HEALTH RELATED QUALITY OF LIFE OF ADULT PATIENTS ON TENOFOVIR VERSUS ZIDOVUDINE BASED REGIMENS AT KENYATTA NATIONAL HOSPITAL, KENYA

JILIAN ORANGA ETENYI (B.PHARM)

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A thesis submitted in partial fulfillment of the requirements for the award of the degree of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance of the University of Nairobi

DEPARTMENT OF PHARMACOLOGY AND PHARMACOGNOSY
SCHOOL OF PHARMACY

UNIVERSITY OF NAIROBI

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DECLARATION

I, Jilian Oranga Etenyi, do hereby declare that this thesis is my original work and has not been presented for the award of any other degree or to any other university.

Signature…… Date……

Jilian Oranga Etenyi

SUPERVISORS' APPROVAL

This is to certify that this research thesis has been submitted for examination with our approval as the University supervisors.

Prof. Faith A. Okalebo,
Department of Pharmacology and Pharmacognosy,
School of Pharmacy
University of Nairobi

Signature..... Date…….....

Dr. Sylvia. A. Opanga,
Department of Pharmaceutics and Pharmacy Practice,
School of Pharmacy
University of Nairobi

Signature..... Date…….....

Dr. Kipruto A. Sinei,
Department of Pharmacology and Pharmacognosy,
School of Pharmacy
University of Nairobi

Signature..... Date…….....

Prof. George O. Osanjo,
Department of Pharmacology and Pharmacognosy,
School of Pharmacy
University of Nairobi

Signature..... Date…….....

UNIVERSITY OF NAIROBI DECLARATION OF ORIGINALITY

Name of Student	: Jilian Oranga Etenyi
Registration Number	: U51/75501/2014
College	: College of Health Sciences
School	: Pharmacy
Department	: Pharmacology and Pharmacognosy
Course Name	: Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance
Title	: Health Related Quality of Life of adult patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital (KNH)

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DEDICATION

I dedicate this work to my late father, Justus Paul Etenyi, for his prayers, encouragement and support during my studies

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ACRONYMS AND ABBREVIATIONS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Treatment/Therapy
ARV	Anti-Retroviral Drugs
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
CCC	Comprehensive Care Centre
CD4	Cluster of Differentiation 4
CNS	Central nervous system
CONSORT	Consolidated Standards for the Reporting of Trials
D4T	Stavudine
DDL	Didanosine
DNA	DeoxyriboNucleic Acid
DRV/r	Darunavir/ritonavir
EFV	Efavirenz
HAART	Highly Active Antiretroviral Therapy
HIV	Human immunodeficiency virus
HLOC	Health Locus of Control
HRQoL	Health Related Quality of Life

KNH	Kenyatta National Hospital
KNH-UoN ERC	Kenyatta National Hospital University of Nairobi Ethics and Research Committee
LPV/r	Lopinavir/ritonavir
MH	Mental Health
MHS	Mental Health Score
MOH	Ministry of Health
MOS-HIV	Medical Outcomes Study HIV Health Survey
NFV	Nelfinavir
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NtRTI	Nucleotide reverse transcriptase inhibitor
NVP	Nevirapine
PEP	Post Exposure Prophylaxis
PEPFAR	U.S President's Emergency Plan for AIDs Relief
PH	Physical Health
PIS	Protease inhibitors
PLHIV	People living with HIV
PMTCT	Prevention of Mother-To-Child Transmission
PROS	Patient Reported Outcomes
QALY	Quality Adjusted Life Year

RNA	Ribonucleic Acid
SF-36	Medical Outcome Study 36-Item Short-Form Survey
TDF	Tenofovir Disoproxil Fumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
UoN	University of Nairobi
USAID	United States Agency for International Development
WHO	World Health Organization
WHOQOL	World Health Organization Quality of Life

DEFINITION OF TERMS

Antiretroviral: These are drugs used in combination of three or more for treatment of infections by retroviruses for example HIV.

Comprehensive Care Centre: This is a place where attempts to care for the entire patient and all his or her needs, not only the therapeutic and physical ones, is done.

Health Related Quality of Life: This is a multi-dimensional theory that includes spheres related to physical, mental, emotional and social functioning. It goes further than direct measures of population health, life expectancy, and sources of death, and focuses on the influence health status has on quality of life.

Quality Of Life: The overall welfare of persons and societies, with regard to negative and positive features of life.

Quality-Adjusted-Life-Year (QALY): Components of measure of utility which combine life years increased as an outcome of health interventions/health care programs with a judgment about the quality of these life years.

Years of life lost: This is the years of potential life lost due to premature deaths. It is calculated from the number of deaths multiplied by a standard life expectancy at the age at which death occurs.

Physical health: a state of well-being when all internal and external body parts, organs, tissues and cells can function well as expected without limitation.

Mental health: Mental health or psychological well-being is an integral part of an individual's capacity to lead a fulfilling life, including the ability to form and maintain relationships, to study, work or pursue leisure interests, and to make day-to-day decisions about education, employment, housing or other choices.

Jaundice: This is defined as patient reported yellowing of the eyes.

ABSTRACT

Background: Quality of life improvement is one of the objectives of antiretroviral therapy. It is vital to assess the perception of the patient on their functional status and well-being termed as Health Related Quality of Life (HRQoL). HRQoL is a vital outcome measure in HIV management considering its long survival prospect. Zidovudine and tenofovir are widely used as first line antiretroviral in HIV management. The side effects of antiretroviral may affect one's quality of life.

Objective: The study aimed to compare the Health Related Quality of Life of adult patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital.

Methods: A hospital based comparative cross sectional study was conducted on 501 participants. The participants were conveniently selected and recruited from HIV infected patients attending the Comprehensive Care Centre clinic at Kenyatta National Hospital in 2015-2016. The Medical Outcome Study HIV Health Survey (MOS) questionnaire was used to elicit information on the patient's quality of life. The data obtained were scored and summarized on a scale of 0-100. Two broad aspects of health, Physical Health Summary (PHS) and Mental Health Summary (MHS) were generated. Linear regression analysis was performed to identify the key determinants of HRQoL.

Results: Patients on zidovudine had a better HRQoL than those on tenofovir. The proportion of participants on tenofovir was 60.8 %. The most important determinants of PHS were: presence of any symptom of disease (β -5.58, 95 % CI; -8.07,-3.09), regular source of income (β 2.62, 95 % CI; 0.46, 4.78) and stated inability to cope (β -1.81, 95 % CI; -2.56,-1.10).

The key determinants of the MHS were the ART regimen, presence of any symptom of illness (β -1.24, 95 % CI; -2.253, -0.226), absence of pain (β 0.413, 95 % CI; 0.152, 0.674) and patient stated inability to cope with HIV (β -1.029, 95 % CI; -1.441,-0.617). Presence of any symptom had a negative association with MHS with participants on tenofovir having a higher prevalence of symptoms of illness/side effects. Being on tenofovir based regimens and second line regimens were the risk factors for the presence of side effects/symptoms of illness.

Conclusion and recommendation: Participants on zidovudine based regimens demonstrated better performance across all the aspects assessed and thus had a better HRQoL. There is need for occasional quality of life studies to ascertain the impact of treatment as perceived by the patients.

CHAPTER ONE: INTRODUCTION

1.1 Back ground

The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (1). Disease affects the psycho-social status of an individual by increasing the economic burden, psychological distress and social unacceptability of patients with conditions associated with social stigma. This non-physical effect of disease and medication can lead to despair and even non-compliance, hence need for studies to evaluate HRQoL.

Tenofovir is a nucleotide reverse transcriptase inhibitor (NtRTI) antiretroviral (ARV) drug used in combination with other medications in the management of the HIV infection (2). Zidovudine is an ARV agent which belongs to the class of nucleoside reverse transcriptase inhibitors (NRTIs). Both tenofovir and zidovudine mimic nucleoside bases thereby hinder elongation of the HIV-RNA and thus block multiplication of the virus (2). In Kenya, both tenofovir and zidovudine are used for management of HIV/AIDS and for post exposure prophylaxis (PEP) (2). HRQoL is a measure that accounts to an individual’s well-being including both clinical and non-clinical factors that contributes to well-being and functionality. Currently TDF/3TC/EFV is the preferred first line ART combination for newly diagnosed adult HIV patients in Kenya (3). It is used for all adults including: pregnant women (at any gestational age), breastfeeding women, patients with TB/HIV co-infection, and patients with HBV/HIV co-infection (3). Zidovudine is used as an alternative for tenofovir where tenofovir is not available or bearable to the patient. The advantages and disadvantages of tenofovir and zidovudine are illustrated in **Table 1.1.** This study dealt with participants who were initiated both on the current and earlier treatment guidelines.

Table 1.1: Advantages and possible side effects of tenofovir and zidovudine (4)

Tenofovir	**Zidovudine**
Advantages	
Well tolerated compared to zidovudine considering that it does not cause anaemia.	Used in HIV pregnant mother to prevent mother to child transmission of HIV virus
Once daily fixed dose combination pill makes adherence better when compared to twice daily combination.	Used in newborns born to HIV positive mothers to prevent infection in the newborns
Effective against Hepatitis B making it a preferred choice in HIV- Hepatitis B coinfected patients.	
Associated with resistance- attributed to mutations.	
Approved for use in pregnancy	
Has been accepted for use in children of more than two years.	
Possible side effects	**Possible side effects**
Declines in kidney function, proximal renal tubulopathy (leading to proteinuria and phosphate wasting), and reductions in bone mineral density (BMD)	Anemia, neutropenia, nausea, headache

1.2 Problem Statement

HIV/AIDS is a condition which is highly stigmatized to the extent that it may lead to delayed health seeking behavior and in some instances suicide. Opportunistic infections associated with HIV/AIDS may cause devastating psychological distress and decrease the ability of patients to perform normal duties.

Although the use of ARVs results in significant physical improvement such as increased CD4 counts and decreased frequency of opportunistic infections, the drugs may also cause severe side effects which include pain, neuropathy, anemia and psychological distress among others.

