlessness. If symptoms persist, another drug known as quetapine may also be used. However, research is on going to determine the efficacy of cannabinoids in reducing cannabis dependence in human beings [31].

CHAPTER THREE: METHODOLOGY

3.1 Study Site

The study sites were the drug rehabilitation units situated at Mathari Mental Hospital and Chiromo Lane Medical Centre.

Mathari mental hospital is the national referral hospital for psychiatric disorders. It has a drug rehabilitation unit with a capacity for admitting 35 patients. It is located 6 kilometres from the Nairobi city centre along the Thika Super Highway. It is the only referral hospital for psychiatric disorders in Kenya and hence was conveniently selected as a study site.

A private facility for the treatment of psychiatric disorders was picked. Chiromo Lane is a private hospital for psychiatric disorders. It manages patients with substance use disorders. It is located 4 kilometres from the Nairobi city centre on the western side (Westlands). It has a capacity of 40 patients including those not presenting with SUDs.

The key informants were selected from the two facilities and other locations where they were based. These locations include NACADA office, MOH office, retail chemists and private consultation clinics.

3.2 Study Design

The study had two components; a descriptive cross-sectional study with a quantitative approach and a qualitative component. The study was carried out between the months of April and June 2015 at Mathari mental Hospital and Chiromo Lane Medical Centre.

3.3 Selection of Index Drug

The KEML 2010 provides a list of essential drugs that are to be available at the health facilities at all times. The medicines for SUDs on this list included diazepam, methadone, clonidine, carbamazepine, thiamine and haloperidol. Other drugs not on the KEML 2010 but being used routinely were also assessed. These drugs included disulfiram, topiramate, naltrexone, acamprosate, buprenophine, bupropion and nicotine replacement therapy (NRT).

3.4 Target Population

The target population was hospitals and rehabilitation centres offering pharmacotherapy for SUDs in Nairobi and the identified key informants. The Key informants were selected on the

basis of those who had the information required. These included hospital in-charges/medical superintendents, pharmacy in-charges, consultant psychiatrists, psychologists and community pharmacists. The records studied covered the period between January and December 2014.

3.5 Sampling Techniques

This being a preliminary study, purposive sampling was used to select the hospitals and the key informants. This involved the selection of study participants based on the qualities they possessed. There were no underlying theories or a set number of participants to choose from.

Mathari hospital is the only public hospital offering pharmacotherapy for substance use disorders in Nairobi.

There are 11 accredited private rehabilitation centres in Nairobi [30]. Among these facilities, only Chiromo Lane was found to provide pharmacotherapy for substance abuse disorders. The other facilities offer psychotherapy only. Mathari Mental hospital and Chiromo Lane Medical centre were therefore selected as study sites.

Key informants were also selected purposively and the interviews conducted till saturation was achieved.

3.6 Data Collection Method and Research Instruments

3.6.1 Quantitative Data

Information on availability and affordability was obtained with an interviewer administered data collection form which was the survey tool. It was developed using the medicine price data collection form of the WHO/ HAI manual. Data collection tools were designed, validated and used to collect data.

Relevant records on the medicines from the selected hospitals were checked and the required information recorded on a pre-designed tool. These records included but were not limited to inventory records such as Bin cards, stock cards, delivery notes and S11 books.

The collected data was then entered into an excel sheet awaiting analysis. Both hard and soft copies of the data were stored.

3.6.2 Qualitative Data

In depth interviews were carried out with key informants across various sites which were located within the hospitals or adjacent. Consultants were interviewed at their respective offices/ clinics.

The recommended sample size for in depth interview is 10-50. A total of 13 interviews were carried out with the selected key-informants. The target was to interview at least 5 key informants from each category. The biodata of the key informants is presented in appendix5.

The interviews were conducted between the months of April and May 2015. The informants were selected using purposive sampling on the basis of who had the information required. These included the hospital in-charges/medical superintendents, pharmacy in-charges, consultant psychiatrists, psychologists and community pharmacists.

Appointments were booked in advance and interviews were conducted at the convenience of the interviewee. Interview guides (appendix 1) were used to conduct the interviews. The interviews were tape-recorded and transcribed within 24 hours. Hard and soft copies of data were stored awaiting analysis.

3.7 Data Management and Quality Assurance

A pilot study was conducted to test the data collection tools. A trial interview was conducted with one of the staff at KNH. Adjustments were then made to the data collection tools and the interview guides. Quantitative data was transferred to a Microsoft Excel® spreadsheet awaiting analysis. Qualitative data collected via tape-recording was transcribed within 24 hours. The transcribed data was read and re-read so as to pick out the themes for analysis. Both hard and soft copies of the data were safely stored according to the international data protection act (1998).

3.8 Data Analysis

3.8.1 Quantitative Data Analysis

Accuracy of data entered for analysis was counterchecked by the researcher before analysis. Analysis of numerical data through descriptive and inferential statistics was done using Microsoft Excel®.

Availability of medicines for the period between January-December 2014 was investigated. The indicators on availability of the medicines were determined as a proportion/percentage. The total number of medicines that were available out of the total number of medicines under study gave the percentage availability. The number of expired medicines found at a study site out of the total number of medicines under survey gave the percentage of expired medicines.

The stock out period was taken as the number of days that the medicine was not available at the facility for the period from January to December 2014. The equivalent stock -out period was taken as the number of days the medicine was absent during the study period multiplied by the number of days in a year and divided by the number of days covered by the study.

Affordability was estimated as the number of days' wages of the lowest paid unskilled government worker needed to purchase medicines prescribed as the standard dose. For chronic diseases, it is calculated for a 30-days' supply of medicine. The lowest paid unskilled government worker is in job group A and earns about Kshs. 10,000. The daily wage was therefore obtained as Kshs. 333. To obtain the number of days' wages needed, the cost of the medicine needed for a month was divided by 333.

