

**OUTCOMES OF DIFFERENTIATED SERVICE DELIVERY
FOR NEWLY IDENTIFIED HIV POSITIVE PATIENTS IN
NYATIKE SUB COUNTY MIGORI COUNTY**

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**A Thesis Submitted in Partial Fulfillment of the Requirements for the Award of The
Degree of Master of Science in Epidemiology and Biostatistics
of
Jaramogi Oginga Odinga University of Science and Technology.**

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DECLARATION

I hereby declare that the thesis titled, “outcomes of differentiated service delivery for newly identified HIV positive patients in Nyatike sub county Migori county” submitted to Jaramogi Oginga Odinga University of Science and Technology, is a record of an original work done by me is submitted in the partial fulfilment of the requirements for the award of the degree of Master of Science in Epidemiology and Biostatistics. The results embodied in this thesis have not been submitted to any other University or Institute for the award of any degree or diploma.

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DEDICATION

I dedicate my thesis work to my family and many friends. A special gratitude to my loving parents, Habel and Milia Omusula whose words of encouragement and push for tenacity ring in my ears. My wife Zipporah, and sons, Lee and Hans never left my side and are very special.

I also dedicate this dissertation to my many friends who have supported me throughout the process. I will always appreciate all they have done, especially Amadi Emmanuel for helping me develop my analysis skills for the many hours of proofreading.

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TABLE OF CONTENTS

DECLARATION ii

DEDICATION iii

ACKNOWLEDGEMENT iv

TABLE OF CONTENTS v

LIST OF FIGURES viii

LIST OF TABLES ix

ABBREVIATIONS x

DEFINITION OF OPERATIONAL TERMS xi

ABSTRACT xiii

CHAPTER ONE: INTRODUCTION 1

1.1 Background 1

Figure 1: Categorization of HIV infected individuals (NASCO, 2017). The area of focus of this study circled in red..... 4

1.2 Problem Statement 4

1.3 Objectives 5

 1.3.1. Main Objective 5

 1.3.2 Specific Objectives..... 5

1.4 Research Questions 6

1.5 Justification 6

1.6 Significance..... 7

CHAPTER TWO: LITERATURE REVIEW 8

2.1 Introduction..... 8

2.2 Retention to HIV Care 11

2.3 HIV Viral Load Outcomes 13

2.4 Morbidity and Mortality 16

2.5 Conceptual Framework..... 19

Figure 2: Conceptual Framework showing the relation of differentiated service delivery at enrolment and the HIV care and treatment outcomes one year later. 19

CHAPTER THREE: METHODOLOGY..... 20

3.0 Introduction..... 20

3.1 Study Area	20
3.2 Research Design.....	21
3.3: Target Population.....	21
3.4: Sample Size.....	22
3.5: Sampling Procedure	22
Table 3.1: Sample Size Distribution by Ward and Facility	23
3.6 Inclusion and Exclusion Criteria.....	23
3.7 Data Collection Methods	24
3.8 Instruments Reliability and Validity.....	24
3.9 Data Analysis	24
3.10 Ethical Considerations	25
CHAPTER FOUR: RESULTS	26
4.1 Introduction.....	26
4.2 Demographic and Clinical Characteristics.....	26
Table 4.1: Study population by DC Categorization.....	27
4.3 Key Informant Interviewee Characteristics and Outcomes Summary.....	28
4.4 Retention on Treatment.....	28
Table 4.2: Factors associated with retention on ART amongst PLHIV initiated on ART	29
4.5 Viral Load Suppression.....	29
Table 4.3: DC Categorization and Viral Suppression.....	30
4.6 Morbidity and Mortality	31
Table 4.4: DC categorization and morbidity and mortality	31
CHAPTER FIVE: DISCUSSION.....	32
5.1 Introduction.....	32
5.2 Retention to Care	33
5.3 Viral Load Suppression.....	35
5.4 Morbidity and Mortality	37
CHAPTER SIX: CONCLUSION AND RECCOMENDATIONS	40
6.1 Conclusion	40
6.2 Recommendations.....	40
6.3 Suggestions for Further Studies	41

REFERENCES.....	42
APPENDICES.....	66
Appendix I: Confidentiality Agreement Form.....	66
Appendix II: Informed Consent Form for CCC In-Charges.....	67
Appendix III: Key Informant Interview Guide for CCC In-Charges.....	69
Appendix IV: Data Extraction Form.....	70
Appendix V: Categorization Guide for Patient Files.....	71
Appendix VI: Board of Postgraduate Studies Approval Letter.....	72
Appendix VI: ERC Approval Letter.....	73
Appendix VIII: Approval by the National Commission for Science, Technology & Innovation.....	74
Appendix IX: Migori County Research Approval.....	75

LIST OF FIGURES

Figure 1: Categorization of HIV infected individuals (NASCOPI, 2017). The area of focus of this study circled in red.....	4
Figure 2: Conceptual Framework showing the relation of differentiated service delivery at enrolment and the HIV care and treatment outcomes one year later.	19
Table 3.1: Sample Size Distribution by Ward and Facility	23
Table 4.1: Study population by DC Categorization.....	27
Table 4.2: Factors associated with retention on ART amongst PLHIV initiated on ART	29
Table 4.3: DC Categorization and Viral Suppression.....	30
Table 4.4: DC categorization and morbidity and mortality	31

LIST OF TABLES

Figure 1: Categorization of HIV infected individuals	4
Figure 2: Conceptual Framework showing the relation of differentiated service delivery at enrolment and the HIV care and treatment outcomes one year later.	19

ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Anti-Retro Viral
CCC	Comprehensive Care Clinic
CD4	Cluster of Differentiation
DSD	Differentiated Service Delivery
HCWs	Health Care Workers
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
MOH	Ministry Of Health
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
OIs	Opportunistic Infections
STI	Sexually Transmitted Infection
U=U	Undetectable = Untransmissible
WHO	World Health Organization
CCM	Cryptococcal meningitis
RTIs	Respiratory Tract Infections
KS	Kaposi Sarcoma
EPTB	Extra Pulmonary Tuberculosis
PTB	Pulmonary Tuberculosis
GE	Gastroenteritis
LTFU	Lost To Follow Up
LDL	Lower Detectable level
PLHIV	People Living with HIV
IRIS	Immune Reconstitution Inflammatory Syndrome
MDT	Multi-Disciplinary Team
TWG	Technical Working Group
F/U	Follow Up

DEFINITION OF OPERATIONAL TERMS

Differentiated Service Delivery	Client-centered approach to HIV services that simplifies and adapts them across the board of clinical cascade to meet the preferences and expectations of various groups of HIV-positive people. This may be used interchangeably with Differentiated Care (DC)
Retention/ Continuity in Care	The length of time PLHIV remain in treatment
Viral load Suppression	The act of ART reducing the quantity of HIV in the body (viral load) to levels below 400cp/ml which maintains the immune system to keep it active and guards against disease.
Opportunistic Infections	Diseases occurring due to impaired immunity
Active	Client still on HIV medication and follow up at the facility
Inactive	Client not attended clinic for more than 30 days and not known to be on medication
Well	Client having a CD4 of >200 and WHO stage 1 or 2
Advanced	Client with CD4 <200 or WHO stage 3 or 4
Undetectable	Client having lower than detectable viral load levels
Untransmissible	Client not being able to transmit the HIV virus to an un-infected person after exposure
Categorization	The act of assigning clients as being well or advanced; stable or unstable
Morbidity	The occurrence of opportunistic infections or state of being Unhealthy for a particular disease
Mortality	The number of deaths occurring in a population
Virological failure	Having viral load levels of 1000 copies/ml or more

ART naïve

A client who has never been on ART

Outcomes

The end results of a natural follow up after HIV treatment after a period of time e.g. 12 months, 24 months 36 months etc.

ABSTRACT

Since the inception of differentiated care in Kenya in 2017, patient categorization at enrolment has been based on the CD4 counts and WHO staging as either *well* or *advanced*. The DC operation manual offers separate package of care for the two categories of clients with the *advanced* category getting preferential management, and little is known of the impact of this on treatment outcomes. The purpose of this study was to investigate the effect of categorization at enrolment between October 2018 and September 2019, using 182 HIV patient records and 7 key informant interviewees on treatment outcomes 12 months later in Nyatike Sub County. The focus was on retention to care, viral load suppression, morbidity and mortality. Sample size got by mixed methods and quantitative data analyzed by Chi-square tests and Fischer's exact test where applicable, used to test for association between predictor and outcome variables with risk ratios applied to quantify significant associations. Associations were presented as adjusted risk ratios (aRRs), with 95% CIs. Statistical analysis tests conducted at 5% level of significance while qualitative data was analyzed by generation of themes, and results triangulated with the quantitative data. Categorized as *well*, were 134(74%) client records while 48 (26%) were *advanced*. Retention was better among *advanced* category at (71%) compared to the well (64%) group; however, retention on ART was not associated with DC categorization with RR of 0.96 (0.73 - 1.13). Viral load suppression in the well group was 97% (87/90) compared to 92% (34/37) for the advanced category. There was however no statistical significant association between Viral suppression and categorization [aRR 1.05 (0.95 - 1.17)]. Opportunistic Infection incidence was higher among the advanced category (79% vs 3%, unadjusted risk ratio RR 0.04, 95% CI: 0.01 – 0.10), with higher risk of contracting an OI even after adjusting for age, sex, and WHO staging [aRR (95% CI) = 0.04 (0.02 – 0.13)]. The Ministry of Health should institute measures that improve retention to care and viral load uptake and suppression, while restructuring the model of care that will serve all clients equitably and reduce morbidity and mortality in PLHIV.

CHAPTER ONE: INTRODUCTION

1.1 Background

The treatment of an HIV-infected patient is a comprehensive and multidisciplinary strategy aimed at managing disease progression, preventing opportunistic infections, and preserving a high quality of life. Antiretroviral Therapy (ART), the cornerstone of HIV care, involves the use of a combination of antiretroviral medications to suppress viral replication, therefore lowering viral load and preserving immune function (Gunthard *et al.*, 2016). ART is normally started as soon as a patient is diagnosed with HIV, regardless of CD4 cell count. The choice of ART regimen is influenced by factors such as viral resistance, potential drug interactions, patient preferences, and comorbidities. HIV-infected people should see their healthcare professionals on a frequent basis to monitor their viral load, CD4 cell count, and overall health (Ochodo *et al.*, 2022). Monitoring aids in determining the efficacy of ART and detecting any potential problems.

Because HIV impairs the immune system, individuals are more vulnerable to opportunistic infections (OIs). Preventing common OIs such as *Pneumocystis jirovecii* pneumonia (PJP), *Mycobacterium avium* complex (MAC) infection, and toxoplasmosis is commonly done using prophylactic drugs (Adolescents, 2019). Many HIV patients have co-occurring medical illnesses such as cardiovascular disease, diabetes, or mental health issues. These comorbidities should be addressed alongside HIV treatment. Vaccinations against diseases such as influenza, pneumococcal infections, and hepatitis A and B are advised for HIV-infected patients. Vaccinations aid in the prevention of additional health issues (Crum-Cianflone & Wallace, 2014).

Adherence to the ART regimen, as well as other medication adherence, is critical for its efficacy. Healthcare practitioners should collaborate with patients to devise ways to help them take their prescriptions consistently and appropriately (Sim *et al.*, 2020). Encouragement of a healthy lifestyle and advice to keep a balanced diet, exercise regularly, avoid smoking and excessive alcohol usage, and get enough sleep. These habits contribute to general well-being. A HIV diagnosis can have a substantial influence on a patient's mental and emotional well-being, therefore providing psychological support,

such as counseling and support groups, can assist patients in coping with the disease's complications (Okonji *et al.*, 2020).

