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Cost drivers for Medically Assisted Treatment in HIV control in Nairobi, Kenya.

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DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

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Approval

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ABSTRACT

An estimated 18% of people who inject drugs in Kenya are infected with HIV. Medically Assisted Treatment with methadone offers promise as a HIV prevention strategy among this population. The costs of Medically Assisted Treatment services in two Kenyan public facilities were studied from an economic health care provider perspective. The objectives included: to determine the startup costs of setting up a medically assisted treatment clinic; to determine the annual recurrent costs and; to determine the annual unit cost per patient. The study utilized the cost of production theory. Data was collected from Ngara MAT Clinic and Mathari Teaching & Referral Hospital. Data were collected at the facility level using a micro-costing approach utilizing a modified version of the Drug Abuse Treatment Cost Analysis Program tool. Results showed that the total start-up costs ranged between $213,471.64 and $533,412.99 across the two sites with the cost of setting up a subsequent clinic being 50% less. An additional $316,294.77 and $ 365,080.32 were determined as the total annual recurrent costs necessary to run the program within the existing infrastructure for the different clinics. The annual per-patient cost of providing Medically Assisted Treatment ranged from $ 532 to $590 across the 2 sites, with an average cost of $562. This was lower than costs reported in upper and middle-income countries. Consistent with other studies, the main cost driver for Medically Assisted Treatment was personnel costs accounting for 59% of the total costs. For policymakers, the results of this study offer an opportunity to revisit and strengthen policies on Drug abuse prevention and financing for HIV prevention programs and Medically Assisted Treatment in particular.

Keywords: Medically Assisted Treatment, Methadone, Sub-Saharan Africa, Kenya, HIV Control, Cost

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral Treatment
CDC	Centre for Disease Control
COVID-19	Coronavirus Disease 2019
DATCAP	Drug Abuse Treatment Cost Analysis Program
FTE	Full Time Equivalent
HIV	Human Immunovirus
LMICS	Low- and Middle-Income countries
MAT	Medically Assisted Treatment
MAT	Methadone Maintenance Treatment
NACC	National AIDS Control Council
NASCOP	National AIDS STIC Control Program
OST	Opioid Substitution Therapy
PEPFAR	The President's Emergency Plan For AIDS Relief
PWIDS	People Who Inject Drugs
SASCAP	Substance abuse services cost analysis program
STI	Sexually Transmitted Illnesses
TB	Tuberculosis
TRH	Teaching and Referral Hospital
UMB	University of Maryland Baltimore
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
USA	United States of America
USAID	United States Agency for International Development
WHO	World Health Organization

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CHAPTER ONE: INTRODUCTION TO THE STUDY

1.1 Introduction

This chapter presents a background to the study, the problem statement, research objectives, research questions, rationale, and scope of the study.

1.2 Background of the Study

PWID refers to people who inject drugs (or psychoactive) chemicals for non-medical reasons (WHO 2008). These include opioids, stimulants of the amphetamine type, cocaine, hypno-sedatives, and hallucinogens (WHO, 2008; NIDA, 2014). Heroin is the primary drug used by PWID, according to the National Institute on Drug Abuse (NIDA) (2014). In Kenya, 97% of AIDS patients take heroin (Tun et al., 2015). An estimated 18,000 individuals in Kenya use or inject heroin and other drugs (CDC, 2015).

People who inject heroin and other narcotics are in danger of being infected with human immunodeficiency virus (HIV), hepatitis B and C, and other blood-borne infections through sharing needles (NIDA, 2017). In many regions, sharing infected needles is a primary source of HIV transmission (WHO, 2008). Up to 10% of global HIV infections are attributed to unsafe injecting drug use, including heroin, according to the World Health Organization (WHO), and if Sub-Saharan Africa is removed, up to 30% of global HIV infections are attributed to dangerous injecting drug use (WHO, 2008).

In Kenya, it is estimated that 18-30% of PWID are HIV-positive, whereas the prevalence of HIV in the general community is 5.6%. (CDC, 2015). In comparison to male injecting drug users (16.0%), the HIV prevalence among female injecting drug users (44.5%) is nearly three times greater (United Nations Office on Drugs and Crime (UNODC) 2015). Failure to address injection drug use and HIV risk among PWID in this region may negatively affect attempts to lower the prevalence of new HIV cases (Peterson et al., 2013).

An increasing body of evidence demonstrates the efficacy of medication-assisted treatment (MAT) as an HIV prevention tool for PWIDs(Connock et al., 2007; MacArthur et al., 2012). Unfortunately, access to MAT is inhibited by various factors, including inadequate funding.

The HIV program in Kenya has majorly relied on donors to fund MAT services as a vertical program(McDade et al., 2021). In light of the COVID 19 pandemic and other global health transitions such as shifts in diseases, demography, development assistance for health, and domestic health financing, the future funding for HIV remains uncertain (Kates et al., 2019; Yamey et al., 2019).

Therefore, countries need to finance their own response more efficiently and cost-effectively. More information is needed about the costs of MAT programs so policymakers can advocate and plan for the expansion of these programs. Estimating the unit costs for MAT can be used to project future resource requirements as countries scale up MAT interventions.

1.2.1 Substance Abuse Burden

Substance abuse has become a critical international issue of concern for the health system in the last two decades. According to the United Nations Office of Drugs and Crime (UNODC), there were 269 million people who abused drugs in 2018, up 30 percent from 2009, with adolescents and young adults accounting for the largest share of users. Amongst all abused substances, opioids, usually used via injecting, have been reported to cause the most harm accounting for 75% of all drug abuse-related deaths (Bonnie, 2017; Harm Reduction International, 2020; UNODC, 2020).

Regionally, it is estimated that by 2050 there will be about 14 million more people abusing drugs in sub-Saharan Africa, with East Africa projected to experience over a 30% increase (Donnenfeld, 2019). Kenya is witnessing rapid growth in the population of people who inject drugs, estimated to be 30,500 in 2017. Mirroring global trends, most abusers in Kenya are aged between 18 to 25 years (Kisilu, 2016; Ministry Of Health, 2017; NACADA, 2016).

1.2.2 Health and Socio-economic Effects associated with substance abuse

The physical and psychological effects of substance abuse have been well studied (Fox, 2013; Hensing, 2012; Newcomb & Locke, 2005; Schulte & Hser, 2014; Tsai, 2019). Deaths due to drug use disorders have risen sharply over the past ten years, with opioids accounting for more than half of all drug abuse-related deaths and 42 million healthy life years lost

(Global Burden of Disease Collaborative Network, 2019; Murray et al., 2020). Heroin, the most widely abused opioid, is usually used through injections that increase the risk of transmission of HIV, Hepatitis B, and C (Strain, 2016; UNODC, 2020). Additional risks for these diseases result from substance-induced impaired judgment causing abusers to engage in risky behaviors such as unprotected sex, having sex with multiple partners, or trading sex for money or drugs (Strain, 2016; UNODC, 2020).

Drug abuse also correlates to increased drug-related criminal activity, social exclusion, and family disintegration and is associated with a lack of access to health care (Drug Enforcement Administration, 2019; Sarker & Faller, 2016). It imposes high economic costs on society associated with healthcare, work absenteeism, crime, and premature death (Hall, 2006; Whiteford et al., 2013). For instance, the American National Institute on Drug Abuse estimates the costs of drug abuse in the USA to be more than $740 billion a year. Notably, 55% of this economic burden is borne by those who do not use these substances (Florence et al., 2016; Hagemeier, 2018; Kolb, 2018; Ropero-Miller & Speaker, 2019).

1.2.3 Substance Abuse treatment interventions

The World Health Organization (WHO) recommends medically assisted treatment (MAT) with either methadone or buprenorphine. MAT involves providing oral methadone doses to heroin-dependent patients to reduce cravings for heroin. MAT has been recognized as being effective in the reduction of HIV infections. Indeed, it is estimated that 130,000 new HIV infections outside of sub-Saharan Africa could be prevented every year if access to MAT was sufficient (UNAIDS, 2019). Emerging evidence from neighboring country Tanzania, one of only two settings in Sub-Saharan Africa to implement MAT aside from Kenya, demonstrates feasibility and effectiveness (Bruce et al., 2014; Lambdin et al., 2014).

1.2.4 Kenya MAT Program

MAT with methadone was introduced in Kenya in 2014, as part of national policy initiatives to prevent HIV (Rhodes, 2018). The Programme is sponsored by the United States (U.S.) President's Emergency Plan for AIDS Relief (PEPFAR), through the Center for Disease Control (CDC) and the United States Agency for International Development (USAID), with implementation support from the University of Maryland and the United Nations Office of

Drugs and Crime (UNODC). The services have been scaled up to 8 clinics with approximately 6,000 users enrolled. These clinics provide free integrated services for PWID, including opioid substitution with methadone; Individual and group counseling; HIV testing services; Antiretroviral treatment (ART) and diagnosis and management of viral hepatitis. Patients have to visit the clinic daily for dosing of methadone but have scheduled appointments for other services where they see a clinician or counselor or visit the laboratory. The University of Maryland supports the 2 MAT clinics in Nairobi, the Ngara MAT clinic in Ngara health Centre and the Mathari MAT clinic in Mathari Teaching and referral hospital.

1.3 Problem Statement

The widespread access to ART has reduced HIV incidence from 3.2/1000 to 1.8/1000 from 2014 to 2017, and a 52% reduction in HIV-related deaths in Kenya (National AIDS Control Council, 2018). Despite this progress, the HIV burden remains high among key population subgroups, including PWIDS. PWIDs in Kenya have an HIV prevalence of 18.3%, nearly four times that of the general population (NASCOP, 2016). This sub-population is recognized as one of the drivers of ongoing HIV transmission associated with high rates of new infections in the Nairobi and Mombasa regions (Kurth et al., 2015, Gelmon et al., 2009). In this context, there is a need to scale up harm reduction services such as MAT with methadone to prevent HIV. Methadone has been documented to reduce injecting drugs by 60% thus reducing the risk for HIV acquisition and transmission (Metzger & Zhang, 2010). Improving access to methadone has also been shown to result in the prevention of disabilities and death, enhance workforce productivity and reduce costs of crimes.

Since 2014, Kenya has utilized donor funds to scale up the MAT program as part of HIV prevention efforts. The chronic nature of methadone treatment in the context of decreasing external resources for HIV programs threatens the sustainability of this program. For instance, global funding for HIV programs declined by 7% between 2015 and 2016 (Kates et al., 2019). This is compounded by the limited domestic resources and competing emerging threats such as the COVID-19 pandemic. There is increasing emphasis on countries finding more efficient and cost-effective ways to finance their HIV response, including MAT. This calls for discussions on the costs associated with treatment and alternative funding options.

While measuring and improving drug treatment outcomes have been relatively high on the research agenda, the cost of treatment has received far less attention. Available studies on the cost of MAT services are largely skewed towards developed countries' settings, such as in the USA or emerging economies like Malaysia. Their results are context-specific to their regions and difficult to be applied or generalized to the Kenyan context. Addressing this information gap will provide accurate information on the costs of service provision in low-resource settings like Kenya, thus aiding in resource planning and allocation. The results will also inform the programming of similar interventions in Kenya and globally that are seeking to transform from donor-funded to sustainable models

1.4 Research Objectives

1.4.1 Main objective

The main objective of this study was to determine the cost drivers of medically assisted treatment in Nairobi, Kenya, from the perspective of the health care payer

1.4.2 Specific objectives

1. To determine the startup costs of setting up a medically assisted treatment clinic
2. To determine the annual recurrent costs incurred in implementing medically assisted treatment
3. To determine the annual per-patient cost of medically assisted treatment

1.5 Research questions

1. What are the costs incurred to start up a medically assisted treatment clinic?
2. What are the recurrent costs of medically assisted treatment in a year?
3. What is the annual per-patient cost of providing medically assisted treatment with methadone?

1.6 Scope of the study

This study sought to assess the costs of MAT treatment in Kenya from a health care payer perspective. The geographical scope of this study was limited to Nairobi, the county with

the highest burden of HIV/AIDs in the country. The respondents were MAT clinic leads, program administrators, and healthcare workers from the two MAT clinics.

1.7 Rationale of the study

The UMB-supported program is currently in its last year of implementation, having set up the initial MAT clinic in Kenya in Mathari in 2014 and the Ngara MAT clinic in 2017. Like other similar programs in the region, the program has been faced with declining donor funds over the year; for instance, donor funds for the MAT program declined by 39% ($ 430,396 2020 to $ 261,248 2021).