Taking multiple pills daily may be a burden and an inconvenience to the patients. Furthermore, most treatment facilities may be insensitive to the patient needs given that care is only accessible during the day when patients should be at their work place.

In order to improve care provided to patients on antiretroviral therapy (ART), it is therefore important to assess the impact of ART on HRQoL. Zidovudine is used as an alternative to tenofovir, although it is associated with side effects such as chronic anemia which is likely to affect quality of life. Tenofovir is claimed to have a better safety profile compared to zidovudine with the main side effect being renal toxicity (4,5).

Currently there are increased numbers of people on antiretroviral therapy in Kenya. One of the objectives of ARVs is to improve the patients' quality of life. Much effort has been put on monitoring the clinical and laboratory aspects of the patients with limited concern about their quality of life. There is equally little information on the well-being of patients who are on antiretroviral. HRQoL studies have been conducted in East Africa but they all had varied range of outcomes given the diverse social-cultural conditions in the various countries. A comparative HRQoL study was therefore required to examine whether tenofovir has a better impact on HRQoL than zidovudine.

1.3 Objectives

1.3.1 Main objective

The main objective of this study was to compare Health Related Quality of Life of adult HIV positive patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital and to determine factors that affect Health Related Quality of Life.

1.3.2 Specific objectives

The specific objectives of the study were to:

i. Determine and compare HRQoL of participants on tenofovir versus zidovudine based regimens.
ii. Evaluate prevalence and risk factors for the presence of symptoms of illness/side effects for participants taking either tenofovir or zidovudine based regimens.
iii. Determine factors that affect the HRQoL for participants taking either tenofovir or zidovudine based regimens.

1.4 Research Questions

The research sought to answer the following questions:

1. Is there a difference in the Health Related Quality of Life of patients on tenofovir versus those on zidovudine based regimens at Kenyatta National Hospital CCC?
2. What factors determine Health Related Quality of Life of patients at Kenyatta National Hospital CCC?

3. What is the prevalence and risk factors for presence of symptoms of illness/side effects in the study population?

4. What are the coping strategies adopted by the participants?

1.5 Study hypothesis

1.5.1 Null hypothesis

There is no difference in the HRQoL of patients on tenofovir and zidovudine based regimens.

1.5.2 Alternative hypothesis

Patients on tenofovir based regimens have a higher HRQoL score compared to patients on zidovudine based regimens.

1.6 Justification

In Kenya, the implementation of the current treatment guideline that recommends initiation of ARVs to all sero positive patients irrespective of CD4 has resulted in increased number of people on ARVs. The current study evaluated the treatment aspect of HRQoL of HIV positive patients. Conducting a HRQoL study will help evaluate whether the efficacy obtained from ARVs outweighs its adverse effects. Information obtained from this study will also increase evidence and knowledge on the impact of antiretroviral therapy on HIV positive patients

Quality of life improvement is one of the objectives of ARVs therapy (2) and thus, its evaluation should be routinely performed. Currently few studies have been conducted in Kenya on Health Related Quality of Life of people living with HIV who are on antiretroviral therapy. To our knowledge no studies have assessed the HRQoL comparing participants on tenofovir to those of zidovudine in Kenya.

Routine evaluation of HRQoL and associated factors will identify key areas that the clinicians should closely monitor. It will also assist the clinicians when dealing with patients on either of the regimens and bring out their key concerns.

Health Related Quality of Life study gives variety of information on the patients given their differences in experiences with the disease, effects of antiretroviral regimens and disease progression. Assessment of HRQoL widely depends on the participants' experiences and

perceptions. The obtained information is vital in decision making by the stakeholders towards a direction that benefits the patients more. Patient experiences and their understanding together give a vital data base to inform policy in order to get the best out of the benefits of HIV management. HRQoL assesses the participants irrespective of the clinical parameters and disease staging by the clinicians. A study conducted at Kenyatta National Hospital was required to elicit information on impact of ART given that it is the oldest and most preferred referral hospital in Kenya and also serves some parts of the greater African region. Such study may provide insights on factors that determine HRQoL in patients on HAART.

1.7 Significance of the Study

Assessment of quality of life will inform policy making towards maximizing the benefits of ART and enable identification of key patient groups that required additional attention. The findings will provide evidence to influence treatment selection.

CHAPTER TWO: LITERATURE REVIEW

2.1 General overview of HIV/AIDS and ART uptake globally and in Kenya

According to UNAIDS, 36.7 million people worldwide were living with HIV by the end of 2015 (6). A decline in new infections among adults was noted with the new infections globally remaining static at about 1.9 million annually (6). By 2015, approximately 26 million people were living with HIV/AIDS in Africa and this was estimated as 70% of the world total (6). Sub-Saharan Africa has the highest HIV/AIDS prevalence in the world. By 2015, 17.2 million people in east and south Africa were living with HIV/AIDS (6). Kenya is among the HIV high burdened countries in Africa with a national prevalence of 5.9% (7). It was estimated to have 1.6 million people living with HIV/AIDS by 2015 (8). HIV epidemic in Kenya is termed as extensive, affecting all sectors of society including children, young people, adults, women and men. An intense epidemic has been noted among men who have sex with men, people who inject drugs, sex workers and women (9).

Globally the number of people on ART were 17 million by the end of 2015 (6). Of this number 10.3 million were from East and South Africa. Kenya had the second largest ART treatment programme in Africa with approximately 900 000 people on HAART by June 2016 (6,10,11). Kenyatta National Hospital (KNH) is one of the main facilities in Kenya offering care for people living with HIV. It had a total of 6340 patients on HAART by July 2015 according to the KNH Comprehensive Care Centre Pharmacy report (12).

2.2 Current ART treatment guidelines for adults and adolescents in Kenya

In Kenya, both tenofovir and zidovudine are used for the management of HIV/AIDS with the former being preferred over the later (13). The drugs are used in combination with other drugs as fixed dose combinations. The first and second line regimens for management of HIV/AIDS in adolescents and adults in Kenya are presented in **Table 2.1.**

Table 2.1: First line and second line ART guidelines in Adolescents and Adults

The table was adopted from the Kenya guidelines on use of antiretroviral drugs for treating and averting HIV infection (Rapid Advice-June, 2014) (13).

1.First line antiretroviral drugs for adults and adolescents		
	Preferred regimen	**Alternative regimens**
First-line ART regimens for adolescents (>15 years) and Adults	TDF + 3TC + EFV	TDF + 3TC + NVP AZT + 3TC + EFV AZT + 3TC+ NVP
First-line ART regimens for HIV-infected sexual partner in a sero-discordant relationship		
First-line ART regimens for pregnant women and breastfeeding mothers		
First line ART regimen to start in all women with previous exposure to NVP through PMTCT		
Less than 24 months since previous NVP exposure	TDF + 3TC + ATV/r	TDF + 3TC + LPV/r AZT + 3TC + ATV/r AZT+ 3TC + LPV/r
More than 24 months since previous NVP exposure	TDF + 3TC + EFV	TDF + 3TC + NVP AZT + 3TC + EFV AZT + 3TC + NVP
2.Second line ART in Adolescents and Adults		
If first line ART regimen	**Preferred second line ART**	**Alternate Second line ART regimen**
TDF + 3TC + EFV	AZT + 3TC + ATV/r	AZT + 3TC + LVP/r
AZT + 3TC + EFV/NVP D4T + 3TC EFV/NVP	TDF + 3TC + ATV/r	TDF + 3TC + LPV/r
TDF + 3TC + ATV/r/LPV/r	AZT + 3TC + DRV/r	-

TDF-Tenofovir, 3TC-Lamivudine, EFV-Efavirenz, NVP-Nevirapine, LPV/r-Lopinavir/ritonavir, ATV/r-Atazanavir/Ritonavir, DRV/r- Darunavir/Ritonavir, AZT-zidovudine

2.3 Side effects associated with antiretroviral therapy

Antiretroviral drugs like any other drugs can cause side effects which can be mild or severe resulting in non-adherence to drugs (2). Some of the side effects of antiretroviral are presented in **Table 2.2.**

Table 2.2: Common side effects of antiretroviral therapy

The table was adopted from guidelines for antiretroviral drug therapy in Kenya (14).

NRTIs Renal impairment, bone marrow suppression peripheral neuropathy, pancreatitis, lipodystrophy, hepatitis, lactic acidosis.	**Protease inhibitors** Lipodystrophy, GI intolerance, hyperglycemia, lipid abnormalities
NNRTIs Rash, fever, nausea, diarrhoea, liver toxicity,	**Common adverse effects** Peripheral neuropathy – d4T and ddI Bone marrow suppression – AZT Skin rash and liver toxicity – NVP CNS disturbance – EFV Diarrhoea – NFV Hypersensitivity – ABC Dyslipidemia – PIs and d4T Lipodystrophy – PIs, d4T Renal toxicity – TDF

According to literature, tenofovir is better tolerated compared to zidovudine (4,15,16). The main side effects associated with tenofovir include renal toxicity and bone mineral loss. Zidovudine is associated with anemia and neutropenia (17). The other side effects associated with zidovudine include nausea, vomiting, fatigue and headache (18,19).

2.4 Definition of Health Related Quality of life

Health Related Quality of Life is a multi-dimensional idea that comprises the physical, mental, emotional and social function (20). It is more than a direct measure of population health, life expectancy and causes of death and mostly emphasizes on the effect of health status on the quality of life. HRQoL has been used to measure effects of chronic illness, treatment and both short and long term incapacities (20). It is a multi-dimensional measure of health as viewed by the patient.

Quality of life (QoL) is a wide concept that comprises all features affecting a person including economic status, social functioning, health status, life satisfaction, and well-being. The most important aspects of HRQoL are physical, social, emotional, cognitive functioning, motion, self-care and patients' opinion of their health and symptoms (21).

QoL is sometimes used synonymously with HRQoL in medical literature. HRQoL is usually assessed in research setting though it has importance in the routine clinical setting (21). Evaluation of HRQoL has enhanced communication between patients and service providers and allows patients to state areas that concerns them most (22). HRQoL aids in assessment of functional status changes and treatment impact.