HIV-infected people should be counseled on safe sexual practices to avoid transmission to partners. Family planning methods should be considered in order to prevent mother-to-child transmission and unwanted pregnancies, as well as regular STI screening to avoid difficulties and ensure early treatment. Antiretroviral drugs can have adverse effects, which must be monitored and managed on a frequent basis to ensure patient adherence to therapy (Akelo *et al.*, 2013). HIV-infected patients who also have hepatitis C should be assessed for therapy, as hepatitis C might hasten the progression of HIV-related liver damage (Kwan *et al.*, 2022).

Because HIV is now considered a chronic disease, long-term care planning is essential. This includes addressing age problems, prospective medication modifications, and the changing environment of HIV research and treatment (Watt *et al.*, 2017). It is critical to remember that HIV management should be tailored to each patient's medical history, preferences, and individual needs (Riccardi *et al.*, 2021). Regular communication and teamwork between the patient and their healthcare team are essential for HIV management success (Kwame & Petrucka, 2021).

Over time, HIV care and treatment approaches have been evolving and this is slowly shaping new models of patient care based on either recent findings or the need to adapt to the prevailing circumstances. This has led to the development of the concept of differentiated service delivery (DSD), which refers to a responsive, client-centered approach to HIV services that simplifies and adapts them throughout the cascade to better serve individual needs while reducing unnecessary burdens on the health-care system. A thought of providing a uniform kind of care to all populations infected with HIV does not work for all the close to 37 million people living with HIV today. This has prompted many countries to review HIV service delivery acknowledging the need to deliver differently (IAS, 2021; Maartens *et al.*, 2014). The reducing resources to cater for the increasing need for services have led to innovations and incorporation of methods thought to tackle the high number of clients using limited resources. With differentiated care, patients are managed deferentially based on their initial presentation

(clinical/immunological status at the time of enrollment) and afterwards, after receiving care for at least a year (MOH/NASCOP, 2017).

It is known that HIV poses a three-pronged threat by rising the disease burden, imposing heavier workloads, and increasing the complexity of care with new demands such as anti-retroviral therapy, ART (Barker *et al.*, 2017); overstressing the by infecting healthcare workers and putting HCWs who provide palliative care under psychological stress, resulting in low morale, burnout, and absenteeism (Hanvoravongchai, 2005). Human resource happens to be dwindling in the HIV sector due to the reduced funding scope and thus the need to manage using fewer staff compared to the ever-increasing demands of clients and implementation of other strategies.

This has brought about differentiated care that seeks to categorize clients based on individual needs and offering each client a package that suits him/her. The National STI Control Program (NASCOP) through the Differentiated Care Operational Guide classifies newly identified clients as *well* or *advanced* based on certain criteria as seen in annex 5 that evaluates a client based on the clinical and laboratory findings of their CD4 levels to determine if they need greater care by the clinical staff or can be managed relatively with some ease on the health system (MOH/NASCOP, 2017; WHO, 2017). Those categorized as *well* have a CD4 of over 200 cells per microliter and at WHO clinical stage 1 or 2; while those with CD4 less than 200 or WHO clinical stage 3 or 4 are categorized as *advanced*. The advanced clients are given greater clinical attention and have more frequent hospital visits since they are prone to more harm than their Well counterparts who despite being newly identified HIV positive clients, are relatively healthy (NASCOP, 2018).

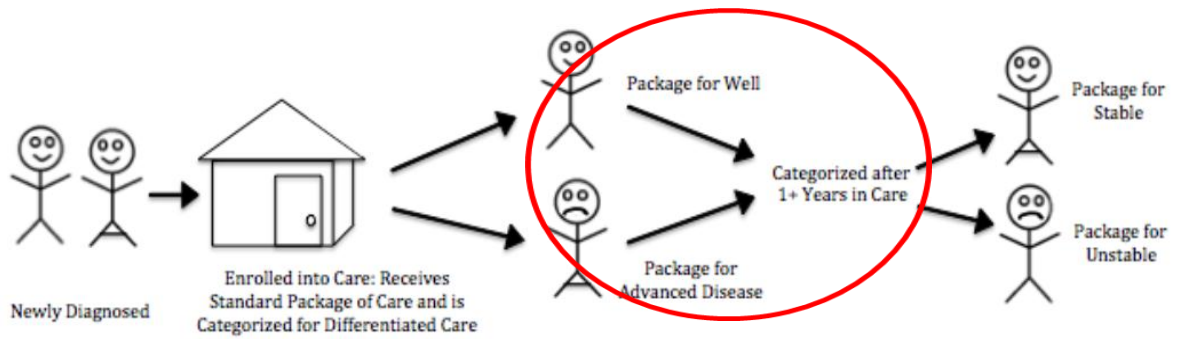


Figure 1: Categorization of HIV infected individuals (NASCO, 2017). The area of focus of this study circled in red

The focus of this study is to analyze and correlate the outcomes of the two groups of clients based on viral load suppression, in care status (Active or Inactive) and morbidity and mortality. It seeks to understand if there is any relationship between being categorized as well and receiving the prescribed care or advanced and receiving the care as prescribed where the clients have more frequent clinical reviews and get closer medical attention and the HIV treatment outcomes a year after their enrolment.

1.2 Problem Statement

Individuals requiring HIV care and treatment have been increasing each day with intensified case identification and treat all guidance thus overstressing the meagre resources available. This brought about differentiated service delivery (DSD) that categorizes clients at enrolment as either *well* or *advanced*; and at one year as either *stable* or *unstable*. Efforts have therefore been directed to the *advanced* and *unstable* clients with the view that they need more attention compared to the *well* and *stable* counterparts so as to improve their treatment outcomes (WHO, 2017). The idea of segregating clients at enrolment offers more attention to the advanced group yet both client groups are new and so require the same level of keenness and care and both new to the HIV diagnosis and more or less go through the same challenges. The overall the purpose of HIV care and treatment is improving the quality of life for the clients and also reduce HIV transmission and this bias seems to favor one group of clients and leaving the other. So as to reduce HIV transmission, individuals already initiated to anti-retroviral

medications are supposed to diligently adhere to taking their medication as prescribed so as to reduce their viral load (Oh & Han, 2021; Yu *et al.*, 2018). The preferences to the *advanced* clients getting more attention than the *well* group gives a biased approach to HIV treatment and care.

In the context of U=U, *undetectable* equals *untransmissible*, the aim therefore is to have a lower than detectable viral load which implies that the viral copies in the system are not likely to be transmitted to another individual either by vertical or horizontal (Jean Louis *et al.*, 2018; LANCETHIV, NOVEMBER 2017; Mahy *et al.*, 2010; Steve Kanters, 2017). This categorization therefore gives much preference to the *advanced* client while the *well* client also needs just as much care so as to reduce transmission and improve their quality of life. Treatment outcomes have continuously been measured routinely and despite this categorization and DSD implementation, a review has not been done to assess the effect of this categorization at enrolment on the intended treatment outcomes to inform change in approach or policy modification. The purpose of this study is therefore to assess the effect of this categorization at enrolment on treatment outcomes in Nyatike Sub County, Migori County.

1.3 Objectives

1.3.1. Main Objective

To investigate the effect HIV patient categorization at enrolment on HIV treatment outcomes at month twelve in Nyatike Sub County

1.3.2 Specific Objectives

- i. To assess the effect of patient categorization at enrolment on their retention to care and Treatment in Nyatike Sub County
- ii. To determine the effect of patient categorization at enrolment on their viral load outcomes in Nyatike Sub County
- iii. To determine the effect of patient categorization at enrolment on morbidity and mortality outcomes in Nyatike Sub County

1.4 Research Questions

- i. What is the effect of HIV patient categorization at enrolment on their retention at one year in Nyatike Sub County
- ii. What is the effect of HIV patient categorization at enrolment on their viral load outcomes at one year in Nyatike Sub County
- iii. What is the effect of HIV patient categorization at enrolment on morbidity and mortality outcomes by one year in Nyatike Sub County

1.5 Justification

The study analyzed the outcomes of the two groups to establish association with patient categorization at enrolment. The study based on an assumption that there is an association between patient categorization and better outcomes for the advanced category. The study however established that there was no association between patient categorization at enrolment and any of the outcomes of interest. The study looked at the effect of patient categorization on retention as an outcome but did not establish any association despite having differences in the retention rates. It also looked at the effect of patient categorization at enrolment on viral load suppression between the two groups. Despite having marginal differences in the viral load suppression rates in favor of the well group, there was no statistical difference thus no association noted. The purpose of any treatment modality is to enhance the quality of life and avoid suffering. This study assessed the effect of patient categorization at enrolment on the morbidity and mortality as outcome. The study established that being in advanced had increased incidence of opportunistic infections compared to the well category. The goal of this research was to establish if there is any difference in the outcomes of the two populations to know if there is need to change approach to care and treatment. Establishing the categorization status and their outcomes may save a life through timely diagnosis even for clients who had previously been ruled as well. It aimed at establishing advantages (if any) of categorizing patients in to the well and advanced groups based on the treatment outcomes at the end of one year.

1.6 Significance

This study was important in evaluating the differentiated service delivery model especially for the newly diagnosed clients. This study can be used to provide insight on decision-making concerning categorizing of clients at enrolment. This study aimed at establishing that the need for equal/similar approach for all clients to access HIV care regardless of the severity of their condition or categorization status. The retention outcomes intended to inform the need to have clients identified earlier or as need may be. The viral load outcomes for the two groups intended to inform the need to tailor make a package for the specific group of clients to achieve better outcomes while the morbidity and mortality outcomes inform the standard of care to provide with view to have better outcomes in the category with unfavorable outcomes.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Differentiated service delivery (DSD) has evolved as a critical concept in global healthcare systems to optimize resource allocation, improve patient outcomes, and increase service delivery efficiency. Globally, differentiated service delivery models are gaining popularity in a variety of healthcare settings throughout the world (Zakumumpa *et al.*, 2020). DSD has been shown in studies to be useful in enhancing patient adherence and health outcomes (Mukumbang *et al.*, 2022). The benefits of task-shifting and community-based care in expanding access to antiretroviral therapy (ART) and lowering the burden on healthcare facilities in Sub-Saharan Africa as stressed by (Grimsrud *et al.*, 2016).

In Africa and specifically Kenya, where healthcare difficulties are prevalent, diversified service delivery has been implemented as a solution to address these issues (Oleribe *et al.*, 2019). Community health professionals have been critical in providing ART and assistance to people living with HIV. Community-based ART administration was found to enhance medication adherence and retention in care among HIV-positive persons in Kenya (Casale *et al.*, 2019). Differentiated service delivery methods in HIV/AIDS care have shown potential in both global and Kenyan settings. Grimsrud and Wilkinson in their work, highlight how the "fast-track" method has been beneficial in reducing the frequency of clinic visits for stable patients on ART, resulting in improved patient satisfaction and lower healthcare expenditures (Grimsrud & Wilkinson, 2021).