Despite successfully documenting and reporting patient treatment outcomes, the costs of providing these effective interventions remain largely unknown. Cognizant of the need for sustainability and transition of services to the government, this study aims to generate cost data essential for informing the county director of health and other policymakers at the Ministry of Health (MOH). First, the study will assist in annual budgeting in terms of estimating costs for specified numbers and types of personnel, facilities, equipment, and other costs necessary to provide MAT services in order to give a view of the cost required to establish a MAT clinic. Secondly, the cost data generated will aid in determining cost drivers and inform efficient use of scarce resources for optimal benefit. Thirdly, this study will help inform other countries wishing to set up MAT clinics on what costs to anticipate and enable them to plan better. Additionally, the cost data generated can be used as a basis for future cost-effectiveness analysis evaluating whether the intervention provides good value for money.

1.8 Definition of key concepts

Addiction: A complex illness characterized by compulsive and at times, uncontrollable drug craving, seeking, and use that persist even in the face of extremely negative consequences (NIDA, 1999). A chronic, relapsing brain disease with a range of physical, behavioral, social, and public health manifestations. Difficult to control due to compulsive drug use and craving, leading to drug-seeking and repetitive use, even in the face of negative health and social consequences. In this study, addiction means the People Who Inject Drugs (PWID) and cannot control not using them.

Costing: The term "costing" used in this study refers to estimating the cost of health interventions or services (Anna Vassall et al, 2017).

Drugs or Psychoactive substances: In this study, this will mean any substance that, when ingested, alters the mind or mental processes.

Medically Assisted Therapy (MAT): Treatment for persons with opioid use disorder by giving prescribed medication daily under medical supervision supported by psychosocial interventions. It may last for several months to many years. In Kenya, methadone and buprenorphine are the recommended medication for MAT. MAT is provided as part of a comprehensive package of health services that include: the prevention, screening, diagnosis, and treatment for HIV, tuberculosis (TB), viral hepatitis, and STI; targeted information, education, and communication, condom promotion, psychosocial support, legal aid, etc.

Methadone: Synthetic opioid agonist drug for maintenance therapy of persons with opioid use disorder. Most widely used treatment for opioid use disorder globally; administered orally once daily under medical supervision. Most effective when the dose is above 60 mg and for an extended duration. Formulated as tablets or syrup, included in WHO Model List of Essential Medicines, XIV Edition.

Opioid Drugs: Generic term for a class of drugs that act on mu-receptors of the brain to relieve pain and produce a sense of well-being. Common opioid drugs include.

- Opiates: these are naturally occurring derivatives of opium poppy which activate opiate receptors of the brain They include: heroin, morphine
- Opioids are synthetic medications that also act on opiate receptors in the brain. They include codeine, pethidine, methadone, buprenorphine, dextropropoxyphene, and pentazocine.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter reviews existing literature on the cost of Medically Assisted Treatment (MAT); and HIV prevention intervention for people who inject drugs (PWIDS). It covers the theoretical review and approaches to costing, empirical review, and conceptual framework gained from reviewing the literature.

2.2 Theoretical review

This study is grounded in the Cost of Production Theory. It utilizes the approaches outlined in the Global Health Costing Consortium's Reference Case for Estimating the Costs of Global Health Services and Interventions (Anna Vassall et al, 2017), providing a set of standardized principles and methods for collecting and evaluating cost data from a provider perspective. These guidelines have been adopted by WHO and UNAIDs in costing TB and HIV services (Cunnama Lucy, 2019; UNAIDS, 2011).

2.3.1 The cost of production theory

This study is anchored on the economic theory of the cost-of-production which states that the price of an object is determined by the sum of the cost of the resources that went into making it. The cost can comprise any of the factors of production (including labor, capital, or land) and taxation. In Health economics, health care is viewed as a good or service that is produced. The inputs to this production process are resources such as personnel (often referred to as labor), equipment and buildings (often referred to as capital), land, and raw materials. The output of a process using health care inputs, such as health care professionals, therapeutic materials, and clinics, could be an amount of health care of a given quality, etc. The cost of production in health is, therefore, the total of all the inputs used to produce health from the capital to human resources of health, amongst others.

The theory is applicable in the study in that determination of set up costs, recurrent costs and annual costs per patient is a factor of the cost of production theory.

2.3.2 Costing Methods

According to Drummond, three stages can be usefully distinguished in costing identification, measurement, and valuation of resources. (Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, 2015).

2.3.2.1 Identification of resource items

The first step involves the Identification of resource items and units of resources utilized to deliver a particular service or produce particular goods. This decision depends on the perspective of the study and the type of cost being assessed.

The perspective of the study

There are different perspectives utilized in health costing studies, but most literature broadly classifies costs as societal or provider. Vassal, however, argues for the need for additional justification and listing of the groups/payers whose cost has been captured in the estimate, for example, a societal perspective should specify whether it is the cost to the client only or more broadly to the household, community, or society. In the same way, a provider perspective should specify whether both health and non-health providers are included(Anna Vassall et al, 2017).

There have been increasing calls to low- and middle-income countries to adopt societal perspectives when conducting economic studies. Chalkidou, (2018), among other researchers disputes this notion and argues that one size does not fit all and that the one who pays must set or have a major say in setting the perspective. Even though the societal perspective offers decision-makers a full set of the costs and consequences of alternative actions; practical political and infrastructural constraints may limit this perspective and data availability, which may vary from one setting to another. Hence, the choice of which perspective to take should be guided by first, the objective of the study, second, the intended user or use, and third, the feasibility based on available resources and data (Chalkidou et al., 2018).

Financial and Economic costs

Financial costs refer to the resources that are 'paid' for i.e. payments that the program makes. Economic costs, on the other hand, include the financial costs and also consider the value of

the opportunity forgone and other costs not paid for by the program, such as volunteer time and donations (Anna Vassall et al, 2017). The choice of whether to use financial, economic or both approaches depends on the objectives of the analysis. Financial costing is used where there is a need to compare expenditure against budget allocations or ascertain the affordability of the project; On the other hand, economic costs are used where the purpose of the study is to address project sustainability or to consider replicating the project elsewhere. In this case, all costs of all resources consumed are recorded whether or not they were paid for from the project budget(Lepadatu, 2012). As this study seeks to inform project scale-up and sustainability, it will take into account the costs of donated goods and services. This study, therefore, utilized the economic costs approach.

2.3.2.2 Measurement

The second step involves the measurement of resource consumption in natural units. This step usually involves the identification of cost items and then measuring their volumes through either gross costing, where input use is estimated in total or micro-costing, where the analyst estimates the usage of each input separately. Researchers such as Hendriks et al. (2014), who have compared micro-costing vis gross costing approaches largely suggest that the micro-costing is likely to be more accurate due to the assumption that it captures the resources used more comprehensively(Hendricks, 2014). Other researchers argue that the data required for gross costing may be easier to access and that micro-costing is more time demanding, specific to the setting, and expensive to undertake (Wordsworth, 2005)

2.3.2.3 Valuation

The next step that follows is valuation which encompasses placing a monetary value on the resource items and calculating the unit costs of a particular service. Two main approaches to valuation exist; bottom-up and top-down. The top-down approach relies on comprehensive sources and divides by the total number of patients. In the bottom-up approach method, patient utilization data needs to be multiplied by unit prices, leading to individual patient cost estimates. Therefore, such detailed, bottom-up data collection on resource use is recommended as often as possible. Chapko and other researchers searched for agreement between bottom-up and top-down methods and highlighted each method's strength for assessing different cost constructs. Top-down is usually simpler to perform since it relies on overall expenditure rather than a detailed picture of all the input units contributing to providing a particular service and their respective costs. However, this approach has been largely criticized as being less accurate due to equating expenditure with cost. Additionally,

different input types' specific contributions towards a particular service's cost may not be identified. Bottom-up on the other hand, is costly. Therefore, researchers conducting cost analyses need to carefully consider the purpose, methods, characteristics, strengths, and weaknesses when selecting a method for assessing cost (Chapko et al., 2009). Hendricks further proposes that a combination of top-down and bottom-up approaches should be used in low and middle-income countries depending on the importance and data availability for each ingredient in costing(Hendriks et al., 2014)

2.3.3 Classification of costs

2.3.3.1 Classification based on inputs

The main type of cost classification is by inputs. Inputs are considered as either recurrent items (those that are used up in a year and are usually purchased regularly) or capital items (those that last longer than a year)(UNAIDS, 2011). This is summarized in Table 2.1.

Table 0.1 Classification of costs

Type of Cost	Components
Capital costs	Vehicles, Equipment, Buildings, Training, Non-recurrent social mobilization activities, Start-up activities: activities that are likely to last the lifetime of the project
Recurrent costs	Personnel, Supplies, Vehicles, Operation and Maintenance, Buildings, Training, Operating costs

Source: UNAIDS Costing Guidelines for HIV Prevention Strategies (UNAIDS, 2011)

2.3.3.2 Classification by traceability: Direct and Indirect Costs

Costs are termed direct costs when they are directly required or are traceable to a particular product or service. On the other hand, indirect costs are not easily identifiable or traceable to specific products or services. Indirect costs represent the value of economic resources lost because of morbidity or mortality. In health, these costs are further broken down into three categories we use for quantifying health care interventions. These are direct medical or health care costs, direct non-medical, and indirect costs. Direct medical costs go directly into the provision of care such as supplies and personnel while direct non-medical costs of resources are related to the provision of care but do not go directly into the provision of healthcare. Examples of direct non-medical costs include overhead and utilities for the hospital such as water and electricity etc. On the other hand, indirect costs are the costs of

lost patient productivity such as the time lost seeking care or mortality loss. Depending on the objectives of the economic analysis or the decision problem, decision-makers may be interested only in direct, indirect, or total costs. Most studies reviewed on costing methadone treatment incorporated direct medical costs (Burgos et al., 2018; Kirtadze, 2012; Mogaka et al., 2021; Reimer et al., 2019). Since our study perspective is from the payer, we will incorporate the direct costs of MAT.

2.3.3.4 Classification by behavior: Fixed and Variable Cost

Fixed costs are those that do not vary with changes in output and would accrue even if no output was produced. Variable costs on the other hand refer to costs that change proportionately to the level of output while total Cost is the sum of fixed, variable, and semi-variable costs.

2.3.4 Standardized costing data collection tools

There have been increased calls for economic studies to consider standard economic costing methods capturing costs across implementation framework phases to support comparisons and replicability(Bowser et al., 2021).

The DATCAP was the first standardized approach to collect resource use data and estimate the economic costs of substance abuse treatment for individual programs and clients. The DATCAP has undergone several transformations since the early 1990s to improve clarity, coverage, respondent burden, electronic entry, and precision. The DATCAP family of instruments (Program, Brief, and Client) enables researchers and treatment providers to estimate treatment costs more accurately and compare different programs (French et al., 2008). The instrument is designed to collect and organize detailed information on resources used in service delivery and their associated dollar cost. Resource categories include personnel, supplies and materials, contracted services, buildings and facilities, equipment, and miscellaneous items. The instrument also collects information on program revenues and client case flows. Data are collected directly from program officials with the assistance of a researcher trained to administer the DATCAP. An instruction manual is also provided to program personnel and the actual data collection instrument. Total annual economic costs are based on the data reported for the six resource categories. Estimates for average (per client) weekly and episode costs are calculated from program data on the average daily census, length of stay, and total annual cost. The first summary of all DATCAP studies

was published in 2003 covering 85 substance abuse treatment programs (Roebuck et al., 2003)with another summary published in 2008 (French et al., 2008) covering more than 100 sites. The current edition of the DATCAP tool can be found at www.DATCAP.com.This study, used the standardized DATCAP tool for data collection as it provides standardized estimates, it is based on established economic cost methods, more detailed than the other approaches.

2.3 Empirical Review

2.4.1 Costing of Medical Assisted Treatment services

At the time of this review, there was a paucity of data from African countries with most of the available literature reviewed being predominantly from the high and upper-middle-income countries. Of exception is a recent publication by Mogaka et al. who estimated the cost of providing methadone treatment to one client to be approximately KSh. 4500 (US$ 45) per month. The study used a top-bottom approach with the researcher summing up the costs of salaries, methadone, and consumables and dividing this by the number of patients. Although the costs were comparable with other low- and middle-income countries, the study did not take into account all costs included in provided methadone, such as capital and set up cost, equipment purchase and maintenance cost, training costs, monitoring and evaluation. This study also did not estimate the costs of all services under MAT, such as individual and group therapy sessions that are part of the WHO MAT package. The researcher's perspective was outlined as the government, implementing partner, and the patient but the methods and results sections did not highlight these variables e.g., program costs such as administrative personnel incurred by the implementing partner(Mogaka et al., 2021).

Burgos et al adopted an economic health care provider perspective. They applied an ingredients-based micro-costing approach to quantify the average monthly cost of OST (methadone maintenance) provision at two providers (one private and one public). Outcomes studied were cost per OST contact and cost per person month of OST. The study estimated the daily cost of providing methadone to be between $3.12-5.90 in Mexico, a slightly higher figure than the Kenyan study. However, the study included capital costs and a different methodology (Burgos et al., 2018).