The data was then presented graphically where applicable.

3.8.2 Qualitative data analysis

Deductive approach was used in analyzing qualitative data. The transcribed data was read and research questions were used in grouping the data and looking for similarities and differences in the data collected. Codes were assigned to different themes. The themes identified were then organized into coherent categories that brought meaning to the text.

3.9 Ethical Considerations

Ethical approval was obtained from the by Kenyatta National Hospital and University of Nairobi ethics review committee (KNH/UON-ERC) before the study commenced. The researcher further sought permission from the hospital management of the study sites before commencing data collection.

This study being non-interventional, there was no contact with the patients hence no harm was expected. Informed consent was sought from all the key informants from whom qualitative data was collected.

Since the research involved perusal of records, the researcher ensured that confidentiality was maintained and no unauthorized persons had access to the records. All data was captured anonymously and no data bore direct personal identifiers. The audio tapes were transcribed within 24 hours and both hard and soft copies stored safely. The participant identification code was formatted in such a manner that allowed identification of the cadre of the interviewee. Different abbreviations were used to denote the interviewee per cadre/location.

CHAPTER FOUR: RESULTS

4.1 Availability of Medicines on the KEML 2010

The availability of the medicines on KEML 2010 for the treatment of SUDs was investigated. These medicines were: diazepam (tablets and injections), methadone, clonidine, carbamazepine, thiamine and haloperidol (tablets and injections).

In Mathari, Diazepam (both tablets and injections) and haloperidol (both tablets and injections) were available. Thiamine, clonidine and carbamazepine were out of stock. Data on methadone was not accessed.

All the medicines on the KEML 2010 were available in Chiromo Lane. The percentage of medicines on the KEML 2010 that were available in Mathari was 50% while in Chiromo Lane it was 100%.

There were no expired medicines in Mathari. Medicines which had a short expiry and were still available in substantial quantities were usually re-distributed to other neighbouring facilities that needed them. There was one expired medicine (Methadone) in Chiromo Lane which accounted for 16% of the drugs in the KEML 2010. The explanation given was that it was a donation which was received close to its expiry date and they were not \able to consume it all.

4.2 Availability of Medicines Not on KEML 2010

Availability of medicines not on the KEML 2010 but have proven to be efficacious in evidence-based studies was also checked. These medicines were: disulfiram, naltrexone, acamprosate, buprenophine, bupropion and nicotine replacement therapy (NRT).

Medicines not on the KEML 2010 were completely missing in Mathari. This is because the ordering for the medicines is usually done on the KEMSA standard order form which is adopted from the KEML 2010. Medicines not on this list are usually not purchased except under special circumstances.

Most of the Medicines recommended for use in treatment of SUDs were available at Chiromo. The percentage availability for these medicines was 72% .The medicines that were not available were Acamprosate and Buprenophine which are currently not registered by the regulator for use in Kenya.

Expiries were present in Chiromo at 25% of the medicines not on KEML 2010. This was due to the slow movement of these medicines and /or overstocking.

4.3 Duration of Stock-out

The number of days the selected medicines were out of stock was recorded and the equivalent in a year was determined. The findings are summarized in Table 4.1 below.

Table 4.1 Duration of Stock-out of medicines for the facilities for the period Jan- Dec 2014

Medicines	Duration of Stock out (days)		Stock out days per year n (%)	
	Mathari	Chiromo Lane	Mathari	Chiromo Lane
Diazepam injection	60	0	60(16)	0(0)
Diazepam Tablets	60	0	60(16)	0(0)
Thiamine	180	0	180(49)	0(0)
Haloperidol	30	0	30(8)	0(0)
Clonidine	365	0	365(100)	0(0)
Carbamazepine	60	0	60(16)	0(0)
Methadone	N/a	4	N/a	14(4)
Acamprosate*	365	365	365(100)	365(100)
Disulfiram	365	0	365(100)	0(0)
Buprenophine*	365	365	365(100)	365(100)
NRT	365	0	365(100)	0(0)
Naltrexone	365	0	365(100)	0(0)
Topiramate	365	0	365(100)	0(0)
Bupropion	365	0	365(100)	0(0)