While differentiated service delivery offers tremendous benefits, it faces implementation obstacles. The need to overcome stigma and discrimination hurdles in the context of DSD for HIV/AIDS care is emphasized in Indonesia and by extension, Kenya (Fauk *et al.*, 2021). Concerns about equality and potential discrepancies in access to differentiated care have also been raised, emphasizing the importance of inclusive planning and community engagement (Belay *et al.*, 2022; Dommaraju *et al.*, 2021). Distinctive service delivery models emphasize patient-centered care and empowerment, which aligns with the global shift toward patient involvement in healthcare decision-making. The importance of patient involvement in the design and implementation of DSD models in

improving patient satisfaction and health outcomes is very important in the success of DSD implementation (Huber *et al.*, 2021; Pascoe *et al.*, 2023). On its scalability and sustainability, it is critical to ensure the long-term viability and scalability of diverse service delivery methods. The significance of incorporating DSD into national healthcare policies and initiatives in order to achieve standardized implementation and long-term benefits is emphasized (Kruk *et al.*, 2018; Pollack Porter *et al.*, 2018).

As the healthcare landscape evolves, differentiated service delivery models continue to evolve as well. Beyond HIV/AIDS care, research should focus on analyzing the long-term impact of DSD on other health indices. Furthermore, investigating DSD's applicability in other healthcare areas, including as maternal and child health, may provide insights into its broader potency. Differentiated service delivery models have great promise for enhancing healthcare delivery in Kenya and around the world (Dommaraju *et al.*, 2021; Sanwo *et al.*, 2021). DSD has the potential to improve patient outcomes, relieve load on healthcare facilities, and contribute to more efficient and patient-centered healthcare systems by adapting services to the needs of distinct patient groups. However, successful implementation requires careful planning, stakeholder participation, and adaptation to local situations (Abelman *et al.*, 2020).

Human immunodeficiency virus (HIV) case identification through antibody and antigen testing has helped identify clients infected with the virus and thus realizing the dream of initiating them on antiretroviral drugs. HIV infection is a long-term condition that weakens the body's immune system and the human body becomes susceptible to opportunistic infections (Duggal *et al.*, 2012; Mahungu *et al.*, 2009). Being a chronic infection, the client therefore is prepared through treatment preparation sessions done by an adherence and/or psychosocial counsellor. This is meant to take the client through the new phase of life, encourage positive health and dignity, disclosure to the relevant significant support systems and learn more about the life long medications. Antiretroviral drugs continue to be the hallmark of HIV treatment and prevention (Gunthard *et al.*, 2016; Mahy *et al.*, 2010). As per the Kenyan NASCOP 2016 recommendations (NASCOP, 2016), regardless of CD4 count, antiretroviral medication should begin in all patients who have been diagnosed as HIV positive (with detectable viremia) (Gunthard *et*

al., 2016). This overemphasizes on early initiation to antiretroviral drugs and sustaining the clients on the medication (Fiorentino *et al.*, 2021). This said, the grouping of clients as *well* and *advanced* does not necessarily discriminate on the ART initiation, but rather on the follow up to the medication and any other identified (or unidentified) conditions or challenges that come in afterwards.

Antiretroviral therapy follow up requires experienced personnel to identify any complications or likely complications especially with pregnant women and thus with decentralization of services, the need to have frequent reviews since not all the staffs deployed to the peripheral facilities are as experienced as those deployed in the urban settings (Abrams *et al.*, 2021; Gourlay *et al.*, 2015). The intended aim of decentralization was for ease of accessing HIV treatment and care services as close as possible to those who need them and thus ease of continuity of care to the identified clients coupled with equitable distribution of government health services (Reidy *et al.*, 2014). It also aimed at improving integration of HIV/AIDS service to other services at the peripheral facilities and health care delivery system (Odeny *et al.*, 2013). This however may not have been achieved since capacity building was not adequately done to the staffs being deployed to the facilities.

A flexible and client-centered approach known as "differentiated service delivery" simplifies and adapts HIV services across the continuum to better meet individual requirements and lessen the unneeded strain on the health-care system (Hagey *et al.*, 2018). A thought of providing a uniform kind of care to all populations infected with HIV does not work for all the close to 37 million individuals are HIV-positive today (NASCO, 2017). In this model, the newly identified clients are pooled and given a standard package of care like before they are reviewed and categorized as either *well* or *advanced* where services are offered based on a standard package for the various groups of patients at enrolment. These clients are followed up on over a twelve-month period as monitoring is done through clinical evaluations and laboratory investigations that checks on the CD4 and viral loads as well as other psychosocial aspects of the clients that determine the review after the twelve months (Long *et al.*, 2019).

A further categorization is done at twelve months that determines if a client is either *stable* or *unstable* based on standard criteria as seen in annex six of the Differentiated Care Operational guide. It is at this point that if a client is determined to be stable, the clinical staff may choose to put the client on a form of differentiated care. This is a form of multi months dispensing of drugs that the clinician and pharmacy staffs assign clients longer return dates for clinical review. This therefore means that the client is given drugs to last a longer duration and even if they are to come for another refill of drugs, they do not necessarily need to be reviewed by the clinical person. This therefore reduces the workload at the clinicians' desk and thus freeing up enough time to be used by the *unstable* and the clients yet to reach twelve months on ART follow up.

2.2 Retention to HIV Care

Retaining HIV patients in care and treatment is an important component of public health efforts to control the HIV/AIDS epidemic. Differentiated service delivery is a method that is increasingly being used to improve retention rates and overall results for people receiving HIV care and treatment, particularly in Kenya (Baleeta *et al.*, 2023). Retention in HIV Care and Treatment is the ability of healthcare systems to keep persons engaged in frequent medical visits, medication adherence, and ongoing support services throughout the length of their HIV treatment journey is referred to as retention in HIV care (Holtzman *et al.*, 2015). Maintaining high retention rates is critical for a variety of reasons, including consistent participation in HIV care and treatment results in better health outcomes for individuals (Umeokonkwo *et al.*, 2019), including viral suppression and increased immunological function (Mutasa-Apollo *et al.*, 2014); Individuals who are virally suppressed are less likely to spread the virus to others, which aids in HIV prevention efforts (Mwanguzi *et al.*, 2021); Maintaining high retention rates lessens the demand on healthcare resources since stable patients require fewer urgent interventions. Routine care visits help patients comply with their prescription regimens, which is critical for preventing drug resistance (van der Kop *et al.*, 2018).

In the context of HIV care and treatment, differentiated service delivery entails adapting healthcare services to the individual requirements, preferences, and circumstances of distinct patient groups (Okonji *et al.*, 2022). Individuals have various levels of medical

and psychosocial demands, and one-size-fits-all services may not be the most effective method to meet those needs (Wood *et al.*, 2018). Differentiated care delivery approaches have been introduced in Kenya and many other resource-constrained contexts to increase patient retention and overall outcomes (MOH/NASCOP, 2017). Community-Based Care refers to bringing HIV care services closer to patients' homes, typically through community health workers and local clinics, in order to eliminate travel barriers and promote convenience. Multi-Month dispensing in this context refers to giving patients a longer supply of antiretroviral medication, minimizing clinic visits, and enhancing drug adherence while Adolescent-Friendly Services are services that are tailored to the specific requirements of adolescents, such as peer support and age-appropriate therapy (Okonji *et al.*, 2022). Family-Centered Care is providing care that includes family and partners, acknowledging their role in assisting patients on their treatment journeys (Chinyandura *et al.*, 2022) while telemedicine and Mobile Health refers to the use of technology to provide services remotely, such as teleconsultations, SMS reminders, and medication adherence tracking apps (Haleem *et al.*, 2021).

The aim of starting clients on HIV care and treatment is to ensure that they take their medication and are retained on the medication for life while keeping the instructions as given by the health care providers. The decision to continue on medication depends on the health education the client receives at the start of HIV care and the subsequent visits thereafter (Steve Kanters, 2017). This therefore means that the information given by the providers need to be as accurate and be able to allay any fears or concerns raised by the clients as much as possible. Continuous reminders and peer education also keep the clients keen on their health and the need to achieve good adherence and suppression (Ali & Yirtaw, 2019; Coker *et al.*, 2015).

As clients are retained to care and continue to adhere to medication use, they are more likely to suppress or achieve minimal load levels and thus decrease HIV transmission and also improve their own quality of life and free from opportunistic infections (Solomon *et al.*, 2018). Clients get retained to care based on several factors including the proximity to the medical facilities, and other competing tasks. HIV clients have a normal life thus continue with the normal routine of life albeit with frequent if not regular visits to the

facility. Over time, the need to come to the facility just to pick drug refills become another burden to them and thus the introduction of differentiated care where the needs of the clients are evaluated at an individual level (Long *et al.*, 2019). On evaluating the clients that were put on a community ART distribution program in Sub Saharan Africa made the services more accessible and affordable to the clients and to the government. The overall retention percentages performed impressively with 12 months retention being at 97.7% and the 48 months retention being at 91.8% (Decroo *et al.*, 2014). A study done in South Africa looking at retention and viral load suppression among clients put on differentiated care on follow up with an adherence counsellor showed better viral load outcomes and retention levels (Cassidy *et al.*, 2020). These studies have however been conducted on clients that have been on ART for over a year and already on multi months dispensing. This study intends to look at a cohort of clients just enrolling to care (ART naive) and observing their outcomes exactly one year after enrolment.

Retention and Differentiated Service Delivery: Differentiated service delivery models strive to improve retention by addressing barriers that may result in missed visits or treatment interruptions (Belay *et al.*, 2022). These approaches can lessen the difficulty of receiving care, enhance drug adherence, and offer a more patient-centered healthcare experience by personalizing services to individual needs. Implementing diverse service delivery strategies can greatly contribute to boosting retention rates in HIV care and treatment programs in Kenya, where there may be transportation, stigma, and inadequate healthcare resources (Roy *et al.*, 2019). These approaches help individuals stay engaged in care by delivering convenient and patient-centered services, resulting in better health outcomes for both individuals and the larger community.

2.3 HIV Viral Load Outcomes

HIV viral load suppression is the reduction of HIV levels in a person's blood to undetectable levels, often less than 20 or 50 copies of the virus per milliliter of blood, depending on the testing method employed (Fokam *et al.*, 2019). Suppression of viral load is an important goal in HIV treatment because it implies good virus control and minimizes the risk of disease progression and transmission to others. The major treatment method for viral load suppression is antiretroviral medication (ART). Globally, efforts

have been undertaken to scale up HIV treatment and care services, including viral load monitoring and diversified service delivery. Organizations such as UNAIDS, the World Health Organization (WHO), and other partners have been striving to ensure that individuals living with HIV have access to effective treatment and support services, and that viral load suppression is a major indicator of successful treatment programs.

Kenya has played an important role in the fight against HIV/AIDS. The country has undertaken a number of methods to improve viral load control and HIV service delivery. Kenya had made progress in improving access to ART and viral load testing, both of which are required for effective treatment and monitoring, as of 2021. In order to reach more people with HIV care, the country has also investigated diverse service delivery options (MOH/NASCOP, 2017). Community ART distribution has been integrated in differentiated service delivery methods in Kenya, particularly in rural areas where access to healthcare facilities may be limited (Goodrich *et al.*, 2021). These programs seek to reduce the frequency of clinic visits, which can be difficult for some patients due to variables such as distance and time limits (IAS, 2021).