In another study conducted by Kirtadze and the health policy project in Georgia, the unit costs of MAT provision was assessed from the perspective of two service providers; the Ministry of Labor, Health, and Social Affairs (MOLHSA) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM). The study compared average unit costs between two years (2009 and 2010) and found a minimal increase. Unit costs increased only slightly at MOLHSA facilities from 229 GEL ($1331) per month to 236 GEL ($137) per month. At GFATM sites, the monthly per-patient cost of MAT rose slightly between 2009 and 2010 from 217 GEL ($126) to 229 GEL ($133)(Kirtadze, 2012)

Afriandi et al assessed the cost of hospital-based methadone maintenance treatment (MAT) for injecting drug users (IDUs) in Indonesia over a one year observation period from 2006–2007. Similar to the study by Burgos (2018), service delivery costs were estimated based on a micro-costing approach, although, unlike Burgos, the researcher's perspective was societal. This study found the total annual societal costs of running the MAT clinic to be US$123,672 or US$7.57 per client visit. Of total costs, patient costs established the largest share (65%), followed by that of central government (20%), and the hospital (15%) (Afriandi et al., 2010).

In Canada, Zaric et al estimated the cost of providing methadone maintenance treatment in Ontario, Canada, from the public payer's perspective by analyzing a database of all patient clinic visits, laboratory tests for urine toxicology screening, and methadone scripts from a group of methadone clinics in Ontario. The total cost was comprised of physician billing (9.8%), pharmacy costs (39.8%), methadone (3.8%), and performing urine toxicology screens (46.7%). The average cost per day for treatment was $15.48(Zaric et al., 2012).

In China, the country with the most MAT users, Xing et al analyzed the cost and cost-effectiveness of the methadone maintenance treatment (MAT) program in Dehong prefecture, Yunnan province, China. Program costs were collected retrospectively following standard methods using an ingredients methodology. The cost for each participant treated in MAT clinics was about $9.1–16.7 per month(Xing et al., 2012).

Roebuck et al conducted a summary of the results from 85 substance abuse treatment programs that had completed the Drug Abuse Treatment Cost Analysis Program (DATCAP)

in the USA completed over 10 years in the USA, the authors grouped the DATCAPs into 9 treatment modalities and normalized costs to 2001 dollars. The average weekly economic cost per client ranged from $82 per week for outpatient drug court interventions to $1,138 per week for adolescent residential treatment. Labour was overwhelmingly the most utilized resource across all modalities, ranging from 48% to 88% of the total economic cost (Roebuck et al., 2003). Later in 2008, Michael T. French updated the data to include 110 substance abuse treatment programs that had completed the Drug Abuse Treatment Cost Analysis Program in the USA and estimated the weekly cost of Methadone maintenance to be between $87 – $112(French et al., 2008).

2.4.2 Components of Medical Assisted Treatment costs

The European Monitoring center for drugs and drug addiction studied the cost and financing of drug treatment in Europe. Treatment cost data were divided into three cost categories: labor costs, non-pay costs, medications, and indirect costs. Labor costs were the largest component accounting for almost half (48 %) of all expenditure while Non-pay elements i.e. medications, medical materials, and laboratory consumables, accounted for about one-third of the overall cost. Indirect costs such as overheads accounted for, on average, about 15 % of the overall costs of substitution treatment. (EMCDDA, 2011).

Similar findings were observed in a study carried out by Kirtadze where three inputs—personnel, drugs/medical supplies, and utilities accounted for a major portion of costs associated with running MAT programs in Georgia. The most significant budget item was the cost of personnel i.e. salaries of clinical and support staff (Kirtadze, 2012). Likewise, a recent study done in Kenya by Mogaka et al., (2021), found that salaries accounted for 86.4%, methadone 9.6%, tests, and other consumables at 4% of all the direct costs of MAT. However, the study did not consider capital and set up costs, equipment purchases and maintenance cost, training costs, etc.

Burgos (2018) estimated the daily cost of providing methadone in Mexico. Costs were divided by type of input (capital, recurrent personnel, and non-personnel). Costs were further identified as being either “delivery cost” (all costs except for the methadone) or total cost, including methadone. Cost data were obtained from interviews with senior staff and a review of expenditure reports. Service provision data were obtained from activity logs and

senior staff interviews. Outcomes have cost per OST contact and cost per person month of OST (Burgos et al., 2018).

Another study that estimated the capital costs of MAT is a study by Abdul et al that analyzed the cost of MAT treatment in Malaysia, using a retrospective study design. The study was done from the provider perspective using activity-based costing that includes both capital and variable cost associated with the MAT program. The capital cost for the MAT program was US$8013.16 and the variable cost of providing a month of treatment per patient was US$50.43. Approximately 47.19% of this was for methadone and personnel cost accounted for 31.94%. (Abdul et al., 2010).

A growing body of research has used the DATCAP to estimate substance abuse treatment costs and other interventions. Resource categories include personnel, supplies and materials, contracted services, buildings and facilities, equipment, and miscellaneous items. Similar to the studies discussed above, labor was overwhelmingly the most utilized resource across all modalities, ranging from 48% to 88% of the total economic cost(French et al., 2008; Roebuck et al., 2003).

2.4.3 Per patient cost of Medically Assisted Treatment

Most of the studies reviewed showed variability in the per-patient cost of MAT depending on the setting. The unit cost of providing OST treatment per patient per day in world bank classified high-income countries (using 2017 USD rates) ranged from $13.22 to $15.52 and $17.34 in Europe, Canada, and the USA respectively(Connock et al., 2007; EMCDDA, 2011; Ettner et al., 2006; Roebuck et al., 2003; Zaric et al., 2012). Costs among upper-middle-income countries were comparable at $0.33 in China and $3.12 in Mexico and Iran(R.S. et al., 2015; Xing et al., 2012). The cost was $1.3 in low-income Indonesia (Afriandi et al., 2010). This brings to light the need for studies done locally or in similar settings to fill this knowledge gap

2.4 Summary of Literature and Research Gaps

Table 0.2: Summary of Research Gaps

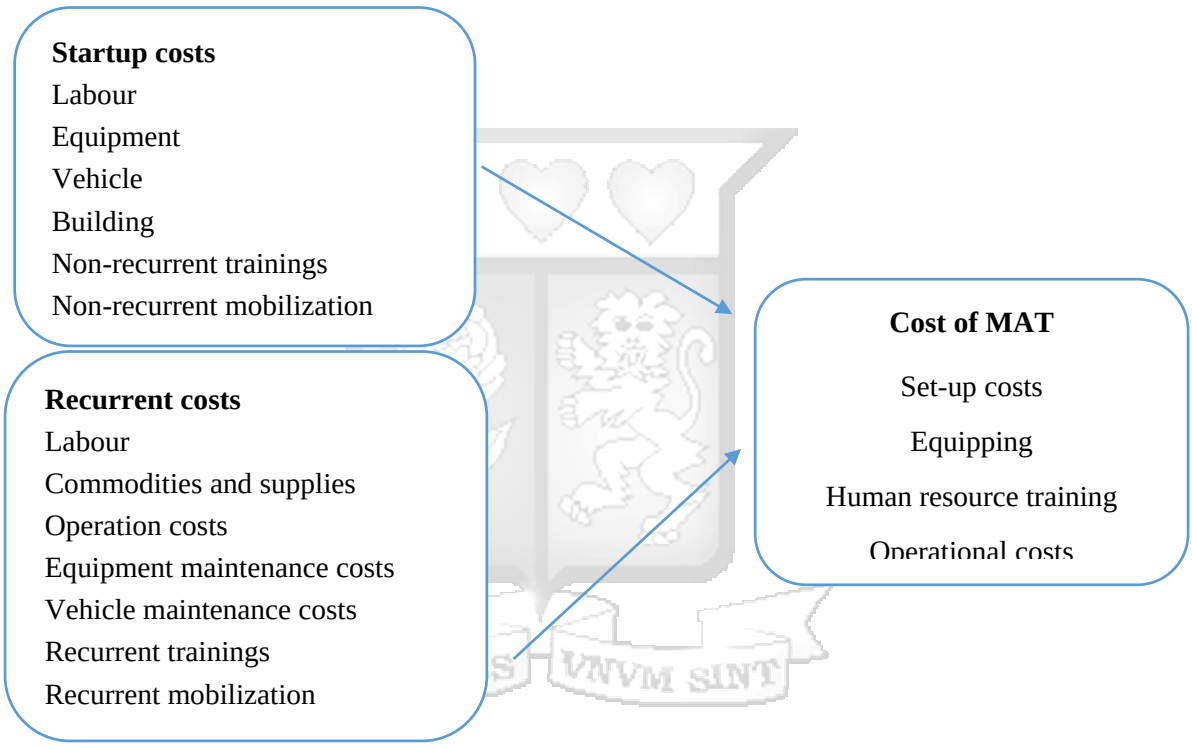
Author	Title	Findings	Research Gaps
Mogaka (2021)	Estimate cost of providing methadone maintenance treatment at a methadone clinic in Nairobi Kenya: direct costs	The findings indicated the cost of providing methadone treatment to one client to be KSh. 4500 (US$ 45) per month	This study was limited to direct costs with the cost estimated as the sum of salaries, laboratory test, methadone, and other commodities costs while the current study includes start-up cost, and other cost categories such as operational cost, training
Burgos (2018)	Cost of provision of opioid substitution therapy provision in Tijuana, Mexico	The total cost per contact at the private and public sites was $3.12 and $5.90, respectively, corresponding to $95 and $179 per person month of OST	This study was carried out in an upper-middle-income country and costs not generalizable to other regions while this study focused on Kenya
Kirtadze and the health policy project (2012)	Assessing the costs of medication-assisted treatment for HIV	The monthly per-patient cost of MAT rose slightly between 2009 and 2010 from 217 GEL ($126) to 229 GEL ($133). Three inputs—personnel, drugs/medical supplies, and utilities—account for a major portion of costs associated with running MAT programs in Georgia	This study was carried out in an upper-income country and costs are not generalizable to other regions while this study focused on Kenya.
French (2008)	The economic costs of substance abuse treatment: Updated estimates and cost bands for program assessment and reimbursement	The estimated weekly cost of Methadone maintenance was between $87 – $112	This study was carried out in an upper-income country and costs are not generalizable to other regions while this study focused on Kenya.

Source: Researcher (2021)

2.6 Conceptual Framework

The framework adopted for this study largely incorporated components used by Burgos (Burgos et al., 2018). The variable measured (cost) is categorized into two groups: capital and recurrent costs. Capital and recurrent cost components for each intervention were separately estimated. The cost components of both categories were then summed to obtain cost estimates for medically assisted treatment services as outlined in Figure 2.1. The variables are operationalized in Table 2.3.

Figure 0.1 Conceptual Framework



Source: Researcher (2021)

Table 0.3: Operationalization of Variables

Variable	Type of variable	Cost component	Data collection tool	Data Analysis
Startup Costs: inputs that last longer than a year	Independent	Building	Structured Questionnaire; Financial records review	Descriptive analysis and inferential analysis.
		Equipment & vehicle		
		Consultancy costs		
		Non-recurrent training &activities		
Recurrent Costs: inputs that are used up in a year and are usually purchased regularly	Independent	Personnel	Structured Questionnaire; Financial records review	Descriptive analysis and inferential analysis
		Equipment & Vehicle Operation & maintenance		
		Building Operation costs &maintenance		
		Consumables & supplies		
		Methadone drug		
		Recurrent Training &Activities		
Cost of MAT	Dependent	Total costs	Structured Questionnaire; Financial records review	Descriptive analysis and inferential analysis;
		Cost per patient		

Source: Researcher (2021

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter describes the study design, study area, and study population. It also describes and justifies the sampling method, the type of data collected, data analysis, research quality, and ethical issues. The main objective was to estimate the cost of MAT services to inform policy decisions on resource requirements for this intervention.

3.2 Research design

This was mainly a costing study. The period for the costing exercise was one program year corresponding to the PEPFAR donor cycle i.e., 1st October 2020 to 30th September 2021. Data were collected retrospectively by engaging the managers purposively selected based on their knowledge of the clinic operations and the costs incurred. Two managers from each facility and two UMB program staff involved in setting up the clinic were interviewed. In addition, secondary data was collected by reviewing secondary data- most notably, the program financial records.

3.2.1 Costing Strategy

This study adopted an economic perspective where costs were estimated to reflect the real cost of the resources, regardless of whether they were donated or purchased. The decision problem of this study relates to estimating the resource requirements of providing MAT services hence the choice of a health care payer perspective in which only the costs incurred by the payer were considered. Items such as travel costs of patients and other societal costs were not considered.

Micro-costing used a mixed methodology; top-bottom and bottom-up approaches were employed to quantify the costs. The top-bottom approach was utilized to quantify the costs of staff, building, and overheads while the bottom-up approach was utilized to quantify the cost of specific tests and methadone.