Since most pharmacological treatments are generally characterized by adverse effects, there is need for HRQoL assessment to find out whether adverse effects overweigh the desired effects (21). This evaluation is vital as it assists in determining the best treatment option for the patients. HRQoL can serve as a vital tool that evaluates whether there is progress in programs and services (21). Since antiretroviral are lifelong medications, this assessment is vital as it helps to inform policy and assess if there is need for change in treatment guidelines.

The use of HAART and advancement drug therapies has increased life expectancy of patients with HIV infection. There is need for proper adherence in order to reduce disease progression (21). The goals of ART include improvement of Health Related Quality of Life, reduction in symptoms, and suppression of the virus and extension of survival. Adverse effects of potent antiretroviral therapy can worsen HRQoL and result into poor adherence which may led to failure to achieve desired goals (14,21).

2.5 Domains of Health Related Quality of Life

Domains are components of the effects of health related to quality of life. The domains of health are also known as Patient reported outcomes (PROS). There are several domains of health namely physical, psychological, social and environmental (23).

Patient-reported outcomes (PROs) are defined as any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else (24). Such information is reported by individuals themselves or, in some cases, by proxy respondents such as parents for minors or close relatives of individuals unable to report for themselves.

Physical domain refers to the way the disease affects the physical and medical well-being (23). It comprises the effect on the daily activities, dependence on the drugs, fatigue, limitation in movements, concerns about health state, symptoms, sensation, vitality levels, and ability to do daily activities, side effects, adverse drug reactions, pill load and duration of treatment.

The psychological domain is what a patient thinks about themselves and includes depression, anxiety and concerns about spreading disease, feeling angry, positive and negative feelings and spirituality (23). The social domain considers associations with others. It encompasses engaging in social activities, receiving others support, functioning sexually, stigma and social isolation (23).

The environmental domain is concerned about an individual's environs. It includes economic ability, entertainment, security, freedom and quality of the home environment (23). To measure these domains patients are interviewed on the presence and absence of disease and their perception of their general health given that disease can affect ability to function mentally and to carry out one's social function. Other domains of health are: ability to do day to day activities, quality of life and changes from one health status to another. PROS provide additional information to the routine clinical measures of well-being that include CD4 count and viral load.

2.6 Benefits of Health Related Quality of Life evaluation

Previously most assessments of the health status of the patient were based on the health providers and the laboratory tests. HRQoL focuses on the patient's perspective and how satisfied they are with their functioning and treatment effects. Health Related Quality of Life is intended to measure issues that are of importance to the patient's quality of life and to do so in a reliable way (25). WHOQoL instruments place primary emphasis on the patient perception.

HRQoL instruments can be used with other forms of assessment to produce valuable information that indicates areas where patients are most affected and as a result the best choices in patient care will be made by the service providers (25). HRQoL evaluation can form part of treatment effectiveness evaluation. WHOQoL can be used to assess changes in the quality of life of patients on different treatments resulting in a more informed conclusion on patient care (25).

Various instruments have been developed to measure Patient Reported Outcomes and these have been reviewed by Simpson *et al*. The review classified PRO measuring instruments into those measuring quality of life, (generic and HIV-targeted), those measuring symptoms and instruments measuring beliefs about medications (26). Some of instruments adopted for measurement of PRO include MOS-HIV questionnaire, SF-36 questionnaire, Quality of Well-Being (QWB) scale, Nottingham Health Profile (NHP), Sickness Impact Profile (SIP), WHOQoL and Euroqol-5D (EQ-5D) (27).

HRQoL brings out the patients concerns in regard to their quality of life during service delivery. This can also serve as an appraisal instrument to compare the health services provided and the quality of life as reported by the patients (25).

The health care providers knowledge on the nature of disease is enhanced by evaluating how the disease interferes with the subject's well-being across a whole range of areas in regard to the patients quality of life (25). HRQoL helps service providers to make informed choices in policy-making depending on the effect of the intervention on the patient's quality of life (25).

2.7 Factors that determine Health Related Quality of Life in People Living with HIV

A study done by Mutabazi *et al* on the perceptions of quality of life among Ugandan patients living with HIV concluded that patients on antiretroviral therapy experienced an improved quality of life (28). A systematic review that included 49 studies reviewed by Degrote *et al*, classified determinants of HRQoL in HIV in four groups namely: socio-demographic, clinical, psychological and behavioral factors (29).

2.7.1 Socio demographic determinants of Health Related Quality of Life

Good family relationships are associated with good HRQoL while conflicts result in poor quality of life. Parenting improves HRQoL because children bring happiness. On the other hand, ill parents are more concerned about their health because of their children (29).

Socio-economic status has an influence on HRQoL. Employment determines the overall health. HRQoL may be a bidirectional relationship whereby one requires good HRQoL in order to work or work to be responsible for well-being. Low income is associated with a lower mental and overall health. Higher education is associated with higher HRQoL. Low

education leads to lower socio economic status and inability to access therapy. These may be due to poverty and a low education status resulting in poor HRQoL (29).

2.7.2 Clinical and disease related determinants of Health Related Quality of Life

A lower viral status is associated with good HRQoL. Patients with higher CD4 have better physical health. Physical improvement is noted in patients who start ART earlier (29). The Kenyan guidelines for antiretroviral therapy recommend earlier initiation of ART for all people who test positive of HIV as it reduces disease progression to AIDS and also reduces the risk of death (3).

The progression of HIV to advanced stages (III and IV) is associated with diminished physical health which negatively affects future physical health. Longer duration on therapy from diagnosis is linked to better mental health. Longer duration on therapy facilitates development of effective coping that enhances mental health. There is need for continued monitoring of mental health by health care providers even if the physical condition seems to be right (29).

The negative influence of HIV-related symptoms on HRQoL is supported by scientific evidence. A relationship with both physical and mental health is evident (29). There is an inverse linear relationship between number of symptoms and SF-36 scores (29). Each additional symptom is associated with a nearly 1.5 point decrease in physical and mental health scores (29). Symptom status is a strong predictor for HRQoL than functional status, health perceptions, age, sex, biological and physiological markers (29).

In HIV care and management most of the patients have symptoms and side effects as a result of immunosuppression. A number of studies have illustrated the need to keenly evaluate the prevalence of side effects in patients on ART (30,31). A study by Kashifullah *et al* on adverse effects of highly active antiretroviral therapy concluded that it was critical that all health care providers and patients be trained to recognize symptoms and signs of the most important ADRs earlier. Proper management protocols should be readily available and ADR surveillance at facilities offering HAART need to be formalized (32).

2.7.3 Effect of antiretroviral therapy on Health Related Quality of Life

The effect of ART on HRQoL has been described as a balance between reduced HIV-related symptoms and better life expectancy and on the other hand the side-effects. For people with acceptable health status before initiation of ART, these side effects outweigh the benefits.

Sexual dysfunction is an ART side effect, found significantly to impact HRQoL. Patients on ART continuously improve and this has positive effect on HRQoL (29).

2.7.4 The effect of psychological and social factors on Health Related Quality of Life

Depression has a strong negative effect on daily life and HRQoL. Depression can cause some physical problems, (for example loss of appetite and sleeping disorders). The prevalence of depression is higher in PLWHIV than the general population (29).

The ability to cope is very key considering stress can result from HIV diagnosis and treatment and other sources. Good coping is associated with better HRQoL. Coping styles are associated with health locus of control (HLOC). People with internal HLOC believe health outcomes are as a result of one's behavior while those with external HLOC believe the outcomes are as a result of others, fate or luck. Internal HLOC is associated with a better physical health while external HLOC is responsible for lower mental health (29). HIV status being a chronic condition sometimes makes the patient have unpleasant emotional feeling (anxiety) that may adversely affect the patient's quality of life. Anxiety can result in despair depending on the severity of the condition. Coping, an action adopted by an individual to reduce the effect of stress or reduce adversity of stress, is necessary (33). Different coping mechanisms are adopted by patients. These may be either beneficial or harmful. Patients may choose to adopt a range of coping strategies including emotional-focus, behavioral, cognitive appraisal and problem focus coping (34).

A study by Sreelekshmi *et al* observed that care of People Living with HIV/AIDS should be individualized and prioritized when managing anxiety and coping strategies (33). Coping strategies have an effect on Patient Reported Outcomes.

Religious practices could be responsible for both positive and negative coping. Patients who view being HIV positive to be a punishment from God and are being ostracized tend to have a low HRQoL. Social support has a direct influence on health outcomes both negatively and positively. In some of the studies, social support reduces depression resulting in improved quality of life. Neuropsychological status, alcohol use, drug use, adherence, life style and sex risk behaviors, affect quality of life (29).

2.8 Studies conducted on Health Related Quality of Life in East Africa

A multicenter observational study on quality of life and welfare among HIV outpatients in East Africa by Harding and allies in PEPFAR-funded care facilities in Kenya and Uganda, was conducted to gauge well-being and assess the association with patient problems (35). The study concluded that multi-dimensional problems are prevalent, and worsen with deteriorating function. They noted that ART did not seem to be protective of the self-reported physical and mental health dimensions of quality of life. They suggested that management and assessment of well-being be part of HIV care in order to potentiate the benefits of HAART (35) .

A study on HRQoL among HIV positive women in Korogocho was conducted by Otambo *et al* (36). The study assessed factors that affect quality of life among HIV and AIDS positive women. It reported low quality of life. The study suggested that clinicians and health practitioners should consider counseling women with HIV/AIDS in their interaction with them. They should also consider involving them in their health decisions as they are owners of their body who can best explain the manifestation of the condition. These could improve the health care outcomes (36).

A study conducted by Njega *et al* on health adjusted life expectancy among adult PLWHIV was conducted in Kenya. The study observed that Kenyan adult PLWHIV had a bigger proportion of their life in poor health state. It further noted regional differences between the people from Central and Nyanza regions of Kenya (37).