Viral load suppression is an important goal to attain in the context of HIV care in Kenya (NASCOP, 2020). The lowering of the amount of HIV virus in a person's bloodstream to undetectable levels is referred to as viral load suppression. Obtaining and sustaining viral load reduction is critical for the health of those living with HIV and preventing additional virus transmission (Conan *et al.*, 2021). In Kenya and other countries, differentiated care delivery approaches have been introduced to increase viral load suppression rates among HIV patients. These approaches customize healthcare services to individual patient groups' requirements, which can improve treatment adherence, involvement in care, and overall health outcomes. Some diverse service delivery models that can affect viral load suppression include Multi-Month dispensing where providing a three to six-month supply of antiretroviral drugs to stable (established) patients who have achieved viral suppression (Casalini *et al.*, 2023). This minimizes the number of clinic visits and the danger of treatment disruptions; Community-Based ART Refills where Community health workers or local clinics can distribute antiretroviral drugs in patients' communities, minimizing the need for patients to go to healthcare institutions (Fatti *et al.*, 2021);

Group-based models (Adherence Clubs) in which stable patients gather to get medicine refills, counseling, and support. Peer interactions can help to improve adherence to therapy and viral load suppression; Telemedicine and mobile health systems where users can chat with healthcare providers remotely, receive prescription reminders through SMS, and access treatment information and Non-physician healthcare professionals are being trained to fulfill functions traditionally performed by doctors, such as medication management and follow-up appointments (Grimsrud *et al.*, 2023; Mukumbang *et al.*, 2022). This can reduce the strain on healthcare institutions.

When clients are enrolled to care and treatment, the aim is usually to maintain them on an efficacious regimen that will help them achieve HIV viral load suppression levels. The adherence to HIV medication leads to viral load suppression where there is a significant decrease in the amount of HIV viruses in the blood system to the level that the immune system can get the chance to regenerate. At this level, the chances of transmitting the virus to another individual is minimal and can have HIV-free children with proper guidance from the health care providers (Zenzele). This may seem like a daunting task but one should stick to the medication so as to live a healthy and productive life. It is through the suppression of viral loads that the positive clients achieve a reduced ability to transmit the virus to HIV non-infected individuals when they engage in unprotected sexual intercourse or from mother to child during labor and child birth. A study done in South Africa showed that when viral replication was inhibited, no HIV transmission was observed among discordant couples (Cohen *et al.*, 2016).

Suppression is usually a consequence of good adherence to ARV medication. A study done in South Korea to evaluate the suppression and adherence to medication showed lower limits of detection with good adherence to medication (Oh & Han, 2021). Good adherence starts from the time a client is enrolled to care and should be sustained over time so as to achieve sustained suppression. There has been tremendous change in the viral load outcome of patients started on ART over time since a study done Lesotho nurse-led clinics titled still far from 90-90-90. The viral load suppression for children was at 72 % (Puga *et al.*, 2016). This is however not the case in Kenya as the viral load suppression was at 65% for children on ART (Patel *et al.*, 2020). This therefore calls for

increased efforts to have this changed since these children grow to become the drivers of new transmissions they reach adolescence and youth. The suppression among Malawian adolescents and young people, Zambia and Zimbabwe as at December 2016 was as low as 42% compared to the adults at 65%. This shows the burden of disease for this sub population that needed intervention. With this low suppression, disease transmission levels will be high from a population that is thought to be using antiretroviral drugs (Mahon, 2016). Adolescents and youth in the test-and-treat era in Cameroon are more likely to have virologic failure and thus still risk transmission of the HIV virus (Fokam *et al.*, 2019). Differentiated service delivery approaches can assist in overcoming barriers to HIV care and treatment, improving viral load suppression rates (Long *et al.*, 2020). These models can promote treatment adherence and retention in care by personalizing services to patients' needs and lowering the burden of clinic visits, both of which are crucial for attaining and maintaining viral load suppression (Belay *et al.*, 2022).

2.4 Morbidity and Mortality

In the context of HIV care and treatment, differentiated service delivery (DSD) plays an important role in lowering HIV-related mortality, which refers to fatalities caused by problems linked with HIV infection. DSD models seek to improve health outcomes, increase treatment adherence, and optimize healthcare resources (Danforth *et al.*, 2017). DSD can affect HIV mortality through among others improving medication adherence. DSD approaches, such as multi-month dispensing or community-based ART delivery, can improve antiretroviral medication (ART) adherence. Adherence is critical for establishing and maintaining viral suppression, which reduces the risk of HIV-related diseases and mortality dramatically (Njuguna *et al.*, 2019). When the viral load is reduced, the immune system becomes stronger and more capable of combating opportunistic infections (NASCO, 2016).

Timely clinical monitoring including regular monitoring of health and viral load enables healthcare providers to notice changes in health conditions early and, if necessary, intervene quickly and avoid mortality (Post *et al.*, 2018). Timely therapies can halt disease development and consequences, lowering the chance of death. DSD models that provide convenient and patient-centered care can assist in reducing disengagement from

care and treatment. Patients are more likely to obtain appropriate medical attention and assistance if they maintain persistent participation, which can reduce complications and mortality (Robertson *et al.*, 2021). Through these models, opportunistic infections are identified and prevented helping the body build a stronger immune system making people less prone to opportunistic illnesses. These infections are a primary source of morbidity and mortality in HIV positive patients particularly when the immune system is impaired (Li *et al.*, 2020). Some models allow for regular check-ins and assessment thus health care providers are able to spot problems or adverse effects of treatment early. Identifying and addressing these disorders and preventing their progression can lower the chances of death.

Stigma is frequently a barrier to getting medical care, and lowering stigma can lead to more people seeking treatment sooner, ultimately lowering mortality (Kioko *et al.*, 2021; McHenry *et al.*, 2017). Some DSD approaches, such as adherence clubs or community-based treatment, can aid in the reduction of HIV/AIDS stigma. DSD models can be tailored to the individual demands of diverse patient populations, including pregnant women, children, adolescents, and vulnerable populations (Kiplagat *et al.*, 2019). Tailoring care to their specific requirements increases participation and lowers the risk of mortality in these populations (Holmes *et al.*, 2020). While DSD has the potential to reduce HIV-related mortality, its success is dependent on factors such as the DSD model's effectiveness, patient adherence, healthcare infrastructure, and community engagement. DSD initiatives must be continuously monitored, evaluated, and adjusted to ensure that their impact on mortality reduction is sustained.

HIV progression causes immune deficiency and thus opportunistic infections. Late HIV case identification further complicates the reconstitution of the immunity thus reduced chances of fighting minor infections. For the clients already on ART and not adhering to HIV medication are at risk of developing antiretroviral resistance and thus have increased morbidity and mortality and progression to AIDS (Cheng *et al.*, 2018). Early identification of medical conditions helps in early management and averting worse outcomes. The common opportunistic infections that can occur especially in Sub Saharan Africa include pneumonia, tuberculosis, pneumocystis pneumonia, Cryptococci

meningitis among many others. Some of these medical conditions may not manifest as the client is enrolled to HIV care but come to the fold as the clients' immune system begins to pick up while on ART (Grant *et al.*, 2010). This therefore means that the clients categorized as *well* may end up being missed as they may not come back to the clinic as frequent as their *advanced* counterparts do. Studies conducted for clients on multi months dispensing have focused on retention in general without focusing on the proportion of clients exiting from care through mortality while (Faturiyele *et al.*, 2018; Tukei *et al.*, 2020).

2.5 Conceptual Framework

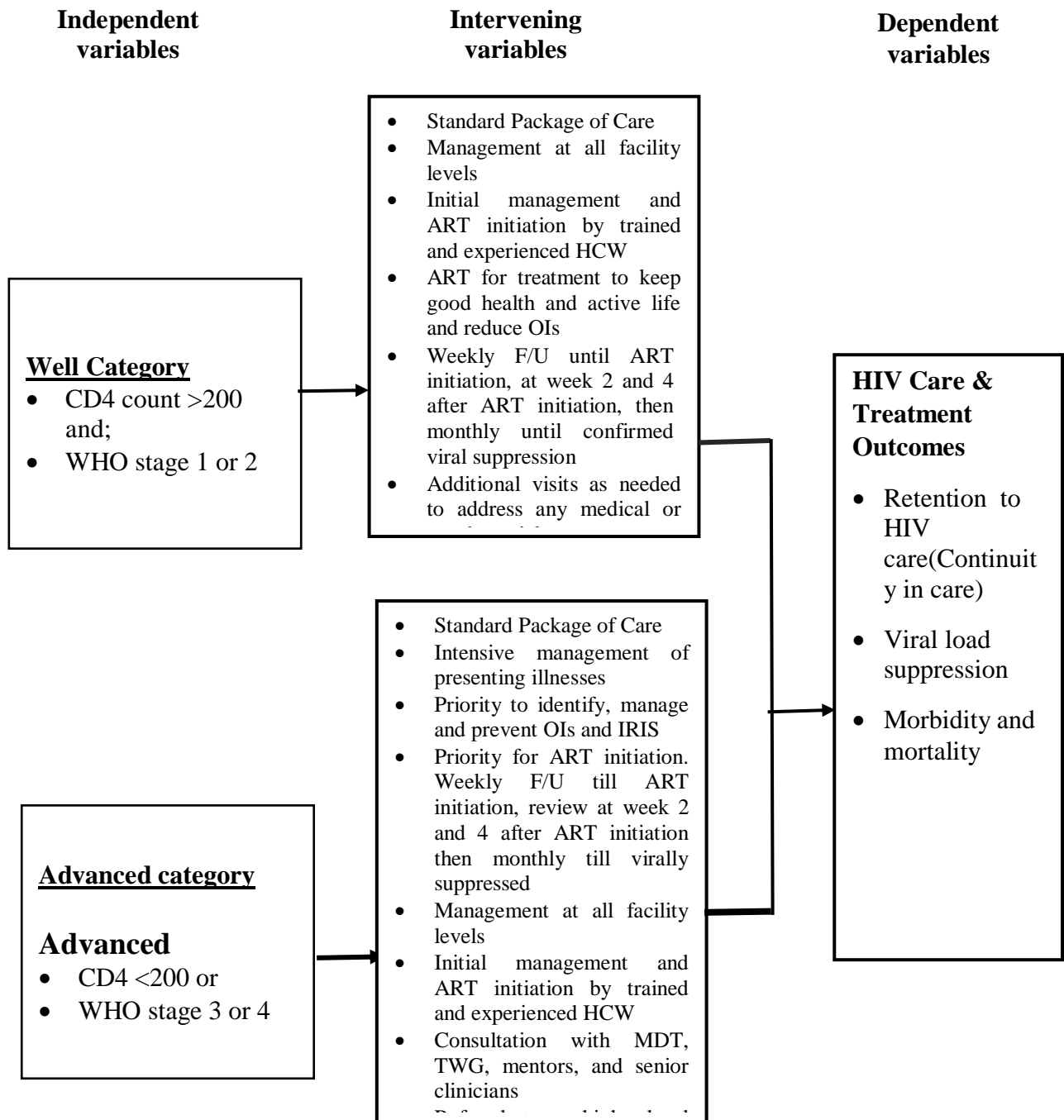


Figure 2: Conceptual Framework showing the relation of differentiated service delivery at enrolment and the HIV care and treatment outcomes one year later.

Author: Self

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter describes the study methods used to conduct this research. It explores the study design of the study, study area and target population. These were followed by sample size calculation, sampling procedures and the inclusion and exclusion criteria. The data collection methods are also described in this chapter and how the reliability and validity of the data collection instruments were tested as well as data analysis and ethical considerations.

3.1 Study Area

This study was done in Nyatike Sub County that is one of eight sub counties of Migori County. The Sub county is divided to seven administrative wards namely Got Kachola, Kachieng ward, Kaler, Kanyasa, Macalder Kanyarwanda, Muhuru ward and North Kadem. The area borders Homa Bay county from Kanyasa and Kachieng wards and borders Tanzania from Kaler and Muhuru wards. The infamous Migingo Island is also part of this sub county and borders closely with Uganda from this region which is in Muhuru ward. The HIV estimates showed Migori to have a HIV prevalence of 13.3% as per the 2018 estimates, (NACC/MOH, 2018) report down from 14.7% in the 2013 report. Migori has a population density of 355 persons per KM² (National Aids Control Council, 2015/2016-2018/2019).