Since Kenyan guidelines recommend "OST-related" services in addition to methadone, psychosocial support, Hepatitis B and C screening services were included in our study (Ministry Of Health, 2017). However, HIV and TB screening costs were excluded as these are captured in other program interventions and budgets and not supported directly through the MAT program. Additionally, we excluded costs of services not related to the expanded definition of OST provision or were not provided to these OST patients e.g., pregnancy tests and hospitalization.

3.3 Sampling

3.3.1 Study Setting and Population

The study sites were the Mathari Teaching and Referral Hospital MAT Clinic and the Ngara Health Centre MAT clinic both in Nairobi. Nairobi County was preferred being the county that has the highest burden of HIV in the country and the highest number of PWIDs. The study populations were facility and program managers identified as knowledgeable on clinic operations and costs incurred.

3.3.2 Sample Size Determination

As at the time of the study, there were a total of 8 MAT clinics in the country and only 2 in Nairobi County. Mathari Teaching and Referral Hospital MAT Clinic and the Ngara Health Centre MAT clinic in Nairobi were purposively selected as the only existing MAT clinics in Nairobi and supported by UMB hence ease of access to financial records. The choice of the two facilities is based on the level and size of the facility; one is located in a Teaching and Referral Hospital (Mathari MAT), while the other (Ngara MAT) is located within a typical health center found in most parts of the country.

3.4 Data Collection Methods

3.4.1 Data Collection

Data was collected by reviewing financial records and interviewing managers using a modified version of the Drug Abuse Treatment Cost Analysis Program (DATCAP) questionnaire. An excel spreadsheet was developed to capture the data.

3.4.2 Data sources

Cost data was obtained from interviews with senior staff and a review of expenditure reports. Volunteer costs were calculated according to the number of volunteer MAT-related days worked and estimates of the daily cost of hiring someone to conduct the same task.

Start-up costs consisting of building space and equipment were collected from interviews with senior staff and confirmed visually during site visits. Equipment costs, such as costs for furniture and medical devices, were amortized over the estimated lifespan of the item and then converted into a daily cost.

Recurrent non-personnel costs consisting of supplies, utilities, and other services (accounting, maintenance, cleaning, security, etc.) were collected from stock records, project accounts, and interviews with personnel.

3.4.3 Outcomes and Variables

The main outcomes studied were the MAT clinic startup costs, the annual recurrent costs, and the MAT cost per patient. Costs incurred were the variables measured and were divided into two categories: Start-up costs defined as the cost of setting up the clinic: Building, Equipment, Staffing, Supplies, and Training, while Recurrent costs, defined as the cost of running the clinic: staff salaries, contract expenditures, purchases of materials and equipment, costs of routine maintenance to equipment, administration or overhead costs, cost of reagents, methadone, and associated drugs. The annual per-patient cost defined as the cost of treating one patient for a year

3.5 Data Analysis

Quantitative data collected was analyzed using Microsoft excel. Descriptive statistics were presented in tables and charts. Health facility characteristics and Cost outcomes were summarized using means and standard deviations, or medians and interquartile ranges for continuous variables. The value of each capital investment in the study was annualized over its expected useful life at a discount rate of 3% per annum, consistent with

conventional methods of economic evaluation (Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, 2015)

3.6 Data Security

The primary data collected was kept securely and only used for this research. A hard copy of the data was locked in secured devices or file cabinets; electronic data was password-protected, and data in the hard copy questionnaires was abstracted and stored in an electronic database that was password protected.

3.7 Ethical considerations

Voluntary participation was sought from the health facilities management after approval had been obtained from the Strathmore University Ethics Review Committee. Participation was out of free will and participants could opt out of the study at any time without penalty. Data collected was treated with the utmost confidentiality and the anonymity of the participants was maintained at all times (using codes), during and after the study.

CHAPTER FOUR: PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction

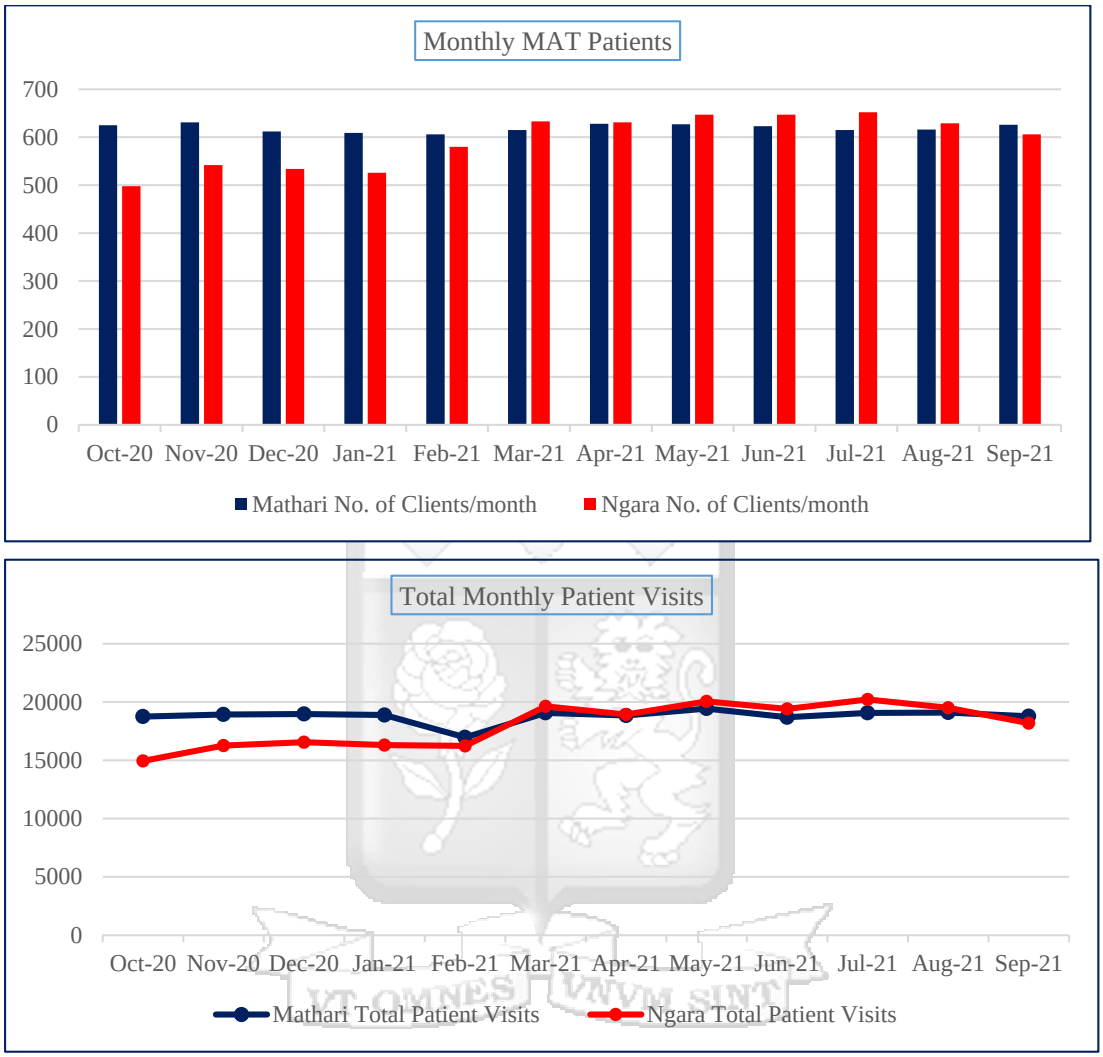
This chapter presents the findings of the study. It first describes how various start-up and recurrent cost components were determined to determine MAT's total costs and unit costs. It also analyzes cost drivers identified at the facilities studied.

4.2 Research Sites

4.2.1 Site characteristics

In 2020/2021, these facilities cared for a total of 1,282 unique patients. A total number of 360 clients were newly registered during the 1-year observation period with the majority, 292 (81%) enrolled in Ngara. The number of unique clients ranged from 606 to 631 in a month in MTRH with a median monthly attendance of 620 and a total of 225,472 client visits in the year. In Ngara, the number of attending clients ranged from 498 to 652 a month with a median monthly attendance of 618 and a total of 216,211 client visits. Comparing the change in the number of unique individuals receiving methadone at baseline and as at the end of the study period, the number increased by 108 in Ngara and one in Mathari (Figure 4.1).

Figure 0.1 Annual attendance by clinic



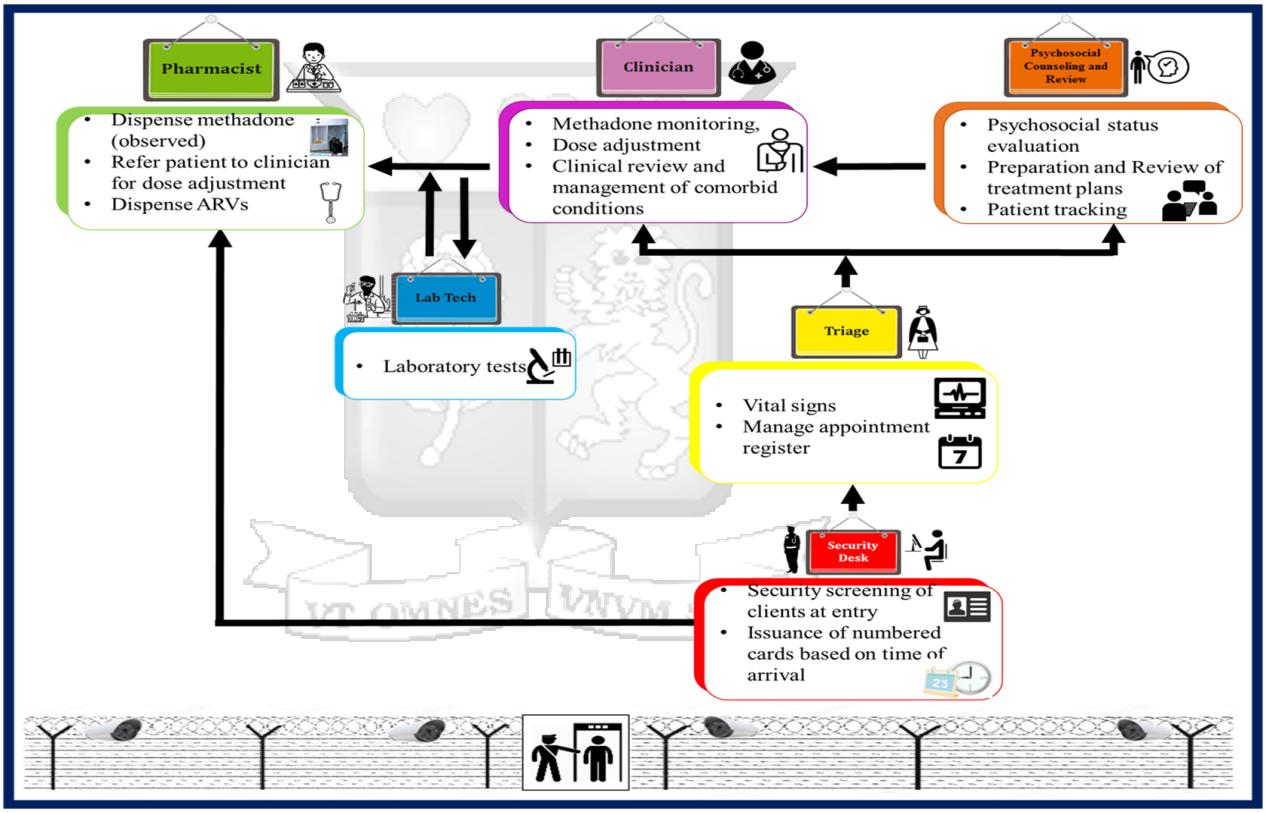
4.2.2 Patient Flow and Services offered

To accurately identify costs, we interviewed the MAT Leads and observed the patient flow to determine the major activities performed in the MAT clinics. The patient flow was similar in the two facilities with clients first going through a security screen at the entrance to the clinic, after which a card is given to each of them showing their position in the queue (Figure 4.2).

There are 2 major patient pathways a) For clients coming for their daily methadone dose, they proceed directly to the pharmacy for methadone dispensing and using a biometric

system linked to the methadone dispensing equipment, the patient is given their appropriate dose of methadone and their consumption observed by the pharmaceutical provider. b) For all new patients and patients with quarterly appointments for other services (counseling, clinical consultation, Laboratory, Psychiatrist review, Pharmacy), patients first visit the triage room from where they were directed to other service points based on their needs. Laboratory tests were offered at enrollment to all patients (Urine toxicology, Hepatitis B & C screening, HIV testing, VDRL screening) and quarterly (HIV testing and Urine toxicology).

Figure 0.2 Site process Map



Source: Researcher (2021)

4.2.3 Cost components

The start-up cost categories included costs related to consultancy, building, equipment, or training and activities; while recurrent costs included costs related to personnel, supplies and consumables, medication, training, information technology, equipment maintenance, or related to administration and overhead.