2.9 Studies comparing Health Related Quality of Life across regimens

A study conducted by Mafirakuvera *et al* in a tertiary care facility in Zimbabwe among patients on ART reported good HRQoL which was positively correlated with income, education and employment (38). Similarly a study comparing HRQoL of patients on efavirenz and nevirapine in Zimbabwe found no significant difference between the two regimens. It however highlighted the need for monitoring and treating depression (39).

2.10 Studies comparing the efficacy of zidovudine and tenofovir

A review by Spaulding *et al* concluded equal virologic response and serious adverse events of both tenofovir and zidovudine containing regimens for patients newly initiated on ART (40). It also reported better immunologic response and adherence on tenofovir based regimens compared to zidovudine based (40). Drug resistance was noted on tenofovir containing regimens though it was reported by only one study (40). A study on a large Nigerian cohort concluded that zidovudine–lamivudine compared to the use of tenofovir-lamivudine or emtricitabine in combination with nevirapine was a strongly predictor of virologic failure which was not explained by other risk factors or criteria for regimen selection (41).

The few studies that assessed Health related quality of life among patients on ART have given varying information. From the above literature it's clear that no studies have been done comparing HRQoL of patients on tenofovir versus zidovudine based regimens.

CHAPTER THREE: METHODS

3.1 Study Design

The study design was a comparative cross sectional study, where data was collected using an adopted researcher administered Medical Outcome Study HIV Health Survey (MOS-HIV) questionnaire **(Appendix 5)**. It had two arms: participants on tenofovir based regimens and those on zidovudine based regimens. The participants were enrolled between December, 2015 and May, 2016.

3.2 Study Site

The study was conducted in Kenyatta National Hospital (KNH) Comprehensive Care Center (CCC). KNH is the oldest public hospital and the main referral and teaching institution in Kenya. KNH had a bed capacity of 2000 and attends to roughly 70000 in-patients and 500000 outpatients according to a study by Innovex Associates Limited done in June 2014 (42). KNH offers specialized health care to Kenya, the great Lake Region, South and Central Africa regions. KNH had 6835 adult patients on tenofovir and zidovudine based regimens, of which 4992 were on tenofovir based regimens while 1680 were on zidovudine based regimens as per July 2015, KNH CCC Pharmacy report (12).

3.3 Study Population

The target population was Kenyan HIV patients on either tenofovir or zidovudine based regimens. The study population included HIV positive patients aged 18 years and above attending clinic at Kenyatta National Hospital in December, 2015 to May, 2016. Two hundred participants on zidovudine based and 301 participants on tenofovir based regimens made up the sample population.

3.3.1 Inclusion Criteria

Patients were included in the study if they were:

1. HIV infected adults of age 18 and above.
2. On either tenofovir or zidovudine based regimens at Kenyatta National Hospital.
3. Had been on the regimen for at least six months.
4. Gave consent to participate in the study.

Patients were excluded if they:

1. Did not meet the above inclusion criteria.
2. Were pregnant.

3.4 Sample Size Considerations

Since this was a comparative cross-sectional study using two independent samples with a continuous primary outcome of interest (HRQoL), the difference between means and standard deviation of the primary outcome of the sample were estimated. Hence the most suitable formula for sample size determination was that as quoted in the Sekabira study (43).

$$2N = \frac{[4(Z\alpha/2 + Z_{1-\beta})^2 \sigma^{2}]}{\delta^2}$$

Where:

$Z\alpha/2$= the standard normal deviate at 95 confidence (1.96)

$Z_{1-\beta}$= the Z-value corresponding to a power of 90 (1.282)

σ^2 = Variance of the outcome of interest HRQoL, (22.5)

δ= Difference between the two means we were willing to allow. This was also known as the precision. The calculated minimal sample was 217 patients. It was inflated by 10% to cater for non-response bias. A sample size of 238 per arm was adopted.

3.5 Sampling Method and Participant Recruitment

3.5.1 Sampling Method: Convenient sampling was done where by participants who gave consent to participate in the study were included in the study until the desired sample size was reached.

3.5.2 Participant Recruitment: The participants were recruited by both the principal investigator and the research assistants as they collected their drugs in the pharmacy. This

minimized interruption of the normal work flow. The participants were informed about the study in a side room next to the pharmacy.

3.6 Definition of Operational Terms

The domains that were measured were general health perception, quality of life, perception of energy levels, lack of distress about health, ability to function physically, absence of pain, score on intellectual skills, ability to function mentally, ability to do day to day activities, social function and health transition.

General health perception is the overall image of well-being as viewed by the patient. This was measured using five items in the MOS-HIV questionnaire. Participants were asked to express their views on their general health and presence of illness (44).

Physical functioning domain measured the ability of one to do usual day-to-day activities. The questions focused on the ability of the participants to do activities that ranged from vigorous, moderate to minor in terms of the energy required to perform the activities. The vigorous activities assessed were ability to dig, fetch water, carry 10 kilograms of weight and split fire wood. The moderate activities were washing clothes, moving a jerrican of water or bundle of fire wood. Ability to perform less involving self-care activities like eating, dressing, bathing and using the toilet were also assessed. Six items were used to assess the physical functioning domain (44).

The **role function** domain refers to how the disease affects a patient's ability to work at their job, do house work or attend school. Role function was measured using two questions. The domain social function was only measured using one question and is defined as the extent to which the patient's social activities such as attending church and visiting relatives were limited by ill health in the past one month. Illness affects one's relations; for example, people who are stigmatized as a result of being HIV positive would tend to avoid visiting relatives and attending other public gatherings (44).

Cognitive functioning is defined as the intellectual ability to reason, recall and solve problems. Side effects or very severe illness can diminish the ability to be attentive, concentrate on activities that require cognitive skills. This domain was measured using 4 questions in the MOS-HIV questionnaire (44).

The **pain domain** assessed the amount of bodily pain experienced by the participants and the degree to which it affected the participants' life. This was elicited using two questions in the MOS-HIV questionnaire. The **domain mental** health was computed from the responses to five questions. The major components of mental health dimension were presence of depression, anxiety, general psychological well-being and loss of behavioral and emotional control (44).

The **energy domain** was measured using 4 questions and these measured the sense of energy or vitality a patient feels. It explores the energy, eagerness and endurance that a person has to perform the necessary tasks of daily living and some chosen chores. The health distress domain is defined as the extent to which participants feels a sense of discouragement and fear as a result of their illness. This was measured using four questions that dealt with the amount of time the participants felt a sense of despair or distress (44).

Quality of life is an overview of how things have been for the last one month for the participants in relation to value for life, health and well-being. One question sought to find out how the participants perceived their quality of life (44). **Health transition** domain measured the change in the participants' physical and emotional health over four week's period. One question was asked to obtain the perception of the participants on health changes. This provided vital information about actual changes in the health status during the period before the administration of the questionnaire (44).

Mental health refers to the emotional, psychological and social well-being of an individual. Mental health is an integral part in HIV management as it determines the overall health of an individual since it affects the way one thinks, conduct themselves and acts (45). HIV infection is highly characterized by stigma and as a result the patients are likely to have mental illness due to stress, adopting negative coping mechanisms to HIV, or directly/indirectly attributed to disease progression. Negative influence of treatment, stress as a result of living with HIV and co-morbidities associated with HIV can also be a trigger for mental illness (46).

Physical health relates to the functioning of the physical body (47). Physical health is a state of physical well-being in which a person is physically fit to perform daily activities without restrictions.

3.7 Data Collection

3.7.1 Training and pre-testing the questionnaire

The research assistants were trained for two days before the beginning of the study. The training included explanation of the nature of the study, objectives and the need for the study. Intensive explanation on the use of the tools was done. Ethical considerations, how to deal with challenges and issues that were involved in a scientific research were explained. Pre-testing was done by both the research assistants and the principal investigator. The questionnaire was pre-tested in 20 participants.

3.7.2 Participants interview and abstraction of participants records

Informed consent was obtained before the start of the interview **(Appendix 3)**. The nature and purpose of the study was explained. The eligibility was assessed with the aid of an eligibility check list **(Appendix 4)** to ensure that only eligible participants were part of the study. Information on socio- demographics and HRQoL of participants were obtained with aid of the appended MOS-HIV interviewer guide **(Appendix 5)**. Ten questions elicited the baseline characteristics of the study participants. MOS-HIV questionnaire is a brief comprehensive health status measure containing 35 questions which assessed ten dimensions of health namely: general health perception, pain, physical functioning, role functioning, social functioning, mental health, energy/fatigue, cognitive function, health distress and quality of life. One item measured how the participants viewed changes from one health state to another over the past one month (health transition). Six additional questions elicited information on the type of symptoms participants were experiencing, satisfaction with service provision, coping ability and mechanisms, adherence to medication and alcoholism/substance dependence.

Data on the recent CD4 count and viral load were extracted from the participants' records. These were done after the participants had completed the other part of the questionnaire.

3.8. Computation of the scores of individual domains of health

The raw scores of each of the domains were computed as described in the MOS-HIV Health Survey User's Manual (44). All the items and scales in the adapted MOS-HIV Health Survey questionnaire were scored so that a higher score indicated better health. Eleven items were reverse coded since a higher pre-coded item value indicated a poor health state to ensure that

a higher scale value indicated better health on all MOS-HIV items and scales. For example question I in section B of the appended questionnaire (**Appendix 5**) the pre-coded responses were: 1.Excellent, 2.Very good, 3.Good, 4.Fair, and 5.Poor. These were reverse coded so that "Excellent was given a higher item value to reflect higher quality of life while poor was given a lower item value to indicate lower quality of life. The reverse coded items were questions i, ii, iii, viii b, viii d, ix a, ix d, xi b, xi c, xii, xiii as indicated in **Table 3.1**

Table 3.1 Questions used for computing, reverse coding and number of items assessed for the individual domains of health (44)

Domains of health	**Questions used to compute the domain**	**Reverse coded items**	**No of items assessed**
General Health Perception	Qi, xi a to xi d	Qi, xi a, xi b and xi c	Five
Physical functioning	Q iv a to iv f	Nil	Six
Role functioning	Q v, vi	Nil	Two
Social functioning	Q vii	Nil	One
Cognitive functioning	Q x a to x d	Nil	Four
Pain	Q ii, iii	Q ii, iii	Two
Mental Health	Q viii a to viii d	Q viii b and viii d	Five
Energy/Fatigue	Q ix a to ix d	Q ix a and ix d	Four
Health distress	Q ix e to ix h	Nil	Four
Quality of life	Q xii	Q xii	One
Health transition	Q xiii	Q xiii	One

Different questions as indicated in **Table 3.1** were used to calculate the raw scores for different domains of health. The questions were as indicated in the appended questionnaire **(Appendix 5)**. The domain general health perception was obtained from questions i, xi a to xi d of the questionnaire. Questions iv a to iv f made up the 6-item physical function scale score. Questions v and vi were used to obtain the role function scale scores. Cognitive function scale scores were derived from four questions x a to x d. Questions ii and iii made up the pain scale score. Five item mental health scale score was obtained from question viii a to viii e. Health distress scores were attained from 4-item questions which included questions ix a to ix d.