C=No. of days covered by the study= 365 days

**Not registered in Kenya*

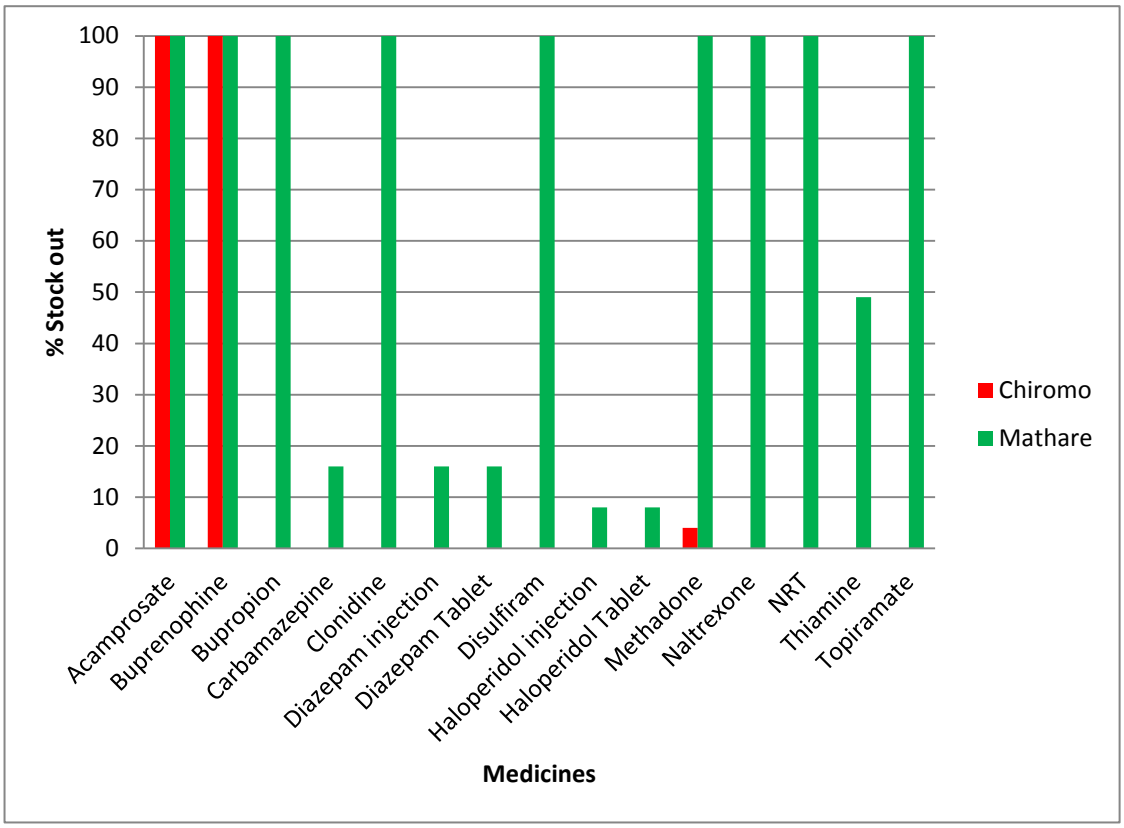

Figure 4.1 Percentage Stock out in the Year 2014

In Mathari, 54% of the medicines were out of stock the whole year in. Of these, 23% were out of stock for 2 months while 8% were out of stock for 6 months. The average stock out period for this facility was 8 months.

In Chiromo Lane, only one medicine was out of stock for 14 days in the year, accounting for 7% of the medicines surveyed. The average stock out period for this facility was 0.5 months.

4.4 Affordability of Treatment

The affordability of treatment was investigated and reported as shown in Table 4.2 below.

Table 4.2 Affordability of medicines

Medicine(A)		No. of units required in a month(B)		Unit price in kshs. (C)		Total cost (D)		Equivalent no. Of days' wages F=D/E	
		Mathari	Chiromo Lane	Mathari	Chiromo Lane	Mathari	Chiromo Lane	Mathari	Chiromo Lane
Diazepam Tablets		42	42	2	20	84	840	0.3	3
Diazepam injection		10	10	30	50	300	500	0.9	1.5
Haloperidol tablets		60	60	3	27	180	810	0.5	2
Haloperidol injection		10	10	200	3000	2000	3000	6.0	9
Methadone		**	900	**	6	**	5400	**	16
Thiamine		10	10	500	308	5000	3080	15	9
Carbamazepine		60	60	5	63	300	3780	0.9	11
Clonidine		*	30	*	30	*	900	*	3
D isulfiram		*	14	*	180	*	2520	*	8
Naltrexone		*	30	*	550	*	16500	*	50
Topiramate		*	90	*	40	*	3600	*	11
Bupropion		*	30	*	90	*	27	*	8
NRT	Gums	*	60	*	40	*	2400	*	7
	Patches	*	30	*	400	*	12000	*	36

B= Was taken as the quantity of the medicine needed for a month of treatment

E= This was identified from the lowest monthly government salary (job group A) = KSHS. 10,000.