4.3 Start-up costs

To determine the start-up costs, data was collected by reviewing the program financial records and through interviews with the Program Manager and the MAT leads who were key in setting up the clinic. This includes the renovation and construction costs as well as the equipment purchases necessary to equip the clinics further described below.

4.3.1 Building costs

To start offering services, renovations were made to an existing building in Mathari while the Ngara clinic was constructed from scratch. The building costs were derived from the program financial records using the actual costs incurred and were converted to 2021 USD. The total cost for renovation of the Mathari clinic was determined to be $95,120.00. The total construction cost for the Ngara clinic was determined to be $73,548.24. These costs represented 19% and 30% of all start-up costs in Mathari and Ngara respectively.

4.3.2 Equipment costs

The total equipment cost per clinic ranged from $82,095.52 (Ngara) and $113,866.62 (Mathari). These included costs for equipment necessary to run the lab and dispense methadone, such as automated methadone dispensers, Electrocardiogram (ECG) machines, desktop computers, servers, and backup. Additional equipment costs were incurred in setting up security measures for the clinic such as the purchase of a biometric door, methadone safe, and set up of a biometric dispensing system. The difference in costs between the 2 clinics was as a result of some equipment's bought for Mathari later found not to be essential and therefore not bought when setting up the Ngara MAT clinic as shown in Table 4-1 below. Equipment costs represented 16% and 46% of all start-up costs in Mathari and Ngara respectively.

Table 0.1 List of Equipment by clinic

Equipment	No. of units Ngara	Total Cost Ngara	No. of units Mathari	Total Cost Mathari
Automated methadone dispenser	2	$ 33,320	2	$ 33,320
Benchtop Fume hood	0		1	$ 14,983
ECG Machine	1	$ 8,000	1	$ 8,000
Internet Connection	1	$ 4,839	1	$ 4,839
Desktop Computers	10	$ 15,707	15	$ 18,548
Power back up system	1	$ 4,839	1	$ 4,839
Methadone safe	0	$ -	1	$ 2,473
Water distiller	0	$ -	1	$ 3,548
Water deionizer	0	$ -	1	$ 2,688
Drug cabinets - lockable	3	$ 581	3	$ 581
Filing cabinet - Suspension type	1	$ 161	1	$ 161
Internal telephone system(PABX)	1	$ 430	1	$ 430
Telephone heads	10	$ 800	13	$ 1,817
Clinician desks	10	$ 2,151	10	$ 2,151
Board room table	1	$ 892	1	$ 892
Pulse Oximeter	1	$ 1,688	1	$ 1,688
Patient Chairs	12	$ 403	25	$ 806
Reception waiting chairs	3	$ 1,500	6	$ 3,316
Examination couches	3	$ 710	3	$ 710
Ward bed	0	$ 516	3	$ 516
Complete CCTV kit – 8 channel	1	$ 1,075	1	$ 1,075

Weighing scales	1	$ 290	1	$ 290
Breathalyzers	2	$ 323	2	$ 323
Pharmacy Fridge	1	$ 806	1	$ 806
HP Printer LaserJet	1	$ 1,290	1	$ 1,290
Water dispenser	3	$ 968	3	$ 968
Analytic balance	0	$ -	2	$ 2,000
Biometric door access	1	$ 538	1	$ 538
TV set	1	$ 269	1	$ 269
Total		$ 82,095		$ 113,866

4.3.3 Non-Recurrent Training and Activities costs

The total cost for non-recurrent training and activities was determined to be $241,101.36 for Mathari and $37,284.84 for Ngara. These costs represented 48% and 16% of all start-up costs in Mathari and Ngara respectively. As Mathari was the first clinic to be set up, training costs included those related to the development of the national Medical Assisted Treatment training curriculum and monitoring tools. Additionally, before its opening, a visit to the MAT clinics in Baltimore exposed the healthcare workers to the management of a mature clinic with experienced providers and this provided an impetus to initiate the services. This initiative, trained nurses and doctors recruited to work in the MAT clinics to gain foundational knowledge on opioid addiction and available treatments. As a train-the-trainer initiative, limited training costs for the National MAT curriculum are ongoing; however, the bulk of the program cost was a one-time expense conducted during the clinic set up intended to foster a robust MAT program for the country. Additional activities were geared toward gaining stakeholder and political support including a benchmarking visit to the Tanzania MAT clinic by the Members of the county assembly of Nairobi before the Ngara clinic set-up (Table 4.2).

Table 0.2 Non-Recurrent training and activities costs

	Mathari	Ngara
Development of training curriculum	$107,532.00	0
Development of tools &registers	$54,288.00	0
Learning visits to Baltimore	$70,170.72	0
Engagement of Health Managers	N/A	$1,710.00
Stakeholder meetings	$6,918.24	$2,913.84
National MAT training	$2,192.40	$2,154.60
Benchmarking visit to Tanzania	N/A	$30,506.40
Pharmacy &Poisons Board Registration	$580.00	$570.00
Total Non-Recurrent Training &Activities	**$241,101.36**	**$37,284.84**

4.3.4 Consultancy costs

The total consultancy cost was determined to be $83,325.01 for Mathari and $20,543.04 for Ngara. Consultancy costs included time, salaries, and travel expenses for the consultant physician, nurse, and pharmacist at the University of Maryland Baltimore (UMB) in the US who have long-term experience providing MAT in some of the oldest clinics in the USA. The consultants were engaged in the design of the clinic, procurement and capacity building of the Kenyan team.

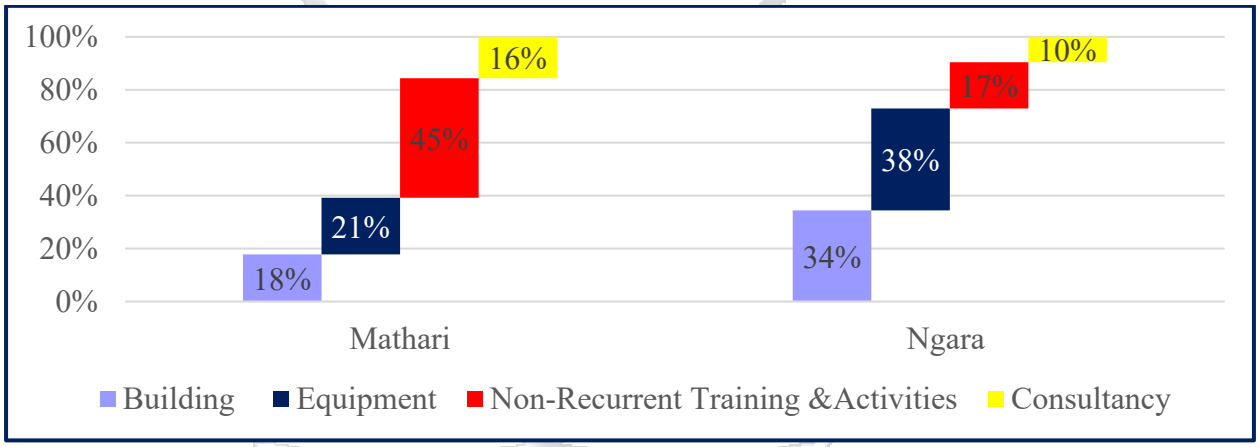
4.3.5 Total Start-up costs

The total cost of setting up a MAT clinic was determined to range between $533,412.99 and $213,471.64 (Table 4.3). Start-up costs for Mathari were two times the startup costs for Ngara. Being the first MAT clinic in the country, training and activity costs together with consultancy costs accounted for 61% of the costs compared to 27% at Ngara (Figure 4.3).

Table 0.3 Start-up costs

Cost Component	Mathari (2021 USD)	Ngara (2021 USD)
1. Building	$95,120.00	$73,548.24
2. Equipment	$113,866.62	$82,095.52
3. Non-Recurrent Training &Activities	$241,101.36	$37,284.84
4. Consultancy	$83,325.01	$20,543.04
Total startup costs	**$533,412.99**	**$213,471.64**

Figure 0.3 Start-up costs Distribution



4.4 Recurrent costs

4.4.1 Personnel Costs

The total annual personnel costs for the 2020/2021 year were determined to be $205,576.80 (Mathari) and $193,239.60 (Ngara) (Table 4.4). These costs represented 56% and 61% of all recurrent costs in Mathari and Ngara respectively (Figure 4.6). All relevant hospital staff that came in contact with the patient were identified and their salaries were adjusted per time dedicated to the clinics. Salaries were based on the current Kenya GOK rates as per the salaries and remunerations guidance (Salary and Renumerations Committee, 2020) and converted to 2021 USD. Salaries for volunteers in the clinic were calculated using the same rates. The pharmacy department accounted for the largest proportion of personnel

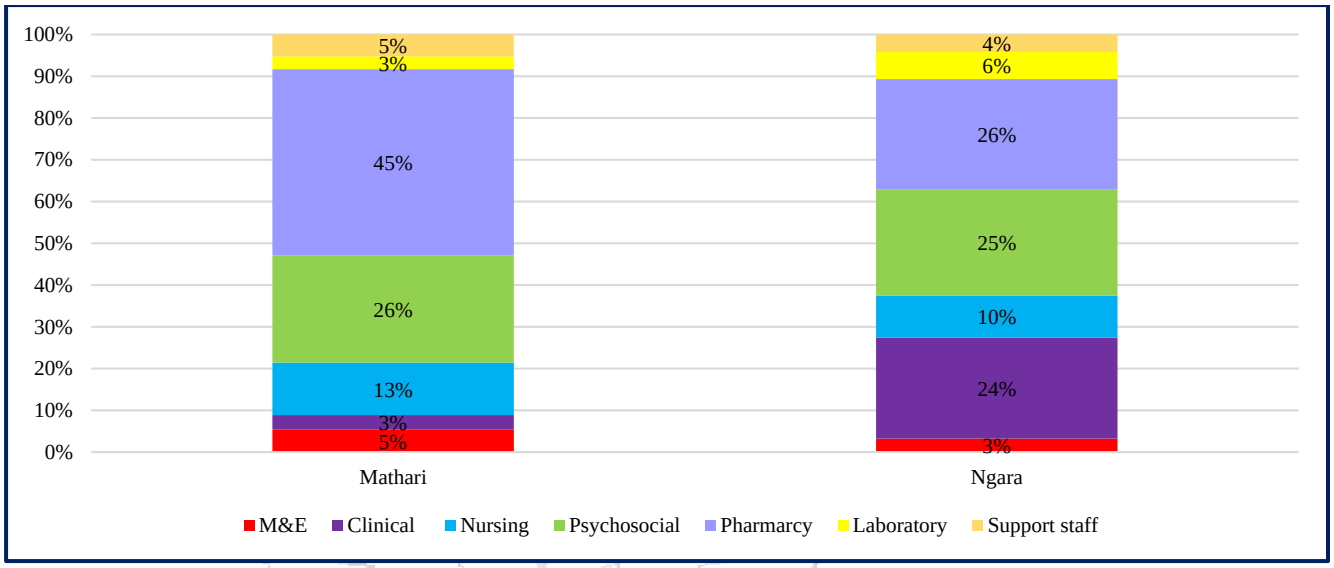
costs and when combined with psychosocial, the two departments accounted for more than half of the total personnel costs in each clinic (Figure 4.4).Differences in staffing between the two clinics were observed with no record clerk in Ngara where the data officer did both roles as the clinic had adopted point of care electronic medical records system; no medical officer in Mathari due to a resignation not replaced with the psychiatrists working hand in hand with the clinician to provide medical care; no social workers in Mathari as the counsellors also doubled up as social workers and no cleaning assistants in Ngara during the reporting period.