During the review period, the administrative units had these number of clients enrolled to HIV care and treatment; Got Kachola 54 clients, Kachieng 147 clients, Kaler 58 clients, Kanyasa 41 clients, Macalder Kanyarwanda 99 clients, Muhuru ward 114 and North Kadem 60 clients as per the Kenya Health Information Systems (KHIS). This region also has the lake as it's characteristic feature more prominent in Kachieg and Muhuru wards, mining more prominent in Macalder Kanyarwanda and sand harvesting in North Kadem ward as part of the economic activities. The community is largely rural and thus some involve in subsistence farming. Because of the lake, fishing is an important activity in this region and may contribute to health seeking behaviours. This region has been receiving support alongside the larger Migori County for HIV care and treatment from a number of HIV stakeholders like the University of Maryland, LVCT Health and USAID

through local implementing partners through the Mwendo project like Blue Cross and Mercy Orphans due to the HIV burden in the region.

3.2 Research Design

This was a quantitative and qualitative study of the outcomes of newly identified HIV infected clients and categorized at enrolment as either well or advanced that used pre-existing data from the registers specifically the treatment preparation registers, which captures all clients enrolled as new and also captures all the parameters that are used to categorize clients as well or advanced i.e. CD4 counts and WHO staging. The study focused on clients enrolled to HIV care between October 2018 and September 2019 and followed them through the ART cohort registers and also used the patient file to verify clinical indicators like opportunistic infections and viral load suppression. Key informant interviews were conducted to get qualitative data from the departmental heads of the comprehensive care clinics. The study used descriptive design to explain the occurrences observed during the study for both the quantitative and qualitative aspects of the study.

3.3: Target Population

The study looked at newly identified HIV positive clients identified and enrolled to HIV care and treatment between October 2018 and September 2019 in the region. Clients who are newly diagnosed of HIV and initiated to ART usually receive routine follow up services meant to maintain them on the medication initiated and in turn achieve viral load suppression and improve quality of life and reduce mortality. This population in question was among the first beneficiaries of DSD at enrolment thus thought to be best suited for this study. For this study area there were 573 clients initiated on HIV care and treatment during the review period distributed across all the seven administrative units of the sub county with Kachieng and Muhuru wards contributing to 25% and 20% respectively of the 573 clients. The study did not have a bias of age or sex but stratified clients in the two groups and followed the trail of events over a one year period with the October 2018 clients being followed to September 2019 while the September 2019 clients being followed to October 2020.

3.4: Sample Size

The sample size was arrived at by use of the Cochran formula. This based on the HIV prevalence rate of 13.3% for Migori County as per the Kenya HIV estimates, 2018

$$n = Z^2pq/e^2$$

z = Normal standard deviation

p = Proportion of population estimated to be positive
(in this case, 13.3%)

Q= 1-p (86.7%)

Error margin (e) = 5%

$$n = 1.96^2 (0.133 * 0.867) / (0.05)^2$$

$$n = 177.19$$

$$n = 178$$

In addition to data extracted from the 178 patients' records, 1 key informant (CCC in-charge) was interviewed from each of the 7 health facilities.

3.5: Sampling Procedure

The study used different methods to select the required sample. The study first involved stratified sampling where the sub county was divided into the 7 administrative wards and the facilities in the respective wards reviewed with the number of new clients enrolled to care within the review period as from the DHIS 2 platform. Facilities are distributed in the wards with 6 in Muhuru ward offering HIV care and treatment services, Got Kachola 8, Kachieng' 6, North Kadem 7, Kaler 5, Kanyasa 7 and Macalder/Kanyarwanda having 8 facilities. The study then purposively selected health facilities with the highest numbers of clients over the study period from each administrative ward. The study then ranked the facilities based on the number of clients that were enrolled to HIV care and treatment during the review period and sample sizes calculated for each of the selected facilities. Based on the identified numbers, the study picked out every third client enrolled in the review period until the sample size for the facility was achieved as in table 3.1 below.

Table 3.1: Sample Size Distribution by Ward and Facility

S/N	DHIS findings			Sample size
	Ward	Facility	New In care Oct 2018-September 2019	Sample from each Facility
1	Got Kachola Ward	Othoch Rakuom	54	17
2	Kachieng' Ward	Karungu SCH	147	45
3	Kaler Ward	Olasi Dispensary	58	18
4	Kanyasa Ward	Otati Dispensary	41	13
5	Macalder Kanyarwanda Ward	Macalder SCH	99	31
6	Muhuru Ward	Muuru SCH	114	35
7	North Kadem Ward	Lwanda Dispensary	60	19
	Totals		573	178

3.6 Inclusion and Exclusion Criteria

The study involved;

- i. Records of all new HIV positive clients identified between October 2018 and September 2019 and initiated to ARV drugs and reviewed them one year after their enrolment

The study excluded records of;

- i. Clients identified positive but declined ART therapy or never been started ARVs because they did not meet the bare minimum of having started on ART
- ii. Clients known to have mental illness and any other chronic medical conditions like diabetes, hypertension and heart disease due to the complexity in following up these clients and the hospital seeking behavior of the mentally challenged clients. The chronic medical conditions excluded due to other underlying conditions that can cause occurrence of other opportunistic infections or hospitalization and affect the outcome of the study
- iii. Expert clients and those known to work or volunteer in the hospital facilities involved in the study were excluded due to their knowledge and daily exposure to medical care at the health facility thus likely to affect the outcome of the study.

3.7 Data Collection Methods

Quantitative data was extracted from a variety of patient level registers and patient files from the selected health facilities by a data clerk. The registers of focus were the HTS testing and linkage register (MOH 362), treatment preparation register (361A), ART cohort register, CD4 tracking log, viral load tracking log and patient files. The data was entered into MS Office Excel spreadsheet in a pre-prepared template (Appendix IV). A line list of client records enrolled during the review period was made and every third client identified. Their records were extracted from the different registers and filled in the prepared template on paper and the information transcribed to the excel sheet by the data clerk. Qualitative data was collected using a designed Key Informant Interview questionnaire guide (Appendix iii). The KII were all administered by the researcher (self) for uniformity of the responses

3.8 Instruments Reliability and Validity

A pilot study was done with 20 client records sampled from Ndiwa dispensary to test the reliability of the data collection tools. The reliability was tested by Cronbach's alpha reliability test that had a score of 78 and corrections addressed before the actual use of the data collection tools. The researcher sought opinion of other experts in the field and from the supervisor on the data collection tools alongside having content validity analysis of the data collected by the tools.

3.9 Data Analysis

The data was coded and cleaned before analysis. To summarize the quantitative data, descriptive statistics were used, including demographic information as well as variables regarded as intervening factors. Chi-square and correlation analyses were used to detect differences and associations between variables, respectively.

The data was coded and cleaned before analysis. Measures of central tendency, including median and interquartile range, were used to describe continuous variables while frequencies and proportions were derived for categorical patient characteristics. Chi-square tests and Fischer's exact test where applicable were used to test for association between predictor and outcome variables with risk ratios applied to quantify significant associations. All associations were presented as adjusted risk ratios (aRRs), with 95%

CIs. All statistical analysis tests were conducted at 5% level of significance. Multivariate logistic regression model was applied to assess associations between patient demographic and clinical characteristics and persistent missing clinical appointments. Data analysis was conducted in Stata version 17.

The Qualitative data was also coded and subjected to analysis through the generation of themes based on the objectives as retention, viral load suppression and morbidity and mortality, which were further, triangulated with the quantitative data results.

3.10 Ethical Considerations

The Board of Postgraduate Studies at JOOUST granted permission to conduct this research and Ethical clearance obtained courtesy of the JOOTRH Ethics Review Committee. Permission to carry out the research was sought from the Ministry of Health, Migori County and Nyatike Sub County, as well as the management of the selected health facilities. The study support persons were required to sign confidentiality agreements due to the sensitive nature of patient level data in the patient files. Study findings were relayed to the Migori County Health Management team, Nyatike Sub County health management team through feedback meetings at the Sub County offices and at the health facilities.

CHAPTER FOUR: RESULTS

4.1 Introduction

The findings and interpretation of the study are presented in this chapter. Sections and subsections have been added to the chapter. Respondents' demographic information, such as age category, gender, marital status, occupation, and nationality has been introduced first. After discussing the demographic findings of the study, the researcher presented the research findings based on the study objectives. Both descriptive and inferential statistics were used to analyze the quantitative data. To describe and summarize the data in form of tables, frequency counts, and percentages, descriptive statistics were used. Inferential statistics were used to aid in making inferences and drawing conclusions. Chi-square tests and Fischer's exact test where applicable were used to test for association between predictor and outcome variables with risk ratios applied to quantify significant associations. All associations were presented as adjusted risk ratios (aRRs), with 95% CIs. All statistical analysis tests were conducted at 5% level of significance. Multivariate logistic regression model was applied to assess associations between patient demographic and clinical characteristics and persistent missing clinical appointments. Data analysis was conducted in Stata version 17.

4.2 Demographic and Clinical Characteristics

A total of 182 PLHIVs initiated on ART in the sampled facilities were included in the study. Overall, 124(68%) were female, 134(74%) aged 25 – 49 years, with median age (IQR) of 31 (26 – 37) years. A majority, 122(67%) were married and Kenyan 173(95%). Forty-nine percent of the participants did not have any documented occupation or were unemployed. At ART initiation, 134(74%) of the participants were categorized as well, with 37 (20%) having a CD4 count of < 200 copies and 31(17%) having a WHO stage of 3 or 4 (Table 4.1).

Study Population characteristics were similar for Nationality ($p=0.439$), Viral Suppression ($p= 0.088$) and retention

Table 4.1: Study population by DC Categorization

Variable	Overall	Well	Advanced	P Value
	Population	n (%)	n (%)	
	(N = 182)	n = 134	n = 48	
Age Category				
< 15 Years	3	3 (2%)	0 (0%)	0.005
15 - 24 Years	32	30 (22%)	2 (4%)	
25 - 49 Years	134	94 (70%)	40 (83%)	
50+ Years	13	7 (5%)	6 (13%)	
Sex				
Female	124	99 (74%)	25 (52%)	0.005
Male	58	35 (26%)	23 (48%)	
Nationality				
Kenyan	173	128 (96%)	45 (94%)	0.439
Tanzanian	9	6 (4%)	3 (6%)	
WHO Stage				
Stage 1	125	109 (81%)	16 (33%)	0.000
Stage 2	26	21 (16%)	5 (10%)	
Stage 3	23	4 (3%)	19 (40%)	
Stage 4	8	0 (0%)	8 (17%)	
Viral Load Suppression				
LDL	121	87 (65%)	34 (71%)	0.088
200 - 999 copies	2	2 (2%)	0 (0%)	
1000+ copies	4	1 (1%)	3 (6%)	
No VL result	55	44 (33%)	11 (23%)	
Retained				
Active on ART	120	86 (64%)	34 (71%)	0.404
Not Active on ART	62	48 (36%)	14 (29%)	
Opportunistic Infection				
Had OI	42	4 (3%)	38 (79%)	0.000
No OI	140	130 (97%)	10 (21%)	

4.3 Key Informant Interviewee Characteristics and Outcomes Summary

All Key Informant interviewees were noted to be clinical officers with an average of 6 years of working experience with a median experience of 7 (range = 4-8) years. The represented facility with the least current in care had 554 clients while the highest had 1553 with all offering differentiated service deliver services. Five out of the seven reviewed facilities reported to use the ART 2018 guidelines in implementation of differentiated care and 6 out of the 7 informants reported that their facilities use the DC operation guide in the implementation of differentiated care. All the respondents reported that all clients have access to CD4 testing services which is free across all the facilities though affected by occasional commodity shortages and infrastructural challenges in some areas as noted by 3 out of the 7 key informant interviewees. The annual cohort retention was reported at averagely 88% with least quoted retention at 78% and the highest being 96% while viral load suppression at 96% with the least reported suppression being 91 and the highest being 98%. Opportunistic infections are identified and managed by the clinical persons as reported by all the seven informant interviewees and the inactive clients identified as those having missed clinical appointment by more than 30 days as reported by all the informants with 4 of them including more categories like death, transfer out and ‘stopped’ a other categories likely to happen before a client completes the 30 days from the last clinical encounter. Tuberculosis and Cryptococcal meningitis were mentioned as the commonest causes of death by 5 out of the seven key informant interviewees.