Each of the questions entailed responses that had a value that ranged from 1-2, 1-4, and 1-6 based on the likert scale. The response given by a participant was the score for that particular question/item. For instance if a participant stated their health limited their social functioning some of the time they got a score of 4 on a scale of 1-6. The sum of the scores of the responses from the questions that compute a particular domain were taken as the raw score

for that particular participant on the same domain. For example since general health perception was computed by 5 item questions, the least the participant could score was 5 while the highest was 25. A score of 5 indicated poor score in general health perception while that of 25 represented better score of the participant in general health perception.

The obtained raw scores were then transformed in order to standardize the scores and facilitate comparison of the domains across studies where MOS-HIV 35 questionnaire was used. The general formula for transformation of the raw scores is represented in **equation 1**

Equation 1: Formula for transformation of scores of the individual domains of health

$$Y = (100*[(RS-MIN)]/ (MAX-MIN)]$$

Where:

MIN=Minimum possible raw scale value if all items are answered

MAX=Maximum possible raw scale value if all items are answered

R.S=Participant's raw score for a given HRQoL dimension

Y=Participant's transformed score for a given HRQoL dimension

The adapted formula for linear transformation for each of the dimensions of health is presented in **Table 3.2**.

Table 3.2 Transformation formula for various dimensions of health using MOS-HIV questionnaire (44)

Scale	**Transformation Formula**
General Health Perception	Lgenheal=(100(25-5)*(General health perception raw score-5)
Physical functioning	Lphys=(100/(18-6))*(physical function raw score-6)
Role functioning	Lrole=(100/(4-2))*(role function raw score-2)
Social functioning	Lsocial=(100(6-1))*(social function raw score-1)
Cognitive functioning	Lcognitive=(100/(24-4)*(cognitive function raw score-4)
Pain	Lpain=(100/(11-2))*(pain-2)
Mental Health	Lmental=(100/(30-5))*(mental health raw score-5)
Energy/Fatigue	Vitality=(100/(24-4))*(energy /fatique raw score-4)
Health distress	Ldistress=(Ldistress -(100/(24-4))*(health distress raw score-4)
Quality of life	Lquality=(100/(5-1))*(quality of life raw score-1)
Health transition	Ltras=(100/(5-1))*(health transition raw score-1)

The transformed scale scores ranged from 0-100 scale where a higher score values represented better HRQoL while lower score indicated poor HRQoL.

3.9. Computation of the Physical and the Mental Health Summary score

The score values obtained in **section 3.8** were used to obtain both the Physical and Mental Health Summary scores. Both the Physical Health Summary score (PHS) and the Mental Health Summary score (MHS) final values were derived from the 10 scale scores of MOS-HIV health survey (44). Z-score transformation for standardization of the scores to the standard Roche patient population was done. This was done for the individual scales using the following equations:

PF_Z = (PF - 80.4395425)/24.2176719
GH_Z = (GH - 56.792402)/24.550145
PN_Z = (PN - 64.7941176)/28.8807702
RP_Z = (RP - 73.1371549)/40.7722411
SF_Z = (SF - 84.6862745)/21.2559432
MH_Z = (MH - 69.2284314)/18.8444325
VT_Z = (VT - 62.130719)/20.3233407
HD_Z = (HD - 71.1437908)/24.0487778
CF_Z = (CF - 83.5147059)/20.4626273
QL_Z = (QL - 69.1421569)/19.7661596

Abbreviations: PF = physical functioning; MH = mental health; HD = health distress; QL = quality of life; CF = cognitive functioning; VT = vitality; PN = pain; RF = role functioning; SF = social functioning; GF = general life.

The obtained transformed individual scales scores above were used to calculate the Physical and Mental Health Summary scores. These were achieved by multiplying the transformed scale scores by the scoring coefficients in **(Appendix 6)** and aggregated as illustrated by the following formulas:

PHS = (MH_Z * -.13017) + (HD_Z * -.07680) + (QL_Z * -.00504) + (CF_Z * .01866) + (VT_Z * .11785) + (PF_Z * .34370) + (PN_Z * .31854) + (RF_Z * .29617) + (SF_Z * .22165) + (GH_Z * .17829); (44)

MHS = (MH_Z * .31592) + (HD_Z * .27676) + (QL_Z * .21939) + (CF_Z * .19615) + (VT_Z * .16052) + (PF_Z * -.06072) + (PN_Z * -.08665) + (RF_Z * -.00325) + (SF_Z * .05690) + (GH_Z * .10158); (44)

The obtained Physical Health Summary and Mental Health Summary score were then transformed to have a mean of 50 and a standard deviation of 10 in order to obtain the final Physical and Mental Summary Scores (44). These were attained using the following equations:

Physical Health Summary score = 50+ (PHS*10)

Mental Health Summary score = 50+ (MHS*10)

Where:

PHS*10= Product of Physical Health Summary score and standard deviation of 10.

MHS*10= Product of Mental Health Summary score and standard deviation of 10.

3.10 Variables

The main outcome variables were scores of the individual domains of health, Physical and Mental Health Summary score these were the dependent variables. The prevalence of symptoms of disease/side effects and coping mechanisms adopted by the participants were obtained. For regression analysis, the outcome variable was prevalence of any physical symptoms of disease and side effects. The independent variables were regimens, socio-demographic traits and HIV related history.

3.11 Data Management

Data was entered in an Epi Info Version 7 database within 24 hours after filling the questionnaire. Evaluation for completeness and accuracy was done daily. Data was backed up weekly. Confidentiality was maintained by use of participant codes instead of identifier information.

3.12 Statistical Analysis

Descriptive data analysis was conducted. Shapiro Wilk test was used to test if the continuous variables were normally distributed. They were summarized using the median and the interquartile range. Categorical variables which included symptoms of disease/side effects, ART regimens participants were on, individual groups of various variables were summarized as counts and percentages. Distribution of all variables was compared across two groups using inferential tests which included Chi-square, Mann-Whitney and un-paired students t-tests. Logistic regression analysis was used to identify the risk factors for any symptoms of disease or side effects. Linear regression with robust estimation was conducted to identify predictors of the Mental and Physical Health Summary scores. Model building was done using a forward stepwise approach. The level of significance was set at 0.05. STATA version 10.0 was used for data analysis.

3.13 Ethical Considerations

The study was conducted after ethical approval was obtained from Kenyatta National Hospital-University of Nairobi (KNH/UoN) Ethics and Research Committee, (Approval Reference Number: KNH-ERC/A/467) **(Appendix 1**). Annual extension of ethical approval was sought from Kenyatta National Hospital-University of Nairobi (KNH/UoN) Ethics and Research Committee, Reference Number: KNH/ERC/R/52 **(Appendix 2**). Institutional approval was also sought from Kenyatta National Hospital.

Informed consent was sought from participants who met the inclusion criteria **(Appendix 3)** and there was no coercion or incentives to participate in the study. Adequate explanations of the nature of the study were provided. Participants were asked to voluntarily participate or withdraw from the study.

Participant identities were concealed by use of serial numbers instead of participant names and any identifier information. Data collection materials were kept under lock and key during the entire study and databases were password protected for limited access. There were no risks involved in this study as the study did not involve a new intervention.

CHAPTER FOUR: RESULTS

4.1 Participants' recruitment

A total of 541 participants were invited to participate. On assessment for eligibility only 501 participated **Figure 4.1**. Among the 501 participants, 301 (60.8 %) were on tenofovir based regimens while 200 (39.9 %) on zidovudine based regimens.