Table 0.4 Total Annual Personnel Cost

		Mathari				***Ngara***			
Department & Cadre	Salary p.m.	No.	% of time	Months	Total Cost	No.	% of time	Months	Total Cost
Pharmacy					**$91,692**				**$ 51,192**
Pharmaceutical Technologist	$522.00	3	100%	12	$18,792	3	100%	12	$18,792
Pharmacists Interns	$2,250.00	6	100%	3	$40,500	0	0	0	$0
Pharmacists	$2,700.00	1	100%	12	$32,400	1	100%	12	$32,400
Psychosocial					**$52,733**				**$ 49,024**
Psychiatrist	$2,974.00	2	30%	12	$21,413	1	20%	12	$7,138
Addiction Psychosocial Counsellors	$522.00	4	100%	12	$25,056	2	100%	12	$12,528
Social Workers	$424.00	0	0	0	$0	3	100%	12	$15,264
Volunteer Counsellors	$522.00	0	0	0	$0	5	100%	3	$7,830
Clinical Psychologist	$522.00	1	100%	12	$6,264	1	100%	12	$6,264
Clinical					**$7,152**				**$ 46,728**
Clinical Officers	$596.00	1	100%	12	$7,152	2	100%	12	$14,304
Medical Officers	$2,702.00	0	100%	12	$0	1	100%	12	$32,424
Nursing					**$25,872**				**$ 19,404**
Registered Nurse	$539.00	4	100%	12	$25,872	3	100%	12	$19,404
Laboratory					**$6,264**				**$ 12,528**
Laboratory Technologist	$522.00	1	100%	12	$6,264	2	100%	12	$12,528

M&E					**$11,064**				**$ 6,264**
Data Officer	$522.00	1	100%	12	$6,264	1	100%	12	$6,264
Record Clerk	$400.00	1	100%	12	$4,800	0	0	0	$0
Support Staff					**$10,800**				**$ 8,100**
Security Officers	$225.00	3	100%	12	$8,100	3	100%	12	$8,100
Cleaning Assistants	$225.00	1	100%	12	$2,700	0	0	0	$0
TOTAL Personnel costs in USD					205,577				193,240

Figure 0.4 Personnel Costs by Departments



4.4.2 Supplies and consumables

The total cost of supplies and consumables was determined to be $29,030.93 in Mathari and $28,531.65 Ngara (Table 4.5). These costs represented 8% and 9% of all recurrent costs in Mathari and Ngara respectively (Figure 4.6). Among these costs, laboratory supplies account for the majority of the supplies in both clinics. To determine the costs of laboratory tests, utilization was based on the National guidelines' recommendations (Ministry Of Health, 2017) and multiplied by the unit cost retrieved from expenditure records (Table 4.6). The costs for screening for HIV were excluded as they are distributed to facilities from the HIV Testing National program and not borne by the MAT program per se. The cost of disposable methadone dispensing cups necessary for methadone dispensing was based on the number of patient visits in the year and determined to be $ 11,273.60 in Mathari and $ 10,810.55 in Ngara respectively.

Table 0.5 Costs of supplies and consumables

Component	Mathari	Ngara
Laboratory supplies costs	$11,232.33	$11,196.10
Office supplies and consumables	$6,525.00	$6,525.00
Dispensing cups	$ 11,273.60	$10,810.55
Total costs supplies and Consumables	**$29,030.93**	**$28,531.65**

Table 0.6 Laboratory Supplies Costs

Item name	Price per Unit	Tests/yr.	Cost/patient	Mathari	Ngara
Urine Toxicology - combo	$ 0.38	4	$ 1.50	$ 930.00	$ 927.00
Urine containers	$ 0.38	4	$ 1.50	$ 930.00	$ 927.00
Vacutainer Needles - G21	$ 0.35	1	$ 0.35	$ 217.00	$ 216.30
Vacutainer tubes - plain	$ 0.35	1	$ 0.35	$ 217.00	$ 216.30
Hepatitis B (HBs Ag) test strips (Rapid)	$ 5.67	1	$ 5.67	$ 3,513.33	$ 3,502.00
Hepatitis C Virus Rapid test strips	$ 8.75	1	$ 8.75	$ 5,425.00	$ 5,407.50
Total Laboratory costs				**$11,232.33**	**$11,196.10**

4.4.3 Cost of methadone and supportive medication

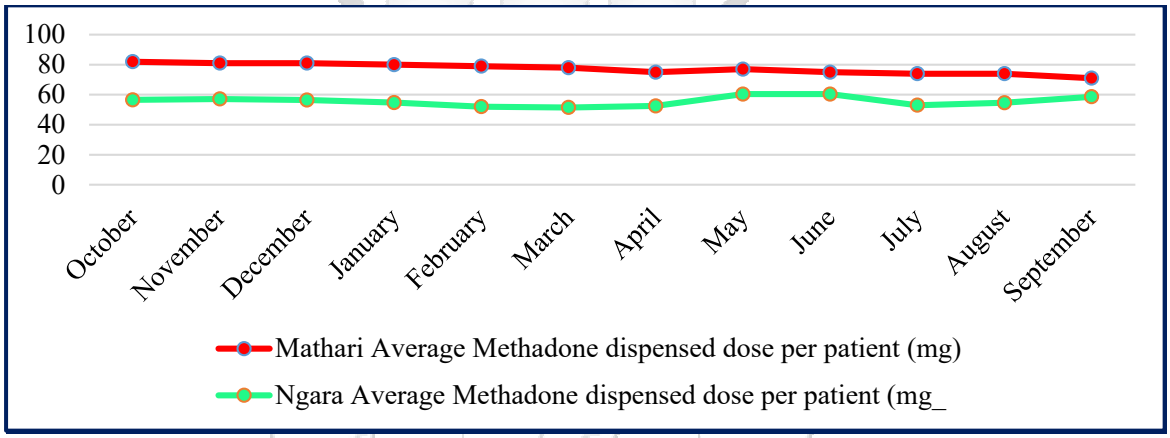
The cost of medications was determined to be $88,912.59 and $62,020.27 for Mathari and Ngara respectively. These included the cost of methadone and other supportive medications (Table 4.7). The supportive medications include the cost of purchasing naloxone and bisacodyl for overdose management and to relieve side effects due to methadone. Methadone and supportive medication costs represented 24% and 20% of all recurrent costs in Mathari and Ngara respectively (Figure 4.6). To calculate methadone costs, the average per patient dose of methadone was abstracted from the facility P8 and P7 reports (national methadone reporting tools) based on the quantities dispensed and the number of patients. The average median methadone dose was lower in Ngara compared to Mathari at 55.66mg and 77.25mg respectively (Figure 4.5). The cost of methadone was

determined by the distributor prices at the time of this study to be $25 per liter (5000mg). To get the annual cost, these costs were multiplied by the number of patient visits in the year and determined to be $ 98,344.185 in Mathari and $ 70,988.8238 in Ngara respectively. This excludes the cost of importation and shipping which was not available at the time of the study.

Table 0.7 Medication costs

Component	Mathari	Ngara
Methadone costs	$87,070.59	$60,178.27
Supportive Medication	$1,842.00	$1,842.00
Total Medication Costs	**$88,912.59**	**$62,020.27**

Figure 0.5 Average Per Patient Dose of methadone dispensed



4.4.4 Recurrent training and activities

The total cost for recurrent training and activities was determined to be $9,840 for Mathari and $7,865 for Ngara (Table 4.8). These costs represented 3% and 2% of all recurrent costs in Mathari and Ngara respectively (Figure 4.6).

Table 0.8 Recurrent Training and Activities costs

	Mathari	Ngara
Trainings	$5,250	$4,125
CMES - Monthly	$1,200	$900
Data review meetings - Quarterly	$400	$400
Patient preparation and Follow ups	$240	$240
Therapeutic groups forums	$600	$600
MDTs	$1,200	$900
MAT Linkage forums	$950	$700
Total Trainings and Activities	**$9,840**	**$7,865**

4.4.5 Equipment maintenance cost and other operational costs

The total cost for equipment maintenance cost and other operational costs was determined to be $9,840 for Mathari and $7,865 for Ngara (Table 4.9). These costs represented 9% and 7% of all recurrent costs in Mathari and Ngara respectively (Figure 4.6).

Table 0.9 Equipment maintenance and other operational costs

	Mathari	Ngara
Annual Preventive & Maintenance Contracts – MAT Equipment, biometrics, Servers, waste collection, internet services, sample networking, security enhancements, power backup	$ 15,000	$ 9,000
Periodic minor repairs and fit outs	$ 7,000	$ 6,000
Methadone bottles disposal	$ 1,920	$ 1,920
Methameasure Annual License Renewal	$ 3,900	$ 3,900
Antivirus	$ 300	$ 225
Internet Connectivity	$ 3,600	$ 3,600
Total Equipment Maintenance and Operation Costs	**$ 31,720**	**$ 24,645**

4.4.6 Total Recurrent Costs

The total recurrent costs for the year 2020/2021 were determined to be $365,080.32 for Mathari and $316,294.77 for Ngara. These include the personnel costs as well as the costs of supplies and consumables, recurrent training and activities, equipment maintenance, methadone, and other medication (Table 4.3).

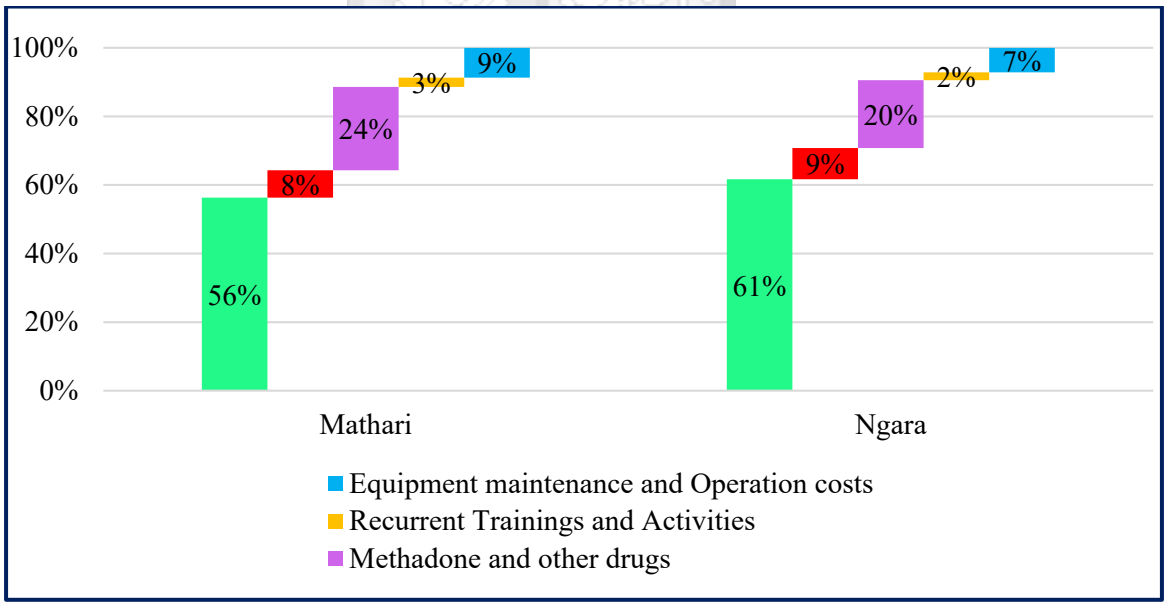
Table 0.10 Total Recurrent Costs

Component	Mathari	Ngara
Personnel Costs	$205,576.80	$193,239.60
Supplies and Consumables	$29,030.93	$28,531.65
Methadone and other drugs	$88,912.59	$62,020.27
Equipment maintenance and Operation costs	$31,720.00	$24,645.00
Recurrent Trainings and Activities	$9,840.00	$7,865.00
Total Recurrent Costs	$365,080.32	$316,294.77

4.4.7 Distribution of Recurrent Costs

Personnel costs contributed to more than half of the recurrent costs in both clinics (Figure 4.4). The distribution of costs across categories was comparable between the clinics as shown in Figure 4.6.

Figure 0.6 Recurrent Costs Distribution



4.5 Per-patient costs

4.5.1 Annual Per patient costs

The annual cost of MAT per patient for the year 2020/2021 was determined to be $590 and $532 respectively for Mathari and Ngara with an average cost of $562 (Table 4.12) This was calculated by dividing the total recurrent cost by the average number of unique patients per clinic assuming a patient had 100% attendance as shown in table 4.11 below.

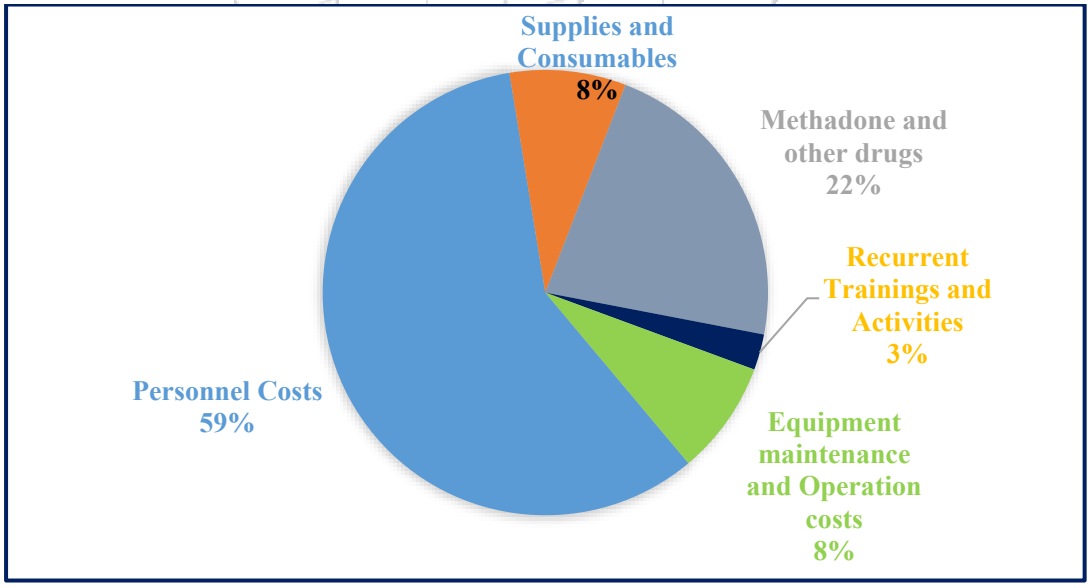
Table 0.11 Per-Patient costs

Expenditure Category	Mathari	Ngara	Average
Total Recurrent Costs	$365,080.32	$316,294.77	$340,687
Number of patients in the year	619	593	607
Annual Per patient cost	$590	$532	$562

4.5.2 Cost Drivers

Labor was the primary cost driver, accounting for >50% of costs in both clinics. Methadone cost was the second largest cost driver, accounting for approximately 22% of the overall cost, followed by supplies at 8%.