4.4 Retention on Treatment

Overall, 66% (120) of all the PLHIVs were retained on ART. Retention was better amongst those who were categorized as advanced at enrollment (71%) compared to those categorized as well (64%); however, retention on ART was not associated with DC categorization. Extremes of ages enrolled on treatment were retained to treatment with all the clients <15 years enrolled still active on treatment a year after enrolment to treatment and those >50 years retained at 92%. Those aged between 15-49 years retained averagely at 63%. Retention was slightly better among the males compared to the females with rates of 71% and 64% respectively. Of those not retained, 33 (54%) were Lost to follow up, 20 (33%) Transferred out and 8 (13%) died. There was no statistically significant

association between either of death ($p=0.306$), LTFU ($p = 0.306$) or transfer out ($p = 0.561$) and categorization status (Well vs Advanced). These are also recorded in table 4.2 below.

Table 4.2: *Factors associated with retention on ART amongst PLHIV initiated on ART*

Characteristics	N	Retained on ART		Unadjusted	RR (95%CI)
		N	%		
DC Categorization					
Well	134	86	64.18	0.96 (0.73 - 1.13)	
Advanced	48	34	70.83		Ref
Age Category					
< 15 Years	3	3	100		Ref
15 - 24 Years	32	21	65.63	0.66 (0.51 - 0.84)	
25 - 49 Years	134	84	62.69	0.63 (0.55 - 0.71)	
50+ Years	13	12	92.31	0.92 (0.79 - 1.08)	
Sex					
Female	124	79	63.71		Ref
Male	58	41	70.69	1.10 (0.90 - 1.37)	
Nationality					
Kenyan	173	116	67.05		Ref
Tanzanian	9	4	44.44	0.66 (0.32 - 1.39)	
WHO Stage					
Stage 1	125	85	68		Ref
Stage 2	26	16	61.54	0.90 (0.65 - 1.26)	
Stage 3	23	14	60.87	0.90 (0.63 - 1.27)	
Stage 4	8	5	62.5	0.92 (0.53 - 1.60)	

4.5 Viral Load Suppression

Of the 182 PLHIVs, a total of 127 (70%) had a documented viral load result at time of data collection. Of these, 121 (95%) were virally suppressed (viral load of <200 copies). Amongst those categorized as well at ART initiation, viral suppression was at 97% (87/90) compared to 92% (34/37) amongst those who were categorized as advanced. However, there wasn't a statistically significant association between Viral suppression and categorization [aRR 1.05 (0.95 - 1.17)] as seen in table 4.3. Observations made with age consideration had 100% viral load suppression for those over 50 years and between

15-24 years while the least viral load suppression among those <15years. Clients between 25-49 years had a viral load suppression of 94% (85/90). Considering sex, females had a viral load suppression of 94% (80/85) while males had 98% (41/42) viral load suppression. The viral load suppression based on the WHO staging at enrolment had 99% among the stage 1 clients and 94% for those in WHO stage 3. The least viral load suppression was noted among those in WHO stage 4 at 67%.

Table 4.3: DC Categorization and Viral Suppression

Factors associated with viral suppression amongst PLHIV initiated on ART (N = 127)

Characteristics	N	Virally suppressed		Unadjusted	RR (95%CI)
		n	%		
DC Categorization					
Well	90	87	96.67	1.05 (0.95 - 1.17)	
Advanced	37	34	91.89		Ref
Age Category					
< 15 Years	2	1	50		Ref
15 - 24 Years	23	23	100	2 (0.50 - 8.04)	
25 - 49 Years	90	85	94.44	1.9 (0.47 - 7.60)	
50+ Years	12	12	100	2 (0.50 - 8.04)	
Sex					
Female	85	80	94.12		Ref
Male	42	41	97.62	1.04 (0.97 - 1.11)	
Nationality					
Kenyan	121	115	95.04		Ref
Tanzanian	6	6	100	1.05 (1.01 - 2.00)	
WHO Stage					
Stage 1	87	86	98.85		Ref
Stage 2	17	15	88.24	0.89 (0.75 - 1.06)	
Stage 3	17	16	94.12	0.95 (0.84 - 1.08)	
Stage 4	6	4	66.67	0.67 (0.38 - 1.19)	

4.6 Morbidity and Mortality

A total of 42(23%) had had an opportunistic infection at time of data collection, with a majority 7(17%) being Pneumonia and TB, also 7(17%). Incidence of OIs was higher amongst PLHIVs who were categorized as advanced at enrollment (79% vs 3%, unadjusted risk ratio RR 0.04, 95% CI: 0.01 – 0.10), with PLHIVs categorised as advanced at higher risk of contracting an OI even after adjusting for age, sex, and WHO staging [aRR (95% CI) = 0.04 (0.02 – 0.13)]. Considering other parameters for morbidity without adjustments, the incidence of morbidity was higher among clients over 30 years' age (32%) compared to 11% for those <29years. The males were more likely to present with opportunistic infection at 36% compared to females at 17%. Clients presenting in WHO stage IV were certain to have an opportunistic infection and reinfection compared to those enrolling while in WHO stage III. WHO stage II and I were less likely to note an opportunistic infection at 31% and 10% respectively.

Table 4.4: DC categorization and morbidity and mortality

Characteristics	N	With OI		Unadjusted RR (95%CI)	Adjusted RR (95% CI)
		N	%		
DC Categorization					
Well	134	4	2.99	0.04 (0.01 - 0.10)	0.04 (0.02 - 0.13)
Advanced	48	38	79.17	Ref	Ref
Age Category					
<29 Years	76	8	10.53	Ref	Ref
30+ Years	106	34	32.08	3.04 (1.49 - 6.22)	1.08 (0.63 - 1.84)
Sex					
Female	124	21	16.94	Ref	ref
Male	58	21	36.21	2.14 (1.27 - 3.60)	1.21 (0.82 - 1.79)
Nationality					
Kenyan	173	40	23.12	Ref	
Tanzanian	9	2	22.22	0.96 (0.27 - 3.37)	
WHO Stage					
Stage 1	125	12	9.6	Ref	Ref
Stage 2	26	8	30.77	3.21 (1.45 - 7.07)	2.37 (1.15 - 4.87)
Stage 3	23	14	60.87	6.34 (3.37 - 11.92)	1.27 (0.77 - 2.10)
Stage 4	8	8	100	10.42 (6.07 - 17.86)	1.71 (1.11 - 2.64)

CHAPTER FIVE: DISCUSSION

5.1 Introduction

This was a quantitative retrospective cohort study of the outcomes of newly identified HIV positive clients and categorized at enrolment as either well or advanced between October 2018 and September 2019 and also qualitative by review of key informant interviews. The study sampled clients from public health facilities with the greatest number of clients currently in care from each of the seven administrative wards in Nyatike Sub County. The majority of the participants sampled were between 25-49 years (80%) with females contributing to 68% of the participants, conforming with estimates of HIV prevalence in the Kenya Demographic Health Survey (NACC, 2018). About half of them (49%) did not have a documented occupation or were unemployed compare to a study in Uganda that had about 78% labor workforce participation (Ochalek *et al.*, 2017). Of the 124 females reviewed, 80% of them were noted to be well at enrolment while among the males, only 60%, (35/58) were categorized as well. This may be attributed to early case identification for females compared to males as in the KENPHIA report on HIV case identification (NAS COP, 2020).

This study showed that 96.85% of the participants were virally suppressed of which 98.89% and 91.89% were well and advanced, respectively. This compares to the UNAIDS 2020 targets of eliminating AIDS as a public health threat by 2030 and in turn reduce annual infections and deaths through HIV viral load suppression (Stover *et al.*, 2021). These findings however differ with the national KENPHIA findings that had overall suppression for 0-64 years at 88.4% (NAS COP, 2020). This also compares with the national viral load and EID dashboard suppression for Migori County around the review period at 94%. Only 8.24% of the participants had less than 1000 copies with the majority being in the *well* category; 6.59% while 4.4% of the participants had 1000 copies and above with the majority; 5 (2.75%) being in the *advanced* category. There was also however no significant association between viral load outcomes and categorization of clients as either well or advanced (p value = 0.088). This compares with a study done on Retention in care and viral suppression in differentiated service delivery models for HIV treatment delivery in sub-Saharan Africa that noted slight increase in viral load

suppression levels between conventional methods and patient categorization (Long *et al.*, 2020).

Of the 48 reported opportunistic infections, 90% (38) were attributed to the *advanced* group. This contradicts with a study done in Netherlands that observed 53% of the participants that presented with late stage HIV infection, had 35% of the participants having advanced disease (Op de Coul *et al.*, 2016). This also disagrees with findings from a study in Lagos Nigeria where the majority of those noted were mild and fungal infections despite having lower CD4 counts that had a median of 184cells per microliter even though this level of CD4 categorizes clients as *advanced* at enrolment (Oladele *et al.*, 2020). Mortalities were however noted in the well group recording 87.5% (7/8) of the cases. This is generally contrary to the expectation since the advanced clients are the ones most likely to die but the findings from the study show otherwise. Six out of the 8 clients that died in the cohort died were female. This however disagrees with a study on HIV infected clients with kidney disease undergoing dialysis where 71.3% of the mortalities were among the males (Cavalcante *et al.*, 2021).

5.2 Retention to Care

The overall annual retention to care for the study sample was 66% compared to 78.1% in a study regarding patient retention looking at Clinical outcomes and attrition factors of HIV-infected patients in Zimbabwe (Mutasa-Apollo *et al.*, 2014). This differs with the figures quoted by the key informant interviewees who reported an average of 88% retention rate with the lowest interviewee reporting 78% and the highest reporting a 96% retention rate. The Zimbabwe study however did not categorize clients based on disease severity at the time of enrolment and looked at patient outcomes at 6, 12, 24 and 36 months while the current study only considered retention at 12 months. Retention among the younger clients aged 0-24 years in this study was 68.57%. This study concurs with a study done in south Western Uganda that reviewed clients 15-24 years although both of them showing retentions less than the WHO threshold of 90% (Mwanguzi *et al.*, 2021). This however disagrees with the findings in this study that show a retention of 65% for this age group. For clients aged between 25-49 years, the retention was noted to be 62% compared a study done in Western Kenya that had 69.8% retention for the young adults.

Clients over 50 years of age, however had a 92% retention, contrary to the findings from the same study for as for the young adults that had a 73.9% retention (Kiplagat *et al.*, 2018).