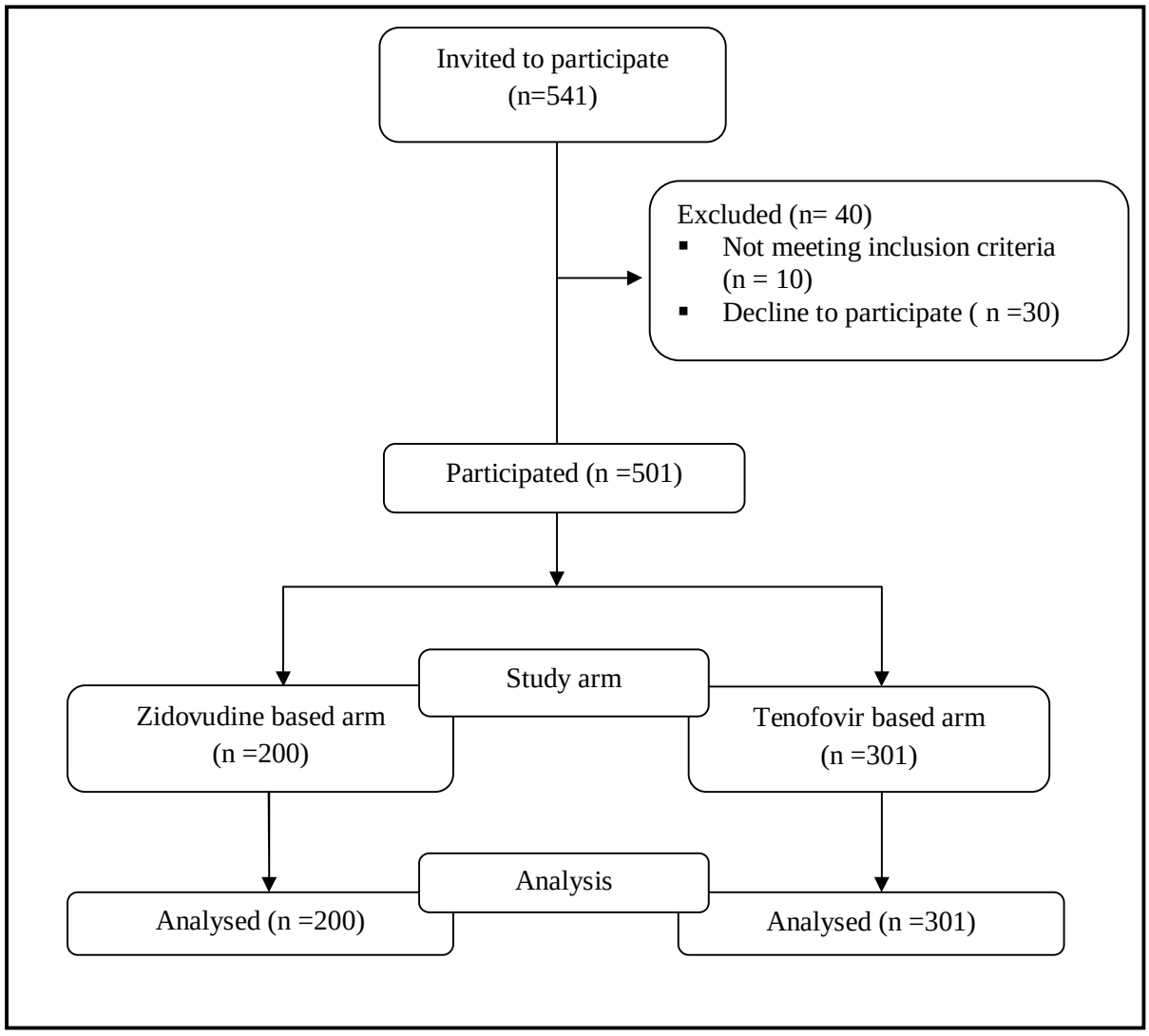

Figure 4.1: CONSORT diagram for participants' recruitment

NOTE: For some variables for instance participants did not give responses and therefore the data provided is only for the participants who gave response.

4.2 Baseline socio-demographic characteristics of the participants

The baseline socio demographic characteristics of the participants are presented in **Table 4.1.**

Table 4.1 Comparison of the baseline socio-demographic characteristics of participants on tenofovir versus zidovudine based regimens (N=501)

Variable	Tenofovir (n, %)	Zidovudine (n, %)	Total (n, %)	P-value[a]
Age (yrs) n=501				
18-35	66 (21.9)	50 (25)	116 (23.2)	
36-45	127 (42.2)	86 (43)	213 (42.5)	
46-64	104 (34.6)	62 (31)	166 (33.1)	0.809
≥65	3 (0.9)	2 (1)	5 (0.9)	
Missing	1 (0.3)	-	1 (0.2)	
Sex n=501				
Male	87 (28.9)	63 (31.5)	150 (29.9)	
Female	212 (70.4)	136 (68)	348 (69.5)	0.619
Missing	2 (0.7)	1 (0.5)	3 (0.59)	
Marital status n=501				
Married	158 (52.5)	106 (53)	264 (52.6)	
Living together	3 (0.9)	5 (2.5)	8 (1.6)	
Single	61 (20.3)	33 (16.5)	94 (18.8)	0.332
Widowed	46 (15.3)	26 (13)	72 (14.4)	
Divorced	33 (10.9)	29 (14.5)	62 (12.4)	
Missing	-	1 (0.5)	1 (0.2)	
Regions n=501				
Nyanza	75 (24.9)	36 (18)	111 (22.2)	
Western	49 (16.3)	28 (14)	77 (15.4)	
Rift valley	13 (4.3)	12 (6)	25 (4.9)	
Nairobi	6 (1.9)	4 (2)	10 (1.9)	0.537
Central	89 (29.6)	62 (31)	151 (30.1)	
Eastern	55 (18.3)	48 (24)	103 (20.5)	
North Eastern	5 (1.7)	3 (1.5)	8 (1.6)	
Coast	5 (1.7)	4 (2)	9 (1.8)	
Missing	4 (1.3)	3 (1.5)	7 (1.4)	
Status disclosure n=501				
Yes	232 (77.1)	158 (79)	390 (77.8)	0.433
No	67 (22.3)	38 (19)	105 (20.9)	
Missing	2 (0.4)	4 (2)	6 (1.2)	
Education level n= 501				
No education	7 (2.3)	2 (1)	9 (1.8)	
Primary	53 (17.6)	48 (24)	101 (20.2)	0.121
Secondary	144 (47.8)	90 (45)	234 (46.7)	
Tertiary University	95 (31.6)	55 (27.5)	150 (29.9)	
Others	0 (0)	2 (1)	2 (0.4)	
Missing	2 (0.7)	3 (1.5)	5 (0.9)	
Religious belief n=501				
No	4 (1.3)	1 (0.5)	5 (0.9)	
Yes	294 (97.7)	197 (98.5)	491 (98)	0.653
Missing	3 (0.9)	2 (1)	5 (0.9)	
Regular source of income n= 501				
No	66 (21.9)	38 (19)	104 (20.8)	0.572
Yes	232 (77.1)	155 (77.5)	387 (77.3)	
Missing	3 (0.9)	7 (3.5)	10 (1.9)	

[a]Fischer's Exact Test

There were more female participants 348 (69.5 %) compared to males. Most participants were aged between 36-45 years. Majority of the participants had attained secondary level education 234 (46.7 %) and 9 (1.8 %) were not educated at all. Married participants made up about half (264, 52.6 %) of the participants.

Most of the participants were from the Central part of Kenya (151, 30.1 %) and most (390, 77.8%) had disclosed their HIV status to at least a friend or relative. Majority of the participants (387, 77.3%) had a regular source of income. Participants with religious belief included those that had at least a belief in a supernatural being. There were no statistically significant differences in the socio-demographic traits across the two arms.

4.3 Baseline medical characteristics of study participants

The baseline medical characteristics of study participants are presented in **Table 4.2**.

Table 4.2 Baseline medical history for participants on tenofovir versus zidovudine based regimens (N=501)

Variable	Tenofovir (n, %)	Zidovudine (n, %)	Total (n, %)	P-value[a]
Duration of HIV infection in years n=501				
≤2.0	39 (13)	5 (2.5)	44 (8.8)	
2.1-5.0	70 (23.3)	46 (23)	116 (23.2)	
5.1-10.0	124 (41.2)	113 (56.5)	237 (47.3)	
10.1-15.0	49 (16.3)	25 (12.5)	74 (14.8)	**<0.001**
>15	19 (6.3)	10 (5)	29 (5.8)	
Missing	-	1 (0.5)	1 (1.2)	
Duration on ART in years n= 501				
≤1.0	35 (11.6)	3 (1.5)	38 (7.6)	
1.1-2.0	30 (10)	7 (3.5)	37 (7.4)	
2.1-5.0	82 (27.2)	62 (31)	144 (28.7)	
5.1-10	121 (40.2)	111 (55.5)	232 (46.3)	**<0.001**
>10	33 (11)	16 (8.0)	49 (9.8)	
Missing	-	1 (0.5)	1 (0.2)	
Adherence Missed drug intake n=501				
Missing	6 (2.0)	1 (0.5)	7 (1.4)	
No	195 (64.8)	142 (71)	337 (67.3)	0.187
Yes	100 (33.2)	57 (28.5)	157 (31.3)	
Recent CD4 count in cells/mm^3 n=501				
<250	41 (13.6)	37 (18.5)	78 (15.6)	
250-499	108 (35.9)	71 (35.5)	179 (35.7)	
500-999	127 (42.2)	73 (36.5)	200 (39.9)	
≥1000	15 (4.9)	9 (4.5)	24 (4.8)	0.414
Missing	10 (3.3)	10 (5)	20 (3.9)	
Recent viral load copies/ml n=158				
≤ 0.01	62 (70.5)	45 (64.3)	107 (67.7)	
1-1000	14 (15.9)	7 (10)	21 (13.3)	0.121
>1000	12 (13.6)	18 (25.7)	30 (19)	

[a]Fischer's Exact Test

There was a statistically significant difference in the duration of infection with HIV infection and the use of ART ($p<0.001$) across the 2 arms. Those on zidovudine had been on treatment longer. About 46.3% had been HIV positive for 5.1 to 10 years and (44.7%) had a CD4 count of >500 cells/mm and above. Out of the participants who had a viral load report, 67.7% had a viral load of less or equal to 0.01copies/ml. Roughly 22% of participants on the tenofovir arm had been on therapy for 2 years and below compared to only 5 % in the zidovudine-arm. In the tenofovir arm 11% of the participants had been on treatment for more than 10 years compared to only 8% on zidovudine arm. The CD4 counts and adherence were comparable across the arms.

4.4 Antiretroviral Regimens of the participants

Table 4.3 presents the type of regimens the participants were treated with.