Figure 0.7 Distribution of Per-patient costs, Average



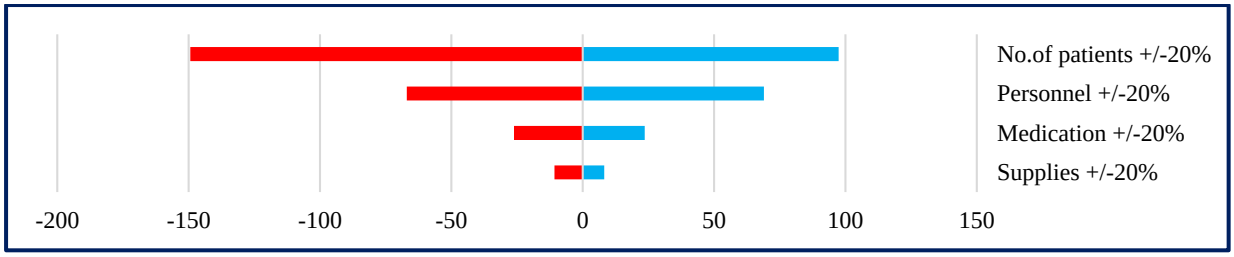
4.6 Sensitivity Analysis

The cost per patient was determined using an idealized patient receiving a full course of treatment and follow-up for one year. The costs were based on the actual costs due to limitations in getting protocol based costs for other line items except Laboratory cost. The methodology however did not take into account patients with missed visits and likely underestimates costs related to relapse as the methodology assumes a full course of successful treatment. A one-way sensitivity analysis was conducted to determine the parameters most likely to affect the cost per patient (Table 4.12). The parameters most sensitive to change are the number of patient visits and the cost of personnel (Figure 4.8). Increasing or decreasing the number of patient visits by 20% resulted in up to 25% change to the overall cost per patient while. Our analysis reflects only a minimal reduction in prices (20%), but given the magnitude of this parameter, if large reductions in the number of patient visits were achieved (such as those seen in take away dosing or alternate day dosing) we could expect significant reductions in the overall cost per patient

Table 0.12 Sensitivity Analysis

Expenditure Category	Revised Per patient cost -20%	Revised Per patient Cost +20%
No. of patients	494(-17%)	740(+25%)
Personnel	522 (-12%)	658(+11%)
Medication	567(-4%)	617(+4%)
Supplies	583(-2%)	602(+2%)

Figure 0.8 Tornado Diagram for One-way sensitivity analysis



CHAPTER FIVE: DISCUSSION, RECOMMENDATIONS, AND CONCLUSION

5.1 Introduction

This chapter presents a discussion of the key findings from the study and provides recommendations that should be taken forward. While measuring and improving drug treatment outcomes has been relatively high on the research agenda, the cost of treatment has received far less attention. To our knowledge, this study is one of the first to examine program costs for the start-up and implementation of MAT in a low-income country. Therefore, the results discussed herein are important in considering costs and cost drivers when establishing and running MAT facilities in Kenya and beyond.

5.2 Discussion

5.2.1 Start-up Costs

In this study, $533,412.99 and $213,471.64 were needed for start-up activities for Mathari and Ngara, respectively. Overall, the study has demonstrated that the cost of setting up a subsequent clinic is half that of an initial clinic with non-recurrent training and activities being more than six times costlier in the initial clinic. Methadone is a controlled narcotic drug and its use requires changes in regulatory processes and guidelines of the central authority of any given country. This could explain the significant costs incurred in stakeholder engagement for buy-in before setting up the clinic. Additionally, as a new intervention in the country, professional skills and knowledge were limited, hence the need for training explaining the significant costs associated with the initial training and curriculum development before the clinic's opening.

The national key population size estimate show a mid-point estimate of 5,024 PWID in Nairobi (National AIDS and STI Control Programme (NASCOP), 2019). Despite this high burden of PWID and the increasing number of hotspots in Nairobi County, MAT sites remain the two, both 4km away from each other with clients residing in other parts of Nairobi having to travel a distance of 30 – 40km return daily to these facilities.

Additionally, access to MAT continues to be a major challenge for clients from regions outside Nairobi and the coast where MAT clinics are yet to be established. This could be attributed to the significant start-up costs observed in this study where costs construction costs accounted for 30% of the start-up costs of the subsequent clinic. Kenya has used donor funding to scale up MAT since 2014. As a vertical program, significant costs were incurred in the creation of separate clinics that may be difficult to replicate in the absence of donor funds. These costs could be minimized if Methadone treatment is integrated into existing government-run primary health care facilities or rehabilitation units in the county referral hospitals. With the roll-out of mobile van dispensing during the COVID pandemic, a similar model could be adopted from the county referral hospitals to distribute methadone to the sub-county level, eliminating the need for multiple stand-alone clinics. Further, existing primary care level health facilities could be utilized as fixed dispensing sites reducing the costs associated with setting up stand-alone full-fledged MAT clinics.

To the best of our knowledge, there was no prior literature on the cost of setting up a MAT clinic at the time of this study.

5.2.2 Recurrent Costs

This study estimated the recurrent cost of MAT for the 2020-2021 fiscal year to range from $316,294.77 and $365,080.32. In both clinics, personnel costs accounted for more than half of all the recurrent costs, and in the sensitivity analysis were associated with more than 10% of the change in cost per patient. As methadone is administered daily, the majority of the personnel costs were associated with methadone dispensing by the pharmacy staff. Consistent with findings that psychosocial support is related to the success of treatment, the psychosocial department was the second department contributing to a higher proportion of costs. There were differences in staffing numbers between the clinics pointing to gaps in the protocols that specify the cadres but not the staff to patient ratios. This gap could also be attributed to the different types of interns being used in the different clinics.

While costing data for MAT is limited, the literature review identified several studies examining direct treatment costs for MAT (Table 2.2). Consistent with prior studies, this study also confirms that the cost of MAT is much less in low-income countries than that in high-income settings and that personnel costs account for the majority of the costs. This may be attributed to differences in the cost of personnel which is significantly less expensive than in more economically developed countries. Consider that the personnel costs for one MAT clinic (including all positions from doctors, nurses, and technicians) are less than the average annual salary of $208,000 for one psychiatrist in the United States. This may be a result of an efficient task-shifting model in use in Kenya, that allows clinical officers and pharmaceutical technologists to provide care in the MAT clinics instead of full-time psychiatrists and pharmacists. However, there exists opportunities to adopt more cost efficient models that reduces on costs incurred in personnel. For example, in Delhi, the doctors and a counsellor are available in the clinic twice per week, while nurses are available on all days to dispense methadone (Rao et al., 2021).If such a model would be adopted, the personnel costs which account for majority of the costs would be further minimized.

Although supplies accounted for an average of 8% of the costs, it is worth noting that the use of non-recyclable methadone dispensing cups was associated with significant costs of more than $10,000 per clinic. These costs could easily be eliminated with the use of recyclable cups or cheaper paper cups.

5.2.3 Per-Patient Costs

The annual per capita cost for MAT determined to range $590 and $532 with an average cost of $562. A recent Kenyan study by Mogaka et al. estimated the direct cost of MAT to be $45 per month or $540 annually. Even though operational and training/activity costs were not outlined in this Kenyan study, the findings were similar pointing towards our finding that these costs account for a negligible proportion of the patient costs (11%). Studies estimating MAT costs outside Kenya determined MAT costs to range from a low of approximately $1,140 per patient annually in middle-income countries to a high of around $5,824 in high-income countries (Table 2.2).

Per-patient costs were most sensitive to changes in patient numbers. An increase in patient numbers, with all factors, held constant, considerably decreases the cost per patient, possibly due to economies of scale. Although outside the scope of this study, both clinics seem to be losing clients, as evidenced by the minimal change in the unique number of patients in the clinic at the end of the period compared with the enrollments during the year. From clinic records, the two clinics have enrolled 2,839, with 1,378 being active as of April 2022. The largest source of attritions is an interruption in treatment (907, 32%). Retention strategies such as active tracking of clients and active enrollment of clients to the clinics could generate more cost efficiencies and resultant decreases in per-patient costs.

Even though altering the cost of methadone was related to minimal changes in expenses, it is essential to note that in this study, a significant difference in the average dose of methadone was observed across the two clinics. Studies examining the dose of methadone vis-a-vis patient outcomes recommend an average maintenance dose of between 60-120mg with lower doses associated with drop-out rates. It, therefore, is important to conduct further studies to examine the reasons for this difference to address the quality of care and, ultimately the costs, as shown in the sensitivity analysis.

The estimated annual per capita cost of $562 can seem expensive in a country with a GDP per capita of $1591(Kenya National Bureau of Statistics, 2021) and a total health expenditure per capita of $179. However, it is important to consider that the average per capita cost of MAT in the United States has been estimated to be between $87-$112 per week, translating to an average of $5,824 per year (French et al., 2008). Despite the United States GDP per capita of $54,000, few would argue that opioid addiction is too expensive to treat or that patients in low-income countries should go without access to care.

5.3 Limitations

Every attempt has been made to identify the full healthcare-related costs of providing medically assisted treatment. As identified in chapter three, this is a far from a straightforward task, and some limitations inevitably exist.

First, this study is limited by the perspective of the analysis. Our focus was on capturing the costs of implementing an effective MAT program and did not include the larger societal costs of treatment, such as the out-of-pocket expenses of patients or lost productivity during treatment. The cost of treatment for the family and society can be significant but is not reflected in this study. However, this is an adequate measure to identify the current health care costs of MAT. Moreover, the presented data provide a starting point for any discussions about the resource implications of any policies to expand MAT services.

A particular problem in this study was the fact that national information is not available on the minimum required resources for setting and running a clinic and thus it has not been possible to provide ideal or protocol-based costs in this study. At best, the costs we present here reflect the current average resources used. More so, the two clinics sampled represents 25 percent of all similar clinics in Kenya and cover 25% of the targeted patient population (National AIDS and STI Control Programme (NASCOP), 2019). Thus, the methodology allows the prediction of the cost of a “typical” MAT clinic once more information is available about national-level standards.

5.4 Recommendations

These study findings have demonstrated the costs of setting up and providing MAT services in the current healthcare structure. They are useful in informing policymakers such as the National AIDS Control Council (NACC) and NASCOP which are working on developing strategies for increasing domestic financing for HIV care as this provides an evidence base that can be tapped into.

Given the impact of substance abuse on public health and the increased risk for long-term medical consequences, the government through the Ministry of Health should invest in prevention programs and early screening to identify those who have already begun to misuse substances and intervene early. Early prevention interventions, carried out before the need for treatment, are critical because they can delay early use and stop the progression from use to problematic use or a substance use disorder (including its severest form, addiction), ultimately reducing health care costs and public health consequences.

Given the significant costs in setting up a MAT clinic, the government should consider other less costly models during scale up of these services to cover wider geographical zones. First, the government should explore a hub and spoke models using established rehabilitation centers or referral hospitals as the hub, where MAT clinics are integrated with other services with fixed dispensing sites in satellite facilities. Integrating MAT in existing psychological departments in county referral hospitals to set up MAT clinics will provide an opportunity to further reduce startup costs and inevitably increase access to these services.

The government and partners should explore and adopt more cost-efficient models in running the clinic for example the use of recyclable dispensing cups only will save approximately more than $ 10,000 per year. Additionally, retention strategies to increase available resources' utilization will further increase efficiencies. To reduce donor reliance, the government can use the findings of these study as a basis of wider research on health financing models to inform policy on domestic financing for HIV programs including MAT. For instance, the government could consider working with NHIF and private insurers to scale up coverage of HIV services as part of Universal Health Coverage.