Clients categorized as advanced recorded slightly better retention rates compared to that of the well category at 71% and 64 % respectively. This contradicted the Ethiopia study, which found that patients with CD4 200 cells/micro-liter (advanced) were more likely to be lost to follow up, despite the fact that the same study found that clients in WHO stages III and IV were less likely to be lost to follow up than those in WHO stage I (Berheto *et al.*, 2014). However, studies in South Africa, Zambia, Switzerland showed that the proportion of people who are lost to follow-up increases as their CD4 count rises at the time of enrollment in care, in agreement with this study (Fiorentino *et al.*, 2021; Schoni-Affolter *et al.*, 2011). Up to 14.29% of clients lost to follow up had been categorized as well while 3.85% had been categorized as advanced which agrees with a study done in Thailand that showed that patients in stage III or IV or with lower CD4 counts are less likely to get lost to follow up (Teeraananchai *et al.*, 2018). A different study conducted in Nairobi, Kenya found that participants with higher CD4 levels are more likely to be kept in care than those with CD4 levels below 200 (van der Kop *et al.*, 2018). In comparison, the higher CD4 are well clients while the CD4 <200 can be considered as advanced. In this study however, the advanced group had better retention outcomes compared to the well. The retention for advanced clients was at 73.91% in this study. However, a qualitative study done in western Kenya by Wachira *et al.* (2014) indicated that the frequency of clinic appointments was a unique barrier to retention and institutionalized populations like students. It is worth noting that the advanced group of clients have frequent hospital visits due to the need to be reviewed by a clinical specialist. Clients categorized as well transferred out at 8.24% while advanced group had 2.75 % being transferred out. This may not necessarily be a bad outcome as seen from other studies that have demonstrated that clients who left care received an official transfer letter re-engaged back to care faster than those who disengaged care without any documentation (Hickey *et al.*, 2016).

Considering sex, there was no significant association between patient categorization and retention. The overall retention in the Uganda study was 65.7% but being male was associated with the likelihood of being retained (Muwanguzi *et al.*, 2021). Female participants constituted 80% of the clients who were 0-24 years. All the males in the same age-bracket in the study were retained to care while females retained at 61%. This can be compared to a study in South Africa that focused on adolescents 10-19 years where it was noted that males were more likely to be retained than females (van Wyk *et al.*, 2020). This also coincides with a similar study documented in South Africa on adolescents where female participants contributed to 53% and noted that the risk of follow up increased with female adolescents and also with being pregnant at enrolment to care (Okonji *et al.*, 2022). These however contradicts with a study in India concluded that clients of female gender were less likely to attrition (Alvarez-Uria *et al.*, 2013).

5.3 Viral Load Suppression

The overall viral load uptake for all the clients was 69.78% which compares closely with a study done in Gombe, rural Uganda that had a viral load uptake of 67% (Nakalega *et al.*, 2020). The females in the study in Uganda had an uptake of 64% while males had a viral load uptake of 69%. There were recommended strategies from this study to have Viral load focal persons to flag out clients missing viral loads and also conduct health education so as to improve the viral load uptake. This can be explained by the challenges of poor infrastructure and poor road network noted by 3 of the 7 key informant interviewees. Previous studies done in Sub Saharan countries however indicated an increase in the uptake of viral load across several counties comparing from 2013 and 2018 (Lecher *et al.*, 2021). The increments range from 1850% in Côte d’voire to 65% in Namibia. The uptakes however had some countries as low as 51.3% in Malawi and a high of 99.9% in Namibia. The uptake in Kenya was 85.8% in 2018 as per the study. This was due to the expansion of viral load testing services in the 8 countries reviewed. This uptake can be compared to a study done in the Yangon region of Myanmar that had an uptake of 57.8% and a suppression of 91.3%, that may indicate challenges with timeliness for accessing a viral load test in resource limited settings (Thinn *et al.*, 2019). The viral load suppression however relatively compare with this study having a

suppression of 95% measured at <200 copies/ml). This is also in line with the UNAIDS 95 95 95 targets to have 95% of HIV positive clients identified, 95% initiated and retained to ART and 95% of them suppressed. Compared to a different study done in Cameroon and Myanmar, the viral load suppression was 84.1% at month 12 (Fokam *et al.*, 2019; Thinn *et al.*, 2019). Studies done in Rwanda however had viral suppression of 91 % in June 2020 for the treat all reviewed cohort (Ross *et al.*, 2020). The study done in Rwanda however did not consider patient categorization but conventional management and a viral load taken at 12 months and had cut off values of <1000copies/ml. These study findings however are in range with the figures quoted by the key informant interviewees of an average of 96% viral load suppression rate. Extreme quotes were by three interviewees where two reported 98% suppression while one reported a 91 % suppression. These figures were however not specific for categorized clients but an overall suppression for all clients.

The well category had a viral load suppression rate of 97% that compares with findings from a study done in North Western Nigeria that concluded that a high CD4 was among the variables associated with viral load suppression. This describes the non-advanced (well) stage of HIV that had a viral suppression rate of 97% (Abdullahi *et al.*, 2021). This was also seen in a study done in Malaysia that showed comorbidity can lead to mild suppression but comprehensive evaluation can help understand better (Syed *et al.*, 2016). It also with a study done in Ethiopia that concluded that clients with higher CD4s and adequate prophylaxis achieves viral load suppression faster than the opposite (Erjino *et al.*, 2023). The viral load suppression for the advanced group of clients in this study was 91.89%, which differs from reports from Zimbabwe for a more resource-constrained setting that had only 30% of all advanced disease cases suppressed (Balachandra *et al.*, 2020).

Suppression among children and adolescents 0-24 years was 96% which had similar outcomes to one conducted in Western Kenya by (Kadima *et al.*, 2018) on the implementation of routine viral load testing and predictors of viral load failure in HIV-infected children and adolescents and another done by Jiamsakul *et al.* (2017), adults, older age, and a higher CD4 count prior to ART were linked to viral suppression (Kadima

et al., 2018). A different study done in the Eastern and South African countries by Bacha *et al.* (2022) showed a viral suppression of 74.6% for participants aged 0-19 years while a separate one done in Amhara Public Health Institute, Ethiopia showed a viral load suppression of 71.7% for <1000 copies/ml with children less than five years having a non-suppression rate of 24% (Shiferaw *et al.*, 2019).

Considering sex, males had an uptake of 72.41% with all the participants having a 97.62% suppression. Females had a suppression of 94.12% despite the low uptake noted earlier. These findings do not differ significantly from those of a Vietnamese study on factors associated with HIV viral suppression while on antiretroviral therapy despite not being done patient categorization where males had 92.9% and females at 93.7% suppression rates (Geter *et al.*, 2019; Rangarajan *et al.*, 2016). The findings in this study however differ significantly with those in Democratic Republic of Congo where the viral suppression for <1000 copies/ml was 81% with the mean viral load for males higher than that of females (Shah *et al.*, 2021).

5.4 Morbidity and Mortality

Opportunistic infections noted in this study was 23% (42) for all participant records with 80% of the morbidities being noted in the advanced category of clients. This occurrence is probable since more infections occur with reduced immunity and HIV disease progression (Furrer, 2016). This however conflicts with a report from Dawro zone in Ethiopia that had 88.4% prevalence of opportunistic infections (Solomon *et al.*, 2018). In the Ethiopia study, CD4 count was associated had a significant association with occurrence opportunistic infections while this was not established in this study. Female participants contributed to 53.06% of all with a 16.94% morbidity while the Ethiopia differs for having 52.9% participation contribution of the morbidity but closely ties closely with reports from Nigeria that had 52.9% female participants contributing to those with opportunistic infections (Akinyemi *et al.*, 2017; Solomon *et al.*, 2018).

Age was not associated with occurrence of opportunistic infections in this study despite having 32.08% prevalence among clients over 30 years compared to 10.53 for those younger than 29 years. This differs with a study done in Semarang City, Indonesia that concluded that age was the variable most associated with the incidence of OI (p-value 0.001). It also differs with a study by

Akiyemi et al. 2017 that concludes that significant factors associated with opportunistic infections in older adults were CD4 count less than 350 (advanced disease) (Akinyemi *et al.*, 2017) similar to one done in Ethiopia among children that indicated that high prevalence of opportunistic infections were associated with decreased CD4 count among other conditions (Mekonnen *et al.*, 2023). Considering participants 0-20 years, none of the 10 participants had an opportunistic infection and none died. Extending the same to 0-25 years in this study had 43 participants with 3 reported opportunistic infections and 1 mortality due to undiagnosed opportunistic infection. This compared to a study done in Kenya for hospitalized children 0-12 years had 22% mortality with 59% of the causes of mortality noted to be tuberculosis and 18% of them reported to be due to pneumonia (Njuguna *et al.*, 2019).

All forms of TB contributed to 22% of all the opportunistic infections in this study. This concurs with a study in Kenyatta National Hospital where tuberculosis was among the three most common opportunistic infections being reported among clients (Chepkondol *et al.*, 2020). This contrasts with a study conducted in Botswana that analysed hospital admissions and discovered that tuberculosis was the most prevalent diagnosis among mortality cases in both HIV-positive and HIV-negative admissions, but that HIV-positive admissions accounted for a higher percentage of fatalities (Barak *et al.*, 2019). However, findings from Nigeria showed oral candidiasis and chronic diarrhea as the commonest opportunistic infections among older adults with CD4 <350 cells/microliter (Akinyemi *et al.*, 2017).

There were 11 identified tuberculosis cases in the two categories with 100% case fatality rate in the well group compared to 12.5% case fatality rate in the advanced group died. This is consistent with an article on advanced HIV disease and mortality in global HIV programming by Boyd *et al.* (2020) that notes that tuberculosis is one of the leading causes of death in advanced HIV disease. This also coincides with five of the seven key informant interviewees who mentioned tuberculosis as the commonest cause of death and two of them also mentioning cryptococcal meningitis alongside tuberculosis as the commonest causes. This concurs with findings from Global HIV/AIDS Mortality and Morbidity concerning tuberculosis and a different excerpt on tuberculosis that emphasize the effect of tuberculosis on HIV infection (Bloom *et al.*, 2017; Danforth *et al.*, 2017). A

different article identifies tuberculosis and cryptococcosis as among the major causes of mortality among HIV clients despite being on prophylaxis (Post *et al.*, 2018). A different study conducted in New York demonstrated the significance of screening all clients at the time of HIV enrollment care for acute and chronic infections and conditions since they are markers of need for more intensive care in the course of treatment in the program and to prevent mortality among the clients (Robertson *et al.*, 2021).

Mortality occurred more among the females with 75% (6/8) contribution of all mortalities with 87.5% of them occurring in married participants and also being in the well category. This conflicts with a study done in Tanzania showed mortality being associated with male gender with positive association with divorced individuals. The study also found that most mortalities occurred among clients with CD4<200cells/microliter and WHO stage III and IV (Gunda *et al.*, 2017). It also contrasts with an assessment of medical records in Ethiopia which showed that ambulatory /bedridden functional status was associated with mortality since this is advanced stage (Birhanu *et al.*, 2021).

CHAPTER SIX: CONCLUSION AND RECCOMENDATIONS

6.1 Conclusion

In this study, nearly three-quarters of the participants were classified as *well* at enrolment with most participants being female. The overall retention was 77.16%, with a better retention among the advanced category; these were however lower than the NASCOP recommendation of 80%. There was however no association between categorization and retention as an outcome. Despite the viral load outcomes being better in the *well* category, there was no significant difference between the *well* and *advanced* categories. While there was higher morbidity in the advanced group, mortality was higher in the *well* category, females contributing to most deaths. There was however no association between categorization and morbidity and mortality.