Therefore a day's wage= Kshs. 333

NRT- Nicotine replacement Therapy

**Medicine not available*

*** Data not accessed*

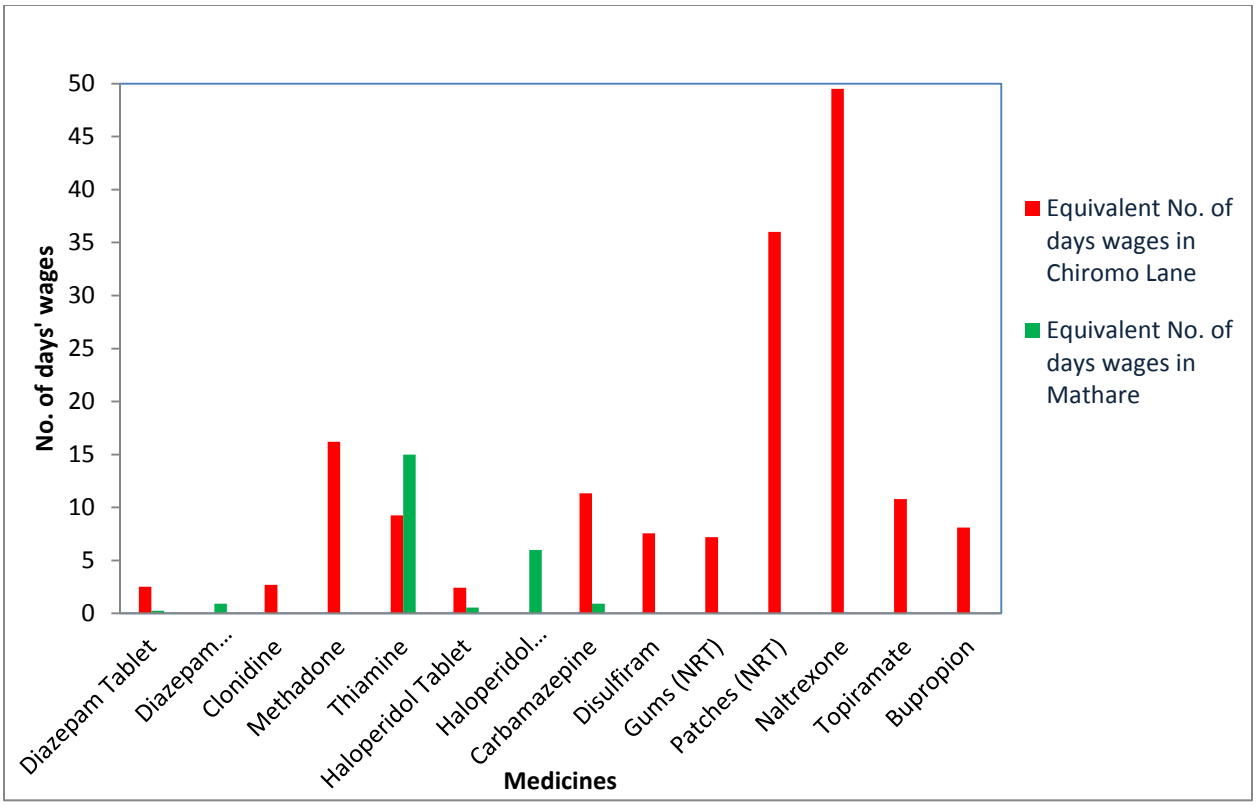

Figure 4.2 No of Days' Wages Required to Purchase Medicines for Substance use disorders

About 70% of the medicines required less than a single day's wage to buy a month's supply in Mathari. In Chiromo Lane all the medicines required more than a single day's wage to purchase.

Cheapest medicine in Mathari was diazepam tablets which required 0.3 days wage to purchase while the most expensive was thiamine, requiring 15 days wage to purchase.

In Chiromo Lane, the cheapest medicine was diazepam injection which required 1.5 days of wage to purchase while the most expensive was naltrexone requiring 50 days of wage to purchase.

In Mathari, it was not possible to stock expensive medicines not on KEML 2010 even if evidence had shown them to be more effective than the ones on the KEML 2010. This is because

the money used for such is usually from the revolving fund or facility improvement fund (FIF) and if patients are not able to pay for the medicines, the fund will collapse.

4.5 Frequency of purchase of Medicines in a Year

The number of times medicines for the treatment of SUDs were purchased in the facilities was investigated and the findings are presented in Figure 4.3 below

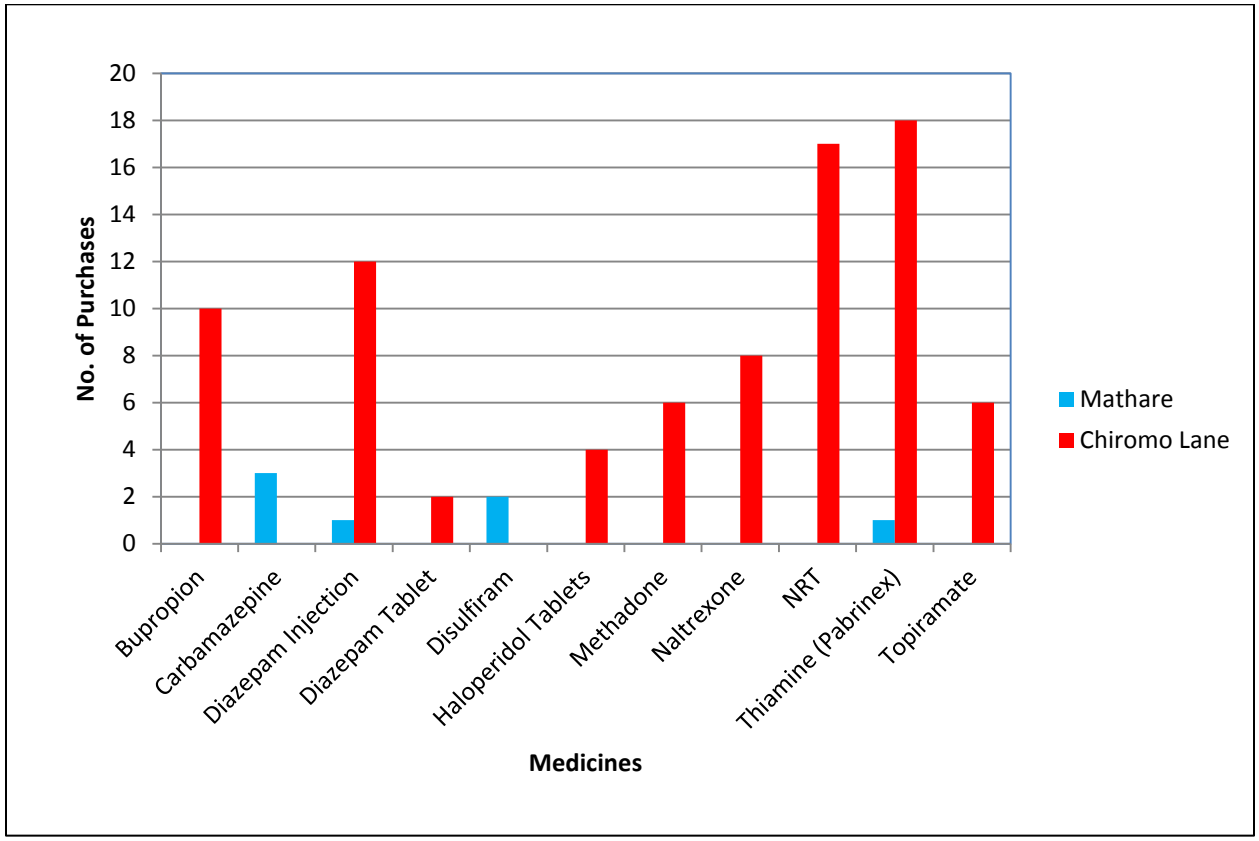

Figure 4.3 Frequency of purchase of Medicines for Substance Use Disorders in the Year Jan- Dec 2014

In Mathari, medicines for SUD treatment were purchased in only four months throughout the year. Carbamazepine was purchased the highest number of times. This medicine is usually used in the management of alcohol withdrawal symptoms.