5.5 Conclusion

The substance abuse burden in low-income countries is continuing to grow with East Africa projected to experience an over 30% increase by 2050. And yet, the treatment gap for

substance use disorders is unfortunately large, driven majorly by a lack of financial resources. The example of the Nairobi MAT clinics provides a reason for optimism in the fight against substance abuse. The analysis clearly shows that quality addiction treatment can be achieved at a fraction of the cost of care in high-income countries by adapting protocols to the local context, task shifting, and collaborative partnerships. Even though the initial costs of setting up such programs can be high, they have the potential to provide significant returns on investment for governments, with societal benefits exceeding treatment costs. As the program grows and outcome data becomes available, a cost-effectiveness analysis would help us further understand the gain in health outcomes to the investment necessary for treating substance abuse in these countries.

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APPENDIX 1: DATA COLLECTION TOOL

SAMPLE QUESTIONNAIRE

SERIAL NUMBER: _____

INTERVIEW OR COMPLETION DATE: _____

FACILITY NAME:

Introduction

1. Participation in this study is entirely voluntary.
2. If you decide to take part, you will be asked to complete a questionnaire to get information on the costs of providing MAT services. If you are not able to answer all the questions successfully the first time, you may be asked to sit through another informational session after which you may be asked to answer the questions a second time. You are free to decline to take part in the study from this study at any time without giving any reasons.

PART I: RECURRENT COSTS

The data in this module correspond to fiscal year DD/MM/YY to DD/MM/YY:

SECTION A. CLIENT INFORMATION

For the fiscal year, what was the program's . . .

A1. Number of new admissions or episodes (excluding readmissions)?

A2. Number of readmissions?

A3. Total admissions?

A4. Total number of active clients?

A7. Average daily census?

A8a. Mean length of stay for all clients (weeks)?

A8b. The median length of stay for all clients (weeks)?

SECTION B: PERSONNEL

B1. For the fiscal year, list all program personnel. Include percentage of time devoted to the program, annual salary, and adjusted salary based on MOH rates.

Personnel Name and/or Title	% of Time Devoted	Annual Salary	Adjusted Salary
		$	$
		$	$

B2. Do these salaries include employee benefits? (Yes/No)

(If 'Yes' Skip to B4)

B3. What was the total cost of employee benefits, as a percentage of annual base salary and in dollar terms, for all personnel during the fiscal year?

Percentage of annual base salary----------Total cost for employee benefits----------

B4. What was the total overtime cost during the fiscal year?

B5. What was the total of any other personnel cost during the fiscal year?

B6. What volunteer labor services did the treatment program receive during the fiscal year? What would be the estimated cost of these volunteer services if the program had to pay for them?

Volunteer Title

Estimated Hourly

$

$

$

SECTION C: CONTRACTED SERVICES

If the treatment program has a contract with a company/corporation/internal department to provide a service, then enter the corresponding cost in questions C1 through C11. If the treatment program has a contract with a person/individual to provide a service, then enter the corresponding cost in Question C12.

What was the cost of the following contracted services during the fiscal year?

C1. Laboratory Services

$

C2. Repairs and Maintenance

$

C3. Security Services

$

C4. Housekeeping Services

$

C5. Advertising Services

$

C6. Pest Control Services $

C7. Transportation Services

$

C8. Wellness and Fitness $

C9. Smoking Cessation

$

C10. Parenting and Day Care

$

C11. Other Contracted Services - Please Specify:

C12. List consultants and contracted personnel, the number of hours they worked, and their average hourly compensation, for the fiscal year. (Exclude costs included in questions C1 through C11, or personnel costs included in Section B.)

SECTION D: BUILDINGS AND FACILITIES

Complete the following set of questions (D1 through D5) for each building or facility utilized by the program during the current fiscal year. Repeat this exercise for additional facilities.

D1. What is the name of the facility and where is the building located?

D2. How large was the total usable space in this building during the fiscal year?

sq. ft. of total usable space

D3. How much of the total usable space in this building was used by the treatment program?

% of total usable building space

D4. If the program space noted in D3 was used full-time by this program during the fiscal year, write 100 in the space below. Otherwise, estimate the percentage of time it was used by this program.

D5. Please provide the annual lease/rental price per square foot, or an estimated fair market value per square foot applicable for this building.

Note: If it is not possible to estimate a fair market lease or rental price, please give us the name, address, and phone number of a local real estate agent/company who may be able to provide an estimate.

SECTION E: EQUIPMENT

1 What was the cost of all leased/rented equipment used by the program during the fiscal year?

2 What was the total depreciation expense for equipment used by the program during the fiscal year? Do not include depreciation on buildings previously included in Section D.

3 Depreciation Method: (Choose one)

A. Straight-line (SL)

B. Declining-balance (DB)

C. Other (Please Specify):

4 What was the fair market value of equipment used by the program during the fiscal year that was donated or received free of charge?

The estimated fair market value of donated/free equipment

SECTION F: SUPPLIES AND MATERIALS

F1. List the cost of supplies and materials purchased during the fiscal year (e.g., medications, medical supplies, office supplies, housekeeping items, linens, food, postage). Do not include items that were depreciated and included in Section E.

F2. Estimate the market value of supplies and materials that were donated or received free of charge during the fiscal year?

SECTION G: MISCELLANEOUS RESOURCES

G1. What was the cost of the miscellaneous items listed below that were used by the treatment program during the fiscal year?

an	Electricity	
$		
b	Gas	$
c	Oil	$
d	Water and Sewer	
$		
e	Garbage	
$		
f	Insurance	
$		
g	Licenses	
$		
h	Federal Taxes	$
i	State Taxes	$
j	Local (e.g., Property) Taxes	
$		
k	Telephone	$
l	Printing and Duplicating	
$		
m	Transportation	$
n	Publications, Subscriptions, and Books	
$		
o	Staff Training	$
p	Staff Travel	$
q	Medical Waste Disposal	
$		
r	Proficiency Test Fees	$
s	Cola Regulation Fees	$
t	Lab Licensing	$

u Other Miscellaneous - Please Specify:

G2. What was the estimated cost of the specific miscellaneous items listed below that were used by the treatment program free of charge during the fiscal year?

a Electricity
$

b Gas $

c Oil $

d Water and Sewer
$

e Garbage
$

f Insurance
$

g Licenses
$

h Federal Taxes $

i State Taxes $

j Local (e.g., Property) Taxes
$

k Telephone $

l Printing and Duplicating
$

m Transportation $

n Publications, Subscriptions, and Books
$

o Staff Training $

p Staff Travel $

q Medical Waste Disposal
$

r Proficiency Test Fees $

s	Cola Regulation Fees	$
t	Lab Licensing	$
u	Other Miscellaneous - Please Specify:	

SECTION 2: START UP COSTS

List the cost of inputs that were performed during the first year of starting up that last longer than a year and their costs

Cost component	**$**
Building	
Equipment & vehicle	
Consultancy costs	
Non-recurrent training &activities	
Other	

APPENDIX 2: PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF THE STUDY: MEDICAL ASSISTED TREATMENT IN HIV CONTROL IN NAIROBI, KENYA: HOW MUCH DOES IT COST?
PROTOCOL VERSION 1.0 DATE: JULY 2021

SECTION 1: INFORMATION SHEET

Investigator: Dr. Rebeccah Namalea Wangusi

Institutional affiliation: Strathmore Business School (SBS)

SECTION 2: INFORMATION SHEET–THE STUDY

2.1 : Why is this study being carried out?

Drug abuse and associated risks such as HIV infection are on the rise. Medical Assisted Treatment (MAT) is a recent introduction in Sub-Saharan Africa and Kenya, it's largely donor-funded and runs as a vertical program. In the context of decreasing external and limited in-country resources, information on sustainable financial models is critical. This calls for discussions on the costs associated with treatment to guide domestic policymakers on alternative funding options. As such, we are carrying out this study to ascertain the costs of providing MAT services to better help policymakers in determining effective financing mechanisms and sustainability mechanisms for HIV-related interventions in Kenya and provide crucial information to similar programs that are seeking to introduce MAT treatment.

2.2 : Do I have to take part?

No. Taking part in this study is entirely optional and the decision rests only with you. If you decide to take part, you will be asked to complete a questionnaire to get information on the costs of providing MAT services. If you are not able to answer all the questions successfully the first time, you may be asked to sit through another informational session after which you may be asked to answer the questions a second time. You are free to decline to take part in the study from this study at any time without giving any reasons.

2.3 : Who is eligible to take part in this study?

Program administrators, MAT clinic directors/Leads, and healthcare workers in the MAT clinics are eligible to take part in the study.

2.4 : Who is not eligible to take part in this study?

This study does not collect patient information and therefore MAT patients are not eligible to take part in this study.

2.5 : What will taking part in this study involve for me?

You will be approached by the investigator and requested to take part in the study. If you are satisfied that you fully understand the goals behind this study, you will be asked to sign the informed consent form (this form) and then taken through a questionnaire to complete.

2.6 : Are there any risks or dangers in taking part in this study?

There are no risks in taking part in this study. All the information you provide will be treated as confidential and will not be used in any way without your express permission.

2.7 : Are there any benefits of taking part in this study?

The information will be used to improve the annual budgeting of MAT services in terms of estimating costs for specified numbers and types of personnel, facilities, equipment, and other costs necessary to provide a MAT service. Secondly, the cost data generated will aid in determining cost drivers and inform efficient use of scarce resources for optimal benefit. Thirdly, this study will help inform other countries wishing to set up MAT clinics on what costs to anticipate and enable them to better plan. Additionally, the cost data generated can be used to evaluate whether the intervention provides good value for money in a future cost-effectiveness analysis.

2.8 : What will happen to me if I refuse to take part in this study?

Participation in this study is entirely voluntary. Even if you decide to take part at first but later change your mind, you are free to withdraw at any time without explanation.

2.9 : Who will have access to my information during this research?

All research records will be stored in securely locked cabinets. That information may be transcribed into our database but this will be sufficiently encrypted and password protected. Only the people who are closely concerned with this study will have access to your information. All your information will be kept confidential.

2.10 : Who can I contact in case I have further questions?

You can contact me, Rebeccah Wangusi, at the Strathmore Business School, or by e-mail **rebeccah.wangusi@strathmore.edu** or by phone **+254 723375892**. You can also contact my supervisor, Dr. Pratap Kumar at the Strathmore Business School, Nairobi, or by e-mail **pkumar@strathmore.**edu or by phone **+254 731848163**

If you want to ask someone independent anything about this research, please contact: The Secretary–Strathmore University Institutional Ethics Review Board, P. O. BOX 59857, 00200, Nairobi, email ethicsreview@strathmore.edu Tel number: +254 703 034 375

I_____have had the study explained to me. I have understood all that I have read and have had explained to me and had my questions answered satisfactorily. I understand that I can change my mind at any stage.

Please tick the boxes that apply to you;

Participation in the research study

I AGREE to take part in this research

☐

I DON'T AGREE to take part in this research

☐

Storage of information on the completed questionnaire

I AGREE to have my completed questionnaire stored for future data analysis

☐

I DON'T AGREE to have my completed questionnaire stored for future data analysis

☐

Participant's Signature: **Date:_/_____/_____**

_____

DD / MM / YEAR

Participant's Name:

Time:_/____

_____

(Please print name) ***HR / MN***

I,_____(Name of person taking consent) certify that I have followed the SOP for this study and have explained the study information to the study participant named above, and that s/he has understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given the opportunity to ask questions which have been answered satisfactorily.

Investigator's Signature: **Date:_/____/_____**

_____

DD / MM / YEAR

Investigator's Name:

Time:_/____

_____

(Please print name) ***HR / MN***

APPENDIX 3: ETHICAL APPROVAL

28th September 2021

Dr Wangusi Rebeccah,
rebeccah.wangusi@strathmore.edu

Dear Dr Wangusi,

RE: Medical Assisted Treatment in HIV Control in Nairobi, Kenya: How Much Does It Cost?

This is to inform you that SU-IERC has reviewed and approved your above SU- master's research proposal. Your application reference number is SU-IERC1144/21. The approval period is 28th September 2021 to 27th September2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-IERC.
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-IERC within 48 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-IERC within 48 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to SU-IERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke/ and also obtain other clearances needed.

Yours sincerely,

Prof Fred Were,
Chairperson; SU-IERC

STRATHMORE UNIVERSITY INSTITUTIONAL ETHICS REVIEW COMMITTEE (SU-IERC)
28 Sep 2021
TEL: +254 (0)703034000
P.O BOX 59857-00200
NAIROBI-KENYA

APPENDIX 4: NACOSTI APPROVAL

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **842792**

Date of Issue: **15/October/2021**

RESEARCH LICENSE

This is to Certify that Dr.. Rebeccah Namalea Wangusi of Strathmore University, has been licensed to conduct research in Nairobi on the topic: MEDICAL ASSISTED TREATMENT IN HIV CONTROL IN NAIROBI, KENYA: HOW MUCH DOES IT COST? for the period ending : 15/October/2022.

License No: **NACOSTI/P/21/13472**

842792

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

VT OMNES VNVM SINT