Table 4.3 ART regimens of participants on tenofovir versus zidovudine based regimens at Kenyatta National Hospital (N=501)

	AZT Based Regimens (n, %)		**TDF based regimens (n, %)**		**Total**
Type of ART regimen					
	AZT/3TC/NVP	89 (17.8)	TDF/3TC/NVP	65 (12.9)	
	AZT/3TC/EFV	82 (16.4)	TDF/3TC/EFV	218 (43.5)	
	AZT/3TC/LPV/r	21 (4.2)	TDF/3TC/ LPV/r	17 (3.4)	
	AZT/3TC/ATV/r	8 (1.6)	TDF/3TC/ ATV/r	1 (0.2)	
	Total	200	**Total**	301	
Percentage of participants on selected drugs (n, %)					
EFV		82 (41)		218 (72.4)	300
NVP		89 (44.5)		65 (21.6)	154
LPV/r		21 (10.5)		17 (5.7)	38
ATV/r		8 (4)		1 (0.3)	9
Total		**200 (100)**		**301 (100)**	**501**
First line therapy		171 (85.5)		283 (94.0)	454
Second line therapy		29 (14.5)		18 (6.0)	47

TDF-Tenofovir, 3TC-Lamivudine, EFV-Efavirenz, NVP-Nevirapine, LPV/r-Lopinavir/ritonavir, ATV/r-Atazanavir/ritonavir, DRV/r-Duranavir/ritonavir, AZT-zidovudine

Majority of the participants were on a first line regimen; 90.6 % compared to only 9.4% on second line regimen. Most of the participants were on TDF/3TC/EFV (43.5 %) while only one participant was on TDF/3TC/ ATV/r. The ratio of participants on tenofovir to zidovudine was 6:4 as presented in **Table 4.3**.

All the study participants were on lamivudine. Out of 47 (20.5%) participants on second line therapy, 29 (14.5%) were on zidovudine while 18 (6%) were on tenofovir. Most participants on tenofovir based regimens were on efavirenz as opposed to the zidovudine-based arm where most were on nevirapine.

4.5 Coping mechanisms and satisfaction with services provided

Most participants embraced sharing about their illness as a coping style (35.4 %). Majority of participants were very satisfied with the quality of service offered by the health care providers. About 28.7% of the participants took alcohol. The coping mechanisms adopted by study participants are presented in **Table 4.4**.

Table 4.4: Coping mechanisms and satisfaction with service provided for participants on tenofovir versus zidovudine based regimens (N=501)

	Tenofovir (n, %)	Zidovudine (n, %)	Total (n, %)	P-values
Coping Strategy n=501				
Acceptance	104 (34.6)	50 (25)	154 (30.7)	**0.034**
Sharing about illness	93 (30.8)	84 (42)	177 (35.3)	
Support group	87 (28.9)	60 (30)	147 (29.3)	
Spiritual support	13 (4.3)	6 (3)	19 (3.8)	
Any other	3 (0.9)	0 (0)	3 (0.6)	
Missing	1 (0.3)	-	1 (0.2)	
Satisfaction with service provision n= 501				
Very good	195 (64.8)	144 (72)	339 (67.7)	
Good	96 (31.9)	47 (23.5)	143 (28.5)	
Fair	8 (2.7)	8 (4)	16 (3.2)	0.138
Bad	1 (0.3)	1 (0.5)	2 (0.4)	
Missing	1 (0.3)	-	1 (0.2)	
Alcoholism/substance dependence n= 501				
Use alcohol	87 (28.9)	54 (27)	141 (28.1)	
Hard drugs	5 (1.7)	5 (2.5)	10 (1.9)	0.704
No drugs	202 (67.1)	139 (69.5)	341 (68.1)	
Missing	7 (2.3)	2 (1)	9 (1.8)	

***P-value of the fisher exact test for comparison across the regimens**

There was significant difference of the coping mechanisms across the regimens in that participants on tenofovir had accepted their HIV status while more of those on zidovudine adopted sharing about illness. When compared to the tenofovir arm, slightly more participants on zidovudine adopted joining support group when compared to those on tenofovir arm.

4.6 Scores on individual domains of health

We measured 10 domains of health and one aspect of health transition. **Table 4.5** presents the findings. **Table 3.1** and **Table 3.2** explain how the individual domains were obtained. These were computed as described in **section 3.8**. Summary statistics included median scores and interquartile range of domains of health. P-values were obtained using two-sample Mann-Whitney test.

Table 4.5 Comparison of scores on domains of Health Related Quality of Life for participants on tenofovir versus zidovudine based regimens

Scores of health	Tenofovir Median [IQR]	Zidovudine Median [IQR]	All Median [IQR]	P-value[a]
General health Perception	85 [65, 90] n=296	90 [80, 95] n=198	85 [70, 95] n=494	**0.001**
Quality of life	75 [50, 100] n=297	75 [75, 100] n=196	75 [75, 100] n=493	**0.029**
Feels energetic (Vitality/Energy)	85 [70, 95] n=301	90 [80, 100] n=195	85 [75, 95] n=496	**0.001**
Lack of distress on health(Health Distress)	80 [72, 80] n=298	80 [76, 80] n=190	80 [72, 80] n=488	0.090
Ability to function physical (Physical functioning)	100 [91.7, 100] n=293	100 [100, 100] n=191	100 [91.7, 100] n=484	**0.007**
Absence of pain (Pain)	93.8 [75, 100] n=300	100 [87.5, 100] n=195	100 [87.5, 100] n=495	**<0.001**
Score on intellectual skills (Cognitive)	97.5 [85, 100] n=298	100 [95, 100] n=192	100 [90, 100] n=490	**<0.001**
Ability to function Mentally (Mental functioning)	88 [76, 96] n=297	92 [84, 96] n=197	88 [80, 96] n=494	**0.005**
Ability to do day to day activities (role functioning)	100 [100, 100] n=300	100 [100,100] n=200	100 [100, 100] n=500	0.215
Social function (Social functioning)	100 [100, 100] n=299	100 [100, 100] n=200	100 [100, 100] n=499	0.125
Health Transition	75 [50, 100] n=299	100 [75, 100] n=199	75 [50, 100] n=498	**0.003**

[a]Two - sample Mann-Whitney test

Participants on zidovudine based regimens consistently gave higher scores compared to those on tenofovir as presented in **Table 4.5**. There was no statistical significance differences between the two arms in lack of distress about health, social function and ability to do day to day activities. The rest of the domains showed statistical significant differences between the two arms.

4.7 Prevalence of symptoms of disease or side effects

Figure 4.2 summarizes the prevalence of symptoms either as a result of disease or side effects in this study. A histogram was plotted on the presence and absence of symptoms of participants on tenofovir based, zidovudine based and total population of study participants.

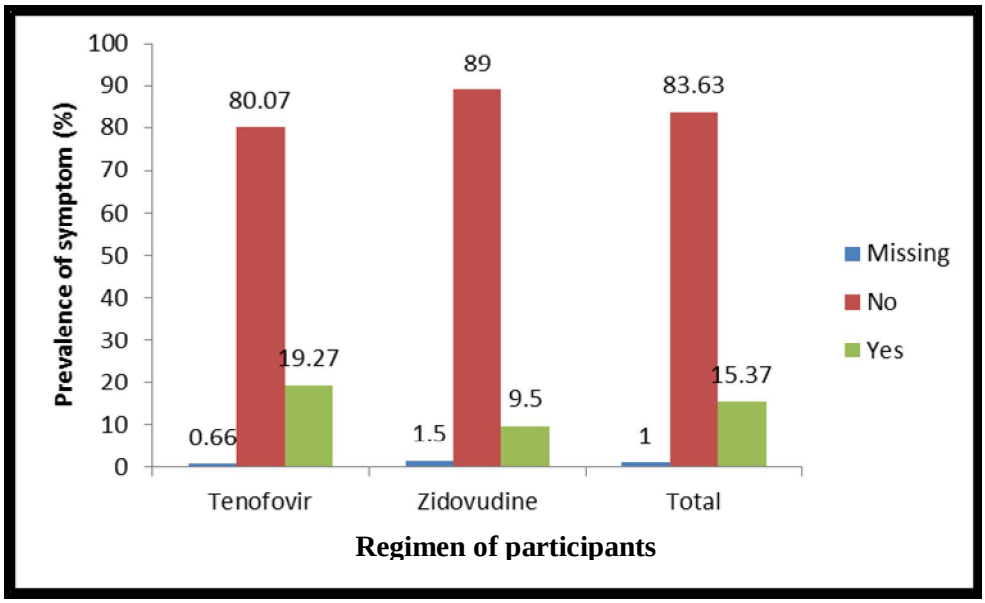

Figure 4.2: Comparison of prevalence of symptoms/side effects for participants on tenofovir versus zidovudine based regimens

Majority of the participants 419 (83.63%) reported that they had no symptoms that compromised their quality of life and only 77 participants (15.37%) of the study population had a symptom that compromised the quality of life. Five (1 %) of the participant did not give a response on the presence of a symptom.

There was a statistically significance difference in the prevalence of symptoms between participants on tenofovir and those on zidovudine based regimens (p=0.005). Of the 77 (15.37%) of the participants who had symptoms that compromised the quality of life 57 (19.27%) were on tenofovir and 20 (9.5%) were on zidovudine based regimens. This study however did not differentiate whether symptoms were as a result of disease or side effects of the drugs. The various symptoms reported by study participants are summarized as counts and percentages as presented in **Table 4.6**.

Table 4.6 Symptoms/side effects reported by the study participants at Kenyatta National Hospital on tenofovir and zidovudine based regimens

Type of symptoms	**N (%)**
Type of skin disorders	
No skin disorder	482 (96.2)
Skin pigmentation	3 (0.3)
Wound	3 (0.3)
Skin rash	2 (0.4)
Itching	3 (0.6)
Ear peeling	1 (0.2)
Pimples	1 (0.2)
Mouth sours	1 (0.2)
Wound in private part	1 (0.2)
Herpes	1 (0.2)
Unspecified skin problem	3 (0.6)
Type of weight disorders	
No weight disorder	487 (97.2)
Weight loss	9 (1.8)
Obesity	3 (0.6)
Unspecified weight disorder	2 (0.4)
Site of pain	
No pain	481 (96.01)
Backache	8 (1.6)
Headache	4 (0.8)
Chest pain	3 (0.6)
Body pain	3 (0.6)
Leg pain	1 (0.2)
Breast pain	1 (0.2)
Psychological problems	
No psychological problems	498 (99.4)
Emotional	2 (0.39)
Loss of concentration and fatigue	1 (0.19)
Liver problem	
No liver problem	498 (99.4)
Yellow eyes	1 (0.19)
Yellow eyes and swollen legs	2 (0.39)
Musculoskeletal	
No musculoskeletal problem	497 (99.2)
Limping	2 (0.39)
Cannot walk	1 (0.19)
Change in physical structure	1 (0.19)
Others	
Tiredness	2 (0.39)
Bad breathe	1 (0.19)
Stroke	1 (0.19)
Blindness	1 (0.19)
Colds	5 (0.99)
Eye problem	1 (0.19)
Swollen legs	1 (0.19)
Swollen neck	1 (0.19)

Most of the participants did not report any skin disorder (482, 96.2%). Out of those who reported a skin disorder the most common were skin pigmentation and wounds (0.3%). Similarly most of the participants did not have weight disorders (487, 97.2%) but 1.8% of the participants reported weight loss. The most common type of pain reported was backache (1.6%).