4.6 In- Depth interview with Key Informants

A total of 13 key informant interviews were carried out with interviewees from various sectors. The biodata of the interviewees is given in appendix 4.

4.6.1 Epidemiology of SUDs

Alcohol was reported to be the substance most abused by 12 (92%) of the key informants. It was closely followed by bhang, tobacco and miraa. Cocaine and heroin were reported to account for a small number of clients who visited the facilities.

The prevalence of particular SUDs also varied regionally; Central province was affected more by alcohol use disorders while coast province had more cases of heroin users. It was also dependent on the availability and cost of the substance. For instance, the cost of both heroin and cocaine could be accounting for the low prevalence of SUDs associated with them.

The age of the patients who present with SUDs ranges from 25-35, teens of ages 16-18 are seen once in a while. The older patients usually present with alcohol use disorders while the younger patients present with use of bhang and hard drugs.

> "……..*the commonest age bracket for these patients is 25-35 years* ". *(Interviewee 02)*

The average number of patients seen by the consultants per day was ten.

> *"……in out- patient clinic I see about 15 continuing patients and 5 new patients. (Interviewee 04)*

The in- patient number varies and is sometimes dependent on availability of beds. Patients in Mathari where the bed capacity is 54 have to be placed on a waiting list and be called when space is available.

The bed capacity in Chiromo Lane is 40, for all patients with psychiatric disorders.

4.6.2 Management Approaches of SUDS

All the key informants interviewed reported that combination therapy was most effective. Both psychotherapy and pharmacotherapy have to be used in order to achieve treatment success and prevent relapses.

> *".....none of them works alone, it has to be a combination ". (Interviewee 01)*

> *"....detoxification alone will not work, psychotherapy alone will not work,you need both". (Interviewee 03)*

However, some of the key informants were not aware of some of the medicines used in management of particular SUDs.

> *".....no, I have not seen any NRT, is it available? Where? " (Interviewee 06)*

Pharmacotherapy was reported to be important during the stages of detoxification and the management of withdrawal symptoms. Psychotherapy on the other hand was reported to help the patient in attitude change and continued abstinence.

> *".....I usually cut a deal with my clients and this helps them to change their attitude and ensure treatment success. (Interviewee 04)*

Medicines are used at almost all the stages of management of SUDs. For instance, detoxification from alcohol, the following were reported to be used by the interviewees: Thiamine, Diazepam, Carbamazepine. For maintenance, medicines for managing craving such as naltrexone are used. Antabuse® (Disulphiram) was found to be very unpopular with the interviewees because of its side effects.

> *".....this medicine should be removed from the list! Do they know what it does to the patient? " (Interviewee 06)*

Traditional/herbal approaches were also employed in the management of SUDs. It was reported by one of the key informants that the use of traditional vegetables and lots of fruits and water reduced the craving for Cannabis.

The training of addiction professionals by NACADA also recognizes the importance of both psychotherapy and pharmacotherapy. The curriculum has modules on both counseling skills and pharmacology, where medicines used for SUDs are discussed.

4.6.3 Guidelines/protocols used in Management of SUDs

The interviewees reported to be using different guidelines for the management of SUDs. Some were not aware of the availability of a Kenya National guideline or protocol.

> *".....I use the National treatment protocol for Substance abuse disorders in Kenya. " (Interviewee 04)*
>
> *"..... I use guidelines from NIDA" (Interviewee 03)*
>
> *".....I use the BNF,a Kenyan guideline cannot be as good as the BNF" (Interviewee 02)*
>
> *"...the management is dependent on the patient's symptoms; I come up with a list of medicines" (Interviewee 06)*

The National treatment protocol for substance use disorders in Kenya is available with only a few practitioners in hard copy. It is not yet available in soft copy and hence not widely accessible.

The National treatment protocol was prepared in partnership between MOH department of Mental Health and the UNODC. The funding was not adequate and the copies were not enough to circulate to all the facilities and practitioners. It is also biased towards the narcotic substances.

4.6.4 Availability of medicines

The medicines on the KEML 2010 were regarded by the interviewees to be more readily available. They however noted that the list was inadequate and needed to be updated as some of the medicines had become obsolete.

Availability varied across the public and private facilities. Interviewees who were affiliated to private facilities reported a higher rate of availability compared to those affiliated to the public facilities.

The lack of medicines in the facilities contributes to delayed treatment and worsening of symptoms. A patient may stay in the ward as they wait for the relatives to come and buy a prescribed medicine which was out-of-stock.

> "…..we have a phone in the rehab which we use to call the relatives to come and buy the medicines" (Interviewee 03)

Availability of medicines for various SUDs differed considerably. For instance an interviewee reported that their facility did not have any form of NRT.

> *"……We have nothing for nicotine dependence, we only do psychotherapy ". (Interviewee 03)*

Most of the interviewees had knowledge of newer and more efficacious drugs which were not on the KEML 2010. However, they reported that the medicines were not readily available.

> *".....yes there are other good drugs but they are not available ". (Interviewee 01)*

> *".....we prefer the atypical antipsychotics but what we have is typical " (Interviewee 04)*

> *"……some medicines I prescribe are usually not available, I do not know where and if the patients buy them " (Interviewee 03)*

Generics were available for most of the medicines surveyed. For some medicines, only originator brands were available.

> *".....for naltrexone, we do not have the generic " (Interviewee 13)*

There are plans by NACADA to contract a manufacturer in India to produce generic naltrexone. This will increase its availability. The naltrexone will be used for "mass treatment " of Alcohol use disorders.

> *"....It is made in India, we want to see how it can be made available at a cheaper price. We want all the level 5 hospitals to have it. " (Interviewee 10)*

There are some drugs which are routinely used in other countries and have been found to be more efficacious but have not been registered for use in the country. This has hindered their availability for use in Kenya.