6.2 Recommendations

- i. All clinic in-charges and HIV implementing partners should ensure continued follow up of clients regardless of the categorization at enrolment or the clinical status of the clients at the time of review.
- ii. The Migori County department of health should improve access to viral load testing to all eligible clients to improve uptake and accurately measure outcomes. The clinicians and all facility teams should follow up clients to adhere to HIV care and treatment
- iii. The Health department of, Migori County and the HIV implementing partners should capacity build clinicians to identify, diagnose and manage opportunistic infections in time to avoid mortalities. For the clinical teams to keenly examine, diagnose, manage and/or appropriately refer conditions identified for further management
- iv. The ministry of Health through NASCOP should consider reviewing the package of care for clients categorized as *well* at enrolment

6.3 Suggestions for Further Studies

Despite achieving its aim and objectives, there are areas that have not been adequately addressed in this study. Moreover, the findings also indicate possible areas for additional research. One of the aspects identified in the study was scope. The study scope was relatively limited and from findings, a wider scope would offer a more informative finding on how to offer services to the newly identified HIV patients. Therefore, there is need to conduct a similar study on a wider scope, encompassing two or more high HIV burden counties, in order to form a stronger basis for policy change on categorization of PLHIV at enrolment. Such a study should be prospective in nature, making observations on the selected cohort of patients for a specified time.

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APPENDICES

Appendix I: Confidentiality Agreement Form

As a volunteer engaged by _____, I am aware that I might have access to private data pertaining to clients who are patients in this document. By checking this box, I agree to the following and accept that I understand my responsibility to protect confidentiality:

- I am aware that client names and any other identifying details are fully secret
- I agree not to disclose, publish, or otherwise make public any data obtained in the course of my work to unauthorized persons or the public
- I am conscious of the complete confidentiality surrounding client names and any other identifying details.
- I understand that I am not permitted to read client information or other confidential documents for my own personal information or unrelated business purposes, though just to the extent and for the purpose of this study
- If I learn of a real breach of confidentiality or a circumstance that might lead to one, whether on my part or that of another person or entity, I commit to report to _____ right away.
- All records, documents, and other papers considered confidential, as well as any copies or extracts thereof, made or acquired by me during this engagement shall be the property of _____ and must be returned to _____ upon termination of engagement. I have read and agree to these statements.

Full names: _____

Email Address _____

Phone Number

07_ _ _ _ _

ID number

Signature

Appendix II: INFORMED CONSENT FORM FOR CCC IN-CHARGES

Title: Outcomes of Differentiated Service Delivery for Newly Identified HIV Positive Patients in Nyatike Sub County Migori County

Facility Identification Number:

Date:

.....

Investigator: Roberts Omusula

Student, Master of Public Health, School of Health Sciences

Jaramogi Oginga Odinga University of Science and Technology

Tel Number: - 0727- 644574

Supervisors: Dr. Daniel Onguru

School of Health Sciences

Jaramogi Oginga Odinga University of Science and Technology

Dr. Sidney Ogola

KEMRI/CGHR, Kisumu

We are requesting you and your child to kindly participate in this research study. The purpose of this consent form is to provide you with the information you will need to help you decide whether to participate in the study or not. This process is called 'Informed Consent'. Please read this consent information carefully and ask any questions or seek clarification on any matter concerning the study.

Introduction: Patient categorization at enrolment has been happening in Kenya since the inception of Differentiated Service Delivery based on the CD4 counts and WHO staging as either well or advanced. Understanding the outcomes of the two categories of clients' one-year post treatment will help understand if the service is worth the effort and to which arm of clients need which specific intervention for better outcomes.

Benefits: The study's findings will be shared with the county health management team, the sub county team and the facilities directly involved in the study and will help focus or refocus on the deserving areas of need

Risks: There will be no risks anticipated to you during this study and no invasive procedures in this study

Voluntariness: The research is entirely voluntary. There will be no monetary compensation for your participation in the study. You have the option to participate in or withdraw from the study at any time. Your refusal to participate will have no effect on your position.

Confidentiality: The data gathered about you, your child, and your family will be kept strictly confidential. Without your written permission, no specific information about you, your child, or your family will be released to anyone. We will, however, discuss general overall findings for all children assessed, but nothing specific to you or your child will be discussed. We will also not reveal your or your child's identity during these discussions.

Question/Concerns: If you ever have concerns you can contact the principal investigator about the study or how the results will be used, Roberts Omusula by calling 0727-644574. In case of concerns about your rights as a participant, you can contact Jaramogi Oginga Odinga Teaching and Referral Hospital Research Committee (JOOUTRH-ESRC)

Consent Form: Participant's Statement:

I _____ hereby AGREE / DISAGREE (Cross out as appropriate) to participate in the study after receiving adequate information about the study research, risks, and benefits. I understand that our participation is entirely voluntary and that I may opt out at any time. I was given ample opportunity to ask questions and seek clarification on the study, and these were satisfactorily addressed.

Interviewer's Signature: _____

Date:

Appendix III: KEY INFORMANT INTERVIEW GUIDE FOR CCC IN-CHARGES

Facility Code _____ Date of Interview _____

Introduction of the study and consenting process

1. What is your Cadre?
 Medical Officer Clinical Officer Nurse
2. How long have you been working in the ART field?
3. What is your total clients currently in care?
4. How many clinical staffs attend to clients in this department?
 M.Os Clinical Officers Nurses
5. Does your facility offer differentiated care services?
 Yes No Don't Know
6. Which guidelines do you follow in implementing differentiated care?
 ART 2018 DC Operation guide 2017 other:
.....
7. Please give me your opinion on;
 - I. The availability of CD4 services to new clients
 - II. Any challenges with the sample transport network
 - III. Interruptions with CD4 testing services
 - IV. Charges for CD4 services to clients seeking the service
8. What is the average annual cohort retention of all your clients?
9. What is the average viral load suppression levels for your facility
10. How does your clinic handle clients presenting with opportunistic infections?
11. Which patients do you consider as inactive? *Why?*
12. What are the commonest causes of death for your clients in the past two years?

Appendix IV: Data Extraction Form

Facility code.....



Ward code.....

Date.....

Number of CUs linked

	S/N	CCC Number	Age	Sex	Marital Status	Occupation	Nationality	Date Tested Positive	Date started ART	CD4 Count	WHO stage	Categorization (Well/Advanced)	Active (Y/N)	Died (Y/N)	O.I(s)	Viral load
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																
16																
17																
18																
19																
20																

Appendix V: Categorization Guide for Patient Files

	Tick as appropriate		
	Well Client	Advanced Disease	
Date of Visit	 WHO stage I or II, and <input type="checkbox"/> CD4 > 200 cells/mm ³ (or > <input type="checkbox"/> 25% for children ≤ 5 years old)	 <ul style="list-style-type: none"> • WHO stage III or IV, or • CD4 ≤ 200 cells/mm³ (or ≤ 25% for children ≤ 5 years old) 	Comments

Source: Dc Operation Guide 2017

Appendix VI: Board of Postgraduate Studies Approval Letter



JARAMOGI OGINGA ODINGA UNIVERSITY OF SCIENCE & TECHNOLOGY
BOARD OF POSTGRADUATE STUDIES
Office of the Director

Tel. 057-2501804
Email: bps@jooust.ac.ke

P.O. BOX 210 - 40601
BONDO

Our Ref: H153/4016/2019

Date: 8th June 2021

TO WHOM IT MAY CONCERN

RE: OMUSULA ROBERTS INYANGALA – H153/4016/2019

The above person is a bonafide postgraduate student of Jaramogi Oginga Odinga University of Science and Technology in the School of Health Sciences pursuing Master of Science in Epidemiology and Biostatistics. He has been authorized by the University to undertake research on the topic: *“Outcomes of Differentiated Service Delivery for Newly Identified HIV Positive Patients in Nyatike Sub County, Migori County”*.

Any assistance accorded him shall be appreciated.

Thank you.



Prof. Dennis Ochuodho
DIRECTOR, BOARD OF POSTGRADUATE STUDIES

Appendix VI: ERC Approval Letter



COUNTY GOVERNMENT OF KISUMU
DEPARTMENT OF HEALTH

Telephone: 057-2020801/2020803/2020321
Fax: 057-2024337
E-mail: ercjoorth@gmail.com

JARAMOGI OGINGA ODINGA TEACHING &
REFERRAL HOSPITAL
P.O. BOX 849
KISUMU

When replying please quote

Ref: **IERC/JOOTRH/481/21**
.....

26th August, 2021

Date.....

To: Omusula Roberts

Dear Omusula,

**RE: REQUEST FOR ETHICAL APPROVAL TO UNDERTAKE A STUDY TITLED:
OUTCOMES OF DIFFERENTIATED SERVICE DELIVERY FOR NEWLY IDENTIFIED HIV POSITIVE
PATIENTS IN NYATIKE SUB-COUNTY, MIGORI COUNTY.**



This is to inform you that **JOOTRH IERC** has reviewed and approved your above research proposal. Your application approval number is **IERC/JOOTRH/481/21**. The approval period is **26th August, 2021 – 26th August, 2022**. 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 **JOOTRH - 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 **JOOTRH - IERC** within 72 hours of notification
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **JOOTRH - IERC** within 72 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 **JOOTRH - 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://oris.nacosti.go.ke> and also obtain other clearances needed.

In case the study site is Jootrh, kindly report to Chief Executive Officer before commencement of data collection.






Yours sincerely,



NANCY MAKUNDA-SECRETARY

JOOTRH-IERC

KISUMU

Appendix VIII: Approval by the National Commission for Science, Technology & Innovation

 REPUBLIC OF KENYA	 NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
Ref No: 963498	Date of Issue: 06/September/2021
RESEARCH LICENSE	
	
This is to Certify that Mr.. ROBERTS Inyangala OMUSULA of Jaramogi Oginga Odinga University of Science and Technology, has been licensed to conduct research in Migori on the topic: OUTCOMES OF DIFFERENTIATED SERVICE DELIVERY FOR NEWLY IDENTIFIED HIV POSITIVE PATIENTS IN NYATIKE SUB COUNTY MIGORI COUNTY. for the period ending : 06/September/2022.	
License No: NACOSTI/P/21/12798	
963498 Applicant Identification Number	 Director General NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION
	Verification QR Code 
NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.	

Appendix IX: Migori County Research Approval

REPUBLIC OF KENYA



**COUNTY GOVERNMENT OF MIGORI
DEPARTMENT OF HEALTH**

Telegrams: "MOH", Migori
Telephone: Suna (059) 20058
Email: migoricountyHMT@gmail.com

COUNTY DIRECTOR OF MEDICAL SERVICES
MIGORI COUNTY
P O BOX 202-40400
SUNA - MIGORI

When replying please quote
MIG/CDH/TR/VOL II/59

Date: 6th October, 2021

To,
SCMOH
Nyatike Sub County

RE: RESEARCH AUTHORIZATION; OMUSULA ROBERTS INYANGALA

The above subject matter refers.

This is to inform you the above named has been authorized to carry out research on "**Outcomes of Differentiated Service Delivery for Newly Identified HIV Positive Patients in Nyatike Sub County,**" at, Migori County for the period ending 6th September, 2022.

Any assistance accorded to him will be highly appreciated.


Dr. Dan Ochiel
County Director of Medical Services
MIGORI COUNTY