Regulations on the handling of opioids could be a hindrance to the availability of these medicines at lower levels of health facilities. These medicines are classified as Narcotics. For instance, methadone which is a synthetic opioid can only be available at facilities from level 4 upwards.

4.6.5 Affordability of medicines

The general opinion of the interviewees was that medicines for the treatment of SUDs were affordable with a few exceptions.

Their argument was that if the patient is able to spend money on the substance of abuse on almost a daily basis, he should be in a position to afford the medicine and avert the adverse health outcomes associated with the use of the substance. This can only be done if the health care worker manages to convince the patient of the benefits associated with abstaining from substance use.

> *"….. A patient spends Kshs. 100 on cigarettes every day. In 10 years, he would have spent 365,000 and increased his risk of getting cancer and cardiovascular diseases 10 times over. Nicorette (a form of cigarette for NRT) costs only Kshs. 350 and can be used for 2 weeks. When you do this kind of mathematics with the patient, they stop saying that medicines are unaffordable" (Interviewee 10)*

The lack of generics for some of the medicines has made the cost to be high and unaffordable to the lowest-paid government worker.

However, there are patients who cannot afford even the cheapest of the medicines. Some do not even have the transport to get to the facilities.

> *".....if the patient lives in Kayole and you want him to come for review in KNH, they might miss the appointment and the medicines because they do not have the Kshs. 200/- required as transport. These are people who live on less than Kshs.100 a day!" (Interviewee 04)*

Most of the payments for the medicines are by out of pocket (OOP). Considering that these are disorders that require long term management, the payments could be catastrophic and drive the patients to the poverty bracket.

Local insurance companies do not cover the cost of SUD treatment. A few international insurance companies cover the cost SUD treatment.

> *".....whenever we have a patient with SUD, they come here to find reasons why they should not pay" (Interviewee 03)*

There is an act of parliament that has compelled the insurance companies to recognize mental illness and include it in their list of diseases.

NHIF cover is also inadequate since it only covers bed charges. Whenever the medicines required are not at the hospital, the patient has to make their own arrangements and get them from outside.

4.6.6 Physical accessibility of treatment centres

There are 46 accredited rehabilitation centres in the country. Most are concentrated in the urban centres.

In Nairobi, there are 11 accredited centres. Most of them offer psychotherapy only. More centres should have their staff trained on offering pharmacotherapy.

There is need to empower nurses and other healthcare workers to provide rehabilitation services. NACADA is doing this via training of addiction professionals.

The services should be decentralized to all the health facilities from level 3 and above to be able to reach the large number of patients who are in those areas.

4.6.7 Effects of inaccessibility of medicines

Inaccessibility of medicines used in the management of SUDs has deleterious effects on patient management. There is delay in delivery of treatment when patients have to buy their own medicines. Increased morbidity was witnessed in facilities where medicines were out of stock for longer periods relapse rates were also higher according to the key informants.

4.6.8 Community support

Support from the community is integral in ensuring compliance with the medication, sustaining abstinence and prevention of relapse.

There is a 24 hour toll free line at NACADA which patients can call and get assistance on issues related to substance use, including treatment. Information such as where they can get medicines e.g. NRT is usually given. They are also advised on the accredited rehabilitation centres from which they can seek treatment.

The family of the patient needs to be counseled on how to handle the patient when at home..

> *".....we need to have family therapy day where they come to the rehab and are taught on how to take care of the patient when he goes back home (Interviewee 04)*

Support groups such as Alcoholic Anonymous (AA) and Narcotic Anonymous (NA) should be formed in all regions to provide psychosocial support.

CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Availability of Medicines

Results obtained in this study show that the essential medicines for substance use disorders are not readily available and may not be affordable to all patients requiring them. This compares well with other studies done in Kenya and other countries on the availability and affordability of essential medicines [32]. The availability of the medicines on the KEML 2010 was high in the private facility (Chiromo Lane) at 100% as compared to the availability in Mathari hospital at 50%. This compares with the study on availability of essential medicines for non-communicable diseases done in Sri-Lanka which showed an availability of 54 % in public facility and 89% in private sector [33]. There were no previous studies done on accessibility of medicines used in treatment of SUDs Kenya.

Stock outs were also common in Mathari, with 54% of the medicines surveyed being out of stock for the whole year. The average stock out period was 8 months. This period is quite long and could interfere with the treatment plan if patients are not able to purchase the medicines elsewhere. Possible explanations given for these rampant stock-outs are poor estimates of consumption and cash flow constraints. This was also reported in the study on access to essential medicines in Kenya done in 2009 [29]. The budgetary allocation for the pharmacy department did not seem to be adequate to support all year round supply of the medicines. There was also lack of mechanisms to counter 'outbreaks' or sudden surges in number of patients.

In Chiromo Lane, 7% of the drugs were out of stock for less than a month. The reason for this was given as unavailability of the drugs in the market at that particular time. Occurrences of stock-outs were rare in the private facility as medicines were procured promptly as per the patients' needs. The average stock out period was quite short at 0.5months.

The medicines that were not on the KEML 2010 were not available at all in Mathari. The proportion of medicines that were available at Chiromo Lane was 75%. There is need to update the essential medicines list to include newer molecules which have shown efficacy through evidence based studies [24].

Availability was also noticed to be dependent on the procurement procedures of the facility. In most public institutions, procurement is done bi-monthly based on a predetermined list of items and availability of funds. Medicines for SUDs were purchased only in 5 out of 12 months in that year. Of the drugs purchased, carbamazepine was purchased the highest number of times.

In Chiromo Lane, Medicines for the treatment of SUDS were purchased in all the 12 months of the year. This could be explained by the fact that purchases are made as per the patient's needs. A drug that is out of stock will be quickly made available once there is a prescription for it. This contrasts with the procurement procedure in Mathari which is not based on individual patient prescription. The difference accounts for the disparity in availability of medicines in the two facilities.

From the key informant interviews, availability was poor in public facilities due to lack of funds and also poor prioritizing. Prolonged public procurement bureaucracy, lack of funds and poor estimation of quantities were named as some of the reasons for the long periods of stock-outs. These reasons were also found in other studies on the availability of essential medicines [34].

Prompt purchasing, good estimation, availability of funds and buying medicines as need arises prevented the occurrence of frequent stock-outs in Chiromo.

SUDs and mental health in general are not regarded with the seriousness they deserve and there is therefore low allocation of funds to this department. Availability is further affected by the fact that most of the medicines are imported. From this study, the availability of locally manufactured medicines seemed to be generally better than that of imported medicines. Therefore, local manufacturing should be encouraged and supported to increase availability. However, further investigations should be done to ascertain the cause of the stock outs.

There were few expired drugs in the study sites. The incidence of expired medicines was less than 10%. This showed good commodity management by the personnel. Some of the medicines found to have expired in the facilities were donated close to their expiry date. This contravenes the guidelines to drug donations which advise against donation of drugs close to their expiry date. This can be achieved through better inventory control by the donor companies and the intermediaries and also communication with the recipient prior to donating the medicines [35].

5.1.2 Affordability of Medicines

Medicines in the Chiromo Lane were significantly more costly than those in Mathari. This study found that the cheapest medicine in Mathari required 0.3 days' wages to purchase while the most expensive medicine required 15days to purchase. In Chiromo Lane, the cheapest medicine required 1.5 days' of wage to purchase while the most expensive medicine required 50 days' of wage to purchase. This finding is supported by the findings in the study done in Kenya in 2009 on accessibility to essential medicines [32].

Medicines that cost more than a day's wage could be out of reach to many patients. There are patients who might not be in any form of employment and may not afford the medicines. About 50% of Kenyans live below 1.00 US $ a day according to a study done by commonwealth in 2011. Citizens in this group are unlikely to afford the medicines [36].

Payments for healthcare in Kenya were usually made by out of pocket payments (OOP). This could easily lead to non-compliance depending on the patient's financial status and could push the patient into the poverty bracket.

From the key informants, the general opinion was that some of the medicines are unaffordable and out of reach for the majority of the population. This was compounded by the fact that most local private insurance companies do not cover for the treatment of SUDs. Insurance companies should be compelled by law not to discriminate against patients with SUDs by not covering their treatment.

Accessibility of essential medicines for the treatment of non-communicable diseases is generally low in low-income countries [37]. However there has been tremendous progress in improving accessibility to other drugs such as antiretroviral drugs, which are more expensive to produce. Medicines for treatment of SUDs are mostly off-patent and therefore cheap to produce. Urgent measures should be taken to improve the availability and affordability of medicines for the treatment of SUDs.

5.1.3 Factors Influencing Accessibility of Medicines for the Treatment of SUDs

Proper planning and budgeting was reported as an important factor in influencing accessibility to medicines. Sound methods for quantification of pharmaceutical commodities are important in ensuring that products do not run out of stock. These methods for estimation of quantities to

order such as morbidity and consumption –based methods are scarcely employed. The use of available statistics on the prevalence of SUDs should inform the proportion of the budget allocated for their treatment. Long procedures in public procurement have led to delays in the provision of the required medicine. Suppliers who do not deliver medicines ordered on time lead to unwarranted stock-out periods.

The KEML 2010 has contributed to the unavailability of medicines in facilities that have to use it. Medicines which are efficacious and are being used in other settings have not yet been included in this list. Some medicines have not yet been registered by the regulator for use in the country hence hindering their accessibility.

5.1.4 Limitations

The study was successfully carried out as planned. However, there were some limitations which could affect the generalizability of these results

Since the other rehabilitation centres or hospitals in Nairobi do not provide pharmacotherapy for substance use disorders, only two hospitals were included in the study. It is acknowledged that a larger sample size would be more precise and provide more information, but would be more costly and time consuming.

At Mathari hospital, data on Methadone was not accessed. This is because the project is still in its preliminary stages and the sponsor has not yet allowed studies on the same.

The interviewees could have given biased information due to the presence of the interviewer. Some interviewees were not available for the interviews despise having booked appointments prior to the day of interview.

This study was not intended to give detailed analysis on accessibility of pharmacotherapy for SUDs but as an overview of the situation in Nairobi which could then give an indication of the situation in the country. This would then help in policy analysis and designing of appropriate interventions on improving access to medicines for the treatment SUDs.

5.2 Conclusion

Most of the essential medicines for the treatment of SUDS were available at both study sites. In Mathari, the availability stood at 54% while in Chiromo Lane it was 100%. There were frequent stock-outs of the essential medicines at Mathari, which could affect the accessibility of the medicines by the poor who would not afford to buy them at a private facility. Medicines found to be efficacious for the treatment of SUDs but not on the KEML 2010 were completely not available at Mathari although they were available at Chiromo Lane. Most of the medicines in Mathari were affordable, costing less than a day's wage with exception of a few which cost more than 30 days' wage and are therefore out of reach for most of the patients.

5.3 Recommendations

i. The government should ensure that hospitals have enough budgetary allocations to purchase essential medicines all year round and avoid stock-outs.

ii. KEMSA or any other designated distributor to supply the medicines ordered promptly and in the requested quantities to prevent stock-outs.

iii. The pharmacists tasked with preparing the list of medicines to be ordered should ensure that quantities ordered are calculated using a valid method such as consumption-based or morbidity-based methods.

iv. Medicines should be selected based on their cost-effectiveness

v. The Pharmacy and poisons board to expedite the registration of some key medicines to enable them to be availed in the Kenyan market.

vi. The Ministry of Health to update the KEML 2010 to include newer and more efficacious drugs currently available.

vii. The Ministry of Health under the division of mental health to prepare and circulate national guidelines or treatment protocols to all the practitioners' country wide.

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APPENDICES

APPENDIX 1: QUESTIONNARES/ INTERVIEW GUIDES

a) HOSPITAL: MEDICAL SUPERINTENDENT/PHARMACIST IN-CHARGE/FACILITY IN-CHARGE

1. Do you have guidelines for the management of SUDs?\
2. What drugs are on the KEML 2010 that are used for management of SUDs?
3. On average, how many patients do you receive in a month for SUD treatment?
4. Where do you get your drugs from?
5. Are there arrangements for acquiring drugs if the source given in 4 above does not deliver?
6. How do patients pay for the drugs?

b) CHEMISTS

1. Do you stock any drugs for the management of SUDs?
2. If yes, which drugs? Give both the originator and generic products. If no, why?
3. How much do the drugs cost?
4. On average, how many patients do you see in a month who require drugs for the treatment of SUDs?
5. Have you encountered any problems in acquiring any drugs used for treatment of SUDs?
6. Have ever had to make a special order for a drug? (import)
7. Do you have any expired medicines in this category?
8. What is your average stock out duration?

c) PSYCHIATRISTS/CLINICAL PSYCHOLOGISTS

1. On average, how many patients do you see in a month for SUDs

2. Do you have the treatment guidelines for management of SUDs?

3. What drugs do you commonly prescribe for specific conditions?

4. Are the drugs in 3 above available and affordable? What are the challenges in accessing them?

5. Are you aware of any new medicines not on the KEML 2010 that are effective in the treatment of SUDs?

6. What are your recommendations?

APPENDIX 2: CONSENT EXPLANATION FORM

Dr. Clarice AmbaleAkatsa

P.O Box 19-90100

Machakos.

I am a post graduate student pursuing a Masters degree in Pharmacovigilance and Pharmacoepidemiology at the School of Pharmacy, University of Nairobi.

For my Masters project, I will be undertaking a study on "Assessment of the accessibility of medicines used in the treatment of substance use disorders".

You have been selected to participate in this study. Your participation is entirely voluntary. Refusal to participate will not lead to any penalty. Your answers will be treated with utmost confidentiality and be used for academic purposes and to inform policy.

Apart from the time you will spend for this interview, there are no other risks associated with this study. No names will be mentioned in the research reports and publications. The voices in the tape recorder will be masked so as to prevent the identity of the interviewees. The reports will have possible identifiers such as names, addresses and tittles removed .Instead, codes will be used.

If you have any questions or concerns, please feel free to contact me on 0723629157 or KNH/UON ethics committee on 2726300 extension 44102. This committee reviews research studies in order to protect participants.

Your co-operation and support is highly appreciated.

APPENDIX 3: PARTICIPANT AGREEMENT

I have fully understood the objectives of this study and hereby sign as a show of my willingness to participate as a volunteer.

Signature……. Date…….

Witnessed by:

Signature……. Date…….

If you have any questions or concerns, please feel free to contact:

The researcher Dr. C. Ambale on 0723629157 or

My lead supervisor: Dr. A. K Sinei on 0722381639

KNH/UON ethics committee on 2726300 extension 44102.

APPENDIX 4: BIODATA OF THE KEY INFORMANTS

	Professional background	Interviewee Number	SEX	YEARS OF EXPERIENCE
1.	Consultant psychiatrist	001	M	10
2.	Consultant psychiatrist	002	M	>10
3.	Consultant psychiatrist	003	M	>10
4.	Consultant psychiatrist	005	F	5-10
5.	Officer from NACADA	010	M	5-10
6.	Officer from MOH	007	M	>10
7.	Clinical psychologist	004	M	>10
8..	Clinical psychologist	006	F	>15
9.	Medical Superintendent	008	M	10-15
10.	Hospital administrator	011	M	5-10
11.	Pharmacist in-charge	012	M	5-10
12.	Pharmacist in-charge	009	F	5-10
13.	Retail pharmacist	013	M	>10

APPENDIX 5: PERMISSION TO COLLECT DATA

MATHARI HOSPITAL

CLEARANCE TO UNDERTAKE PRACTICUM/EXPERIENCE IN MATHARI HOSPITAL

TO: PHARMACYST INCHARGE DATE: 23/3/2015

This is to inform you that (Name/s of Student) DR. CLARICE AMBALE

From (Name of training institution) UNIVERSITY OF NAIROBI

Total hours/period to be covered:-

1. Rehabilitation unit ; from: _____ to: _____
2. Comprehensive Care Centre; from: _____ to: _____
3. Wards (_____); from: _____ to: _____
4. Clinics ----------); from: _____ to: _____
5. PHARMACY 23/3/2015 2 WEEKS
6. ..... ---------- ----------
7. ..... ---------- ----------
8. ..... ---------- ----------
9. ..... ---------- ----------

Has/have been cleared by the office of the Medical Superintendent to start/continue practical experience at Mathari Hospital.

Please accord them/him/her the necessary support.

Thank you.

MATHARI HOSPITAL - C.M.E.D. Date..... Sign..... P.O. Box 40663, NAIROBI

In Charge C.M.E.D

APPENDIX 6: KNH/UON ERC APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/66

17th February, 2015

Dr. Clarice Ambale Akatsa
Dept. of Pharmacy and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Dr. Clarice

Research Proposal: Assessment of the accessibility of medicines used in the management of substance use disorders in self-selected hospitals (P721/12/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 17th February 2015 to 16th February 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH/UON-ERC
The Dean, School of Pharmacy, UoN
The Chairman, Dept of Pharmacology and Pharmacognosy, UoN
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