Table 4.7 Comparison of the prevalence of symptoms/side effects for participants on tenofovir versus zidovudine based regimens

Type of symptom	Tenofovir (n %)	Zidovudine (n %)	Total (n %)	P-value[a]
Pain related	17(5.7)	3 (1.5)	20 (4.0)	**0.015**
Weight related	12 (3.99)	2 (1)	14 (2.79)	**0.038**
Psychological problems				
Emotional	1 ((0.3)	1 (0.5)	2 (0.4)	
Loss of concentration & fatigue	1 (0.3)	0 (0.0)	1 (0.2)	
Liver problem				
Yellow eyes	1 (0.3)	0 (0.0)	1 (0.2)	
Yellow eyes & swollen legs	2 (0.7)	0 (0.0)	2 (0.4)	
Musculoskeletal				
Limping	2 (0.7)	0 (0.0)	2 (0.4)	
Cannot walk	0 (0.0)	1 (0.5)	1 (0.2)	
Change in physical structure	1(0.3)	0 (0.0)	1 (0.2)	
Others				
Tiredness	1 (0.3)	1 (0.5)	2 (0.4)	
Bad breathe	0 (0.0)	1 (0.5)	1 (0.2)	
Stroke	1 (0.3)	0 (0.0)	1 (0.2)	
Blindness	0 (0.0)	1 (0.5)	1 (0.2)	
Colds	5 (1.7)	0 (0.0)	5 (1.0)	
Eye problem	1 (0.3)	0 (0.0)	1 (0.2)	
Swollen legs	1 (0.3)	0(0.0)	1 (0.2)	
Swollen neck	1 (0.3)	0 (0.0)	1 (0.2)	

[a]Two-sample Mann-Whitney test

There was a statistically significance difference in the prevalence of pain and weight related symptoms in participants on zidovudine and tenofovir based regimens (p=0 .015 and 0.038). The most common type of disorder was pain. Participants on tenofovir had a higher prevalence of pain (3.9 %). The most common source of pain was a backache and this was followed by headaches. The second most common disorder was weight-related changes. Nearly 4% of participants on tenofovir had a weight related problem as opposed to only 1% of participants on zidovudine. This difference was statistically significant (p=0.038)

Three participants complained of yellow eyes which is suggestive of jaundice. All these three participants were on tenofovir based regimens. Generally when the prevalence of different symptoms/side effects was compared across the two arms there was no notable statistical

significance difference due to the small numbers of participants that reported the different symptoms/side effects. Statistical analysis for psychological problems, liver problems, musculoskeletal and others categories of symptoms were not done as participants in some treatment arms reported a zero response. Participants on tenofovir had a higher prevalence of pain (5.7% verses 1.5%) on zidovudine as described in **Table 4.7.**

4.8 Factors associated with occurrence of any symptom of illness or side effects

The factors associated with occurrence of any symptom of illness or side effects are presented in **Table 4.8**. Logistic regression analysis was used to identify the risk factors for any symptoms of disease or side effects.

Table 4.8: Risk factors for symptom of disease or side effects for participants on tenofovir versus zidovudine based regimens

Variable	Crude OR (95% CI)	P-Value	Adjusted OR	P-Value
Socio-demographic				
Age	0.98 (0.959,1.010)	0.239	-	
Gender	1.37 (0.782,2.389)	0.272	-	
Married	0.813 (0.499,1.322)	0.404	-	
Region	0.998 (0.886,1.124)	0.976	-	
Had disclosed status	1.024 (0.562,1.864)	0.939	-	
Education level	1.01 (0.739,1.390)	0.933	-	
Regular source of income	0.990 (0.543,1.806)	0.974	-	
Baseline medical characteristics				
HIV duration	1.008 (0.956,1.063)	0.774	-	
ART duration	0.981 (0.916,1.051)	0.586	-	
Missed drug intake	1.345 (0.811,2.231)	0.251	-	
Recent CD4 Count	0.999 (0.999,1.000)	0.276	-	
Recent viral load	1.0 (0.999,1.000)	0.446	-	
Drug related factors				
Zidovudine	0.480 (0.278,0.827)	**0.008**	-	
Tenofovir	2.084 (1.209,3.595)	**0.008**	2.385 (1.356, 4.194)	**0.003**
Nevirapine	0.540 (0.300,0.971)	**0.040**	-	
Efavirenz	1.130 (0.685,1.864)	0.632	-	
Lopinavir/ritonavir	2.520 (1.188,5.341)	**0.016**	-	
Atazanavir/ritonavir	1.570 (0.320,7.701)	0.579	-	
First line	0.421 (0.210,0.843)	**0.015**	-	
Second line	2.376 (1.187,4.757)	**0.015**	2.977 (1.443,6.144)	**0003**
Regimen	1.244 (1.090,1.419)	**0.001**	-	

Both the socio demographic and the baseline medical characteristics were not risk factors for the presence of a symptom of illness or side effect as illustrated in **Table 4.8**. The differences across regimens were most likely related to the side effects as opposed to immunosuppression because the CD4 counts were comparable. Participants on nevirapine had lower odds of presence of symptoms or side effects on bivariable analysis. On adjusting for confounding for being on tenofovir and second line regimens, the associations remained significant.

Nevirapine seemed to be protective and lost significance on adjusting for confounding. Being on efavirenz was equally not a risk factor for a symptom/side effect.

HIV duration, though a potential confounder, had no association with presence of any symptom noted. Similarly the recent CD4 count was not a risk factor for a symptom. The risk factors for presence of a symptom were being on tenofovir based regimens and being on second line regimens. Both zidovudine and tenofovir had a p value of 0.008 but on adjusting for confounding only tenofovir remained statistically significant.

4.9 Determinants of the physical health score

This was a measure of freedom from physical limitations.

Figure 4.3 presents the histogram of the summary score of physical health of participants on tenofovir and zidovudine based regimens. This was obtained from the various scores that compute the Physical Health Summary score as illustrated in **section 3.9.**

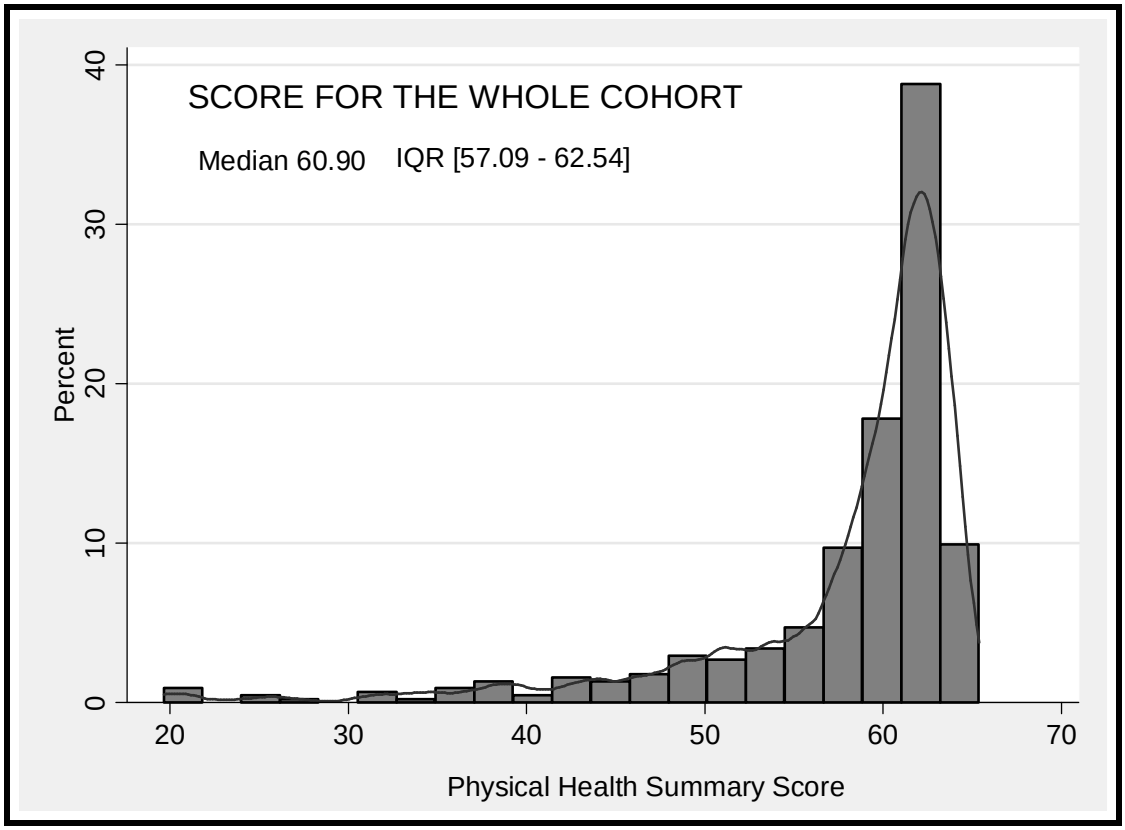

Figure 4.3: Physical Health Summary scores for the whole cohort

The histogram illustrates that majority of the participants had a high Physical Health Summary score. The graph was skewed towards the higher Physical Health Summary score. This is an indication that majority of the participants reported high scores while a few

reported low scores on physical health. The median Physical Health Summary score for study participants was 60.90 with an IQR of [57.09, 62.54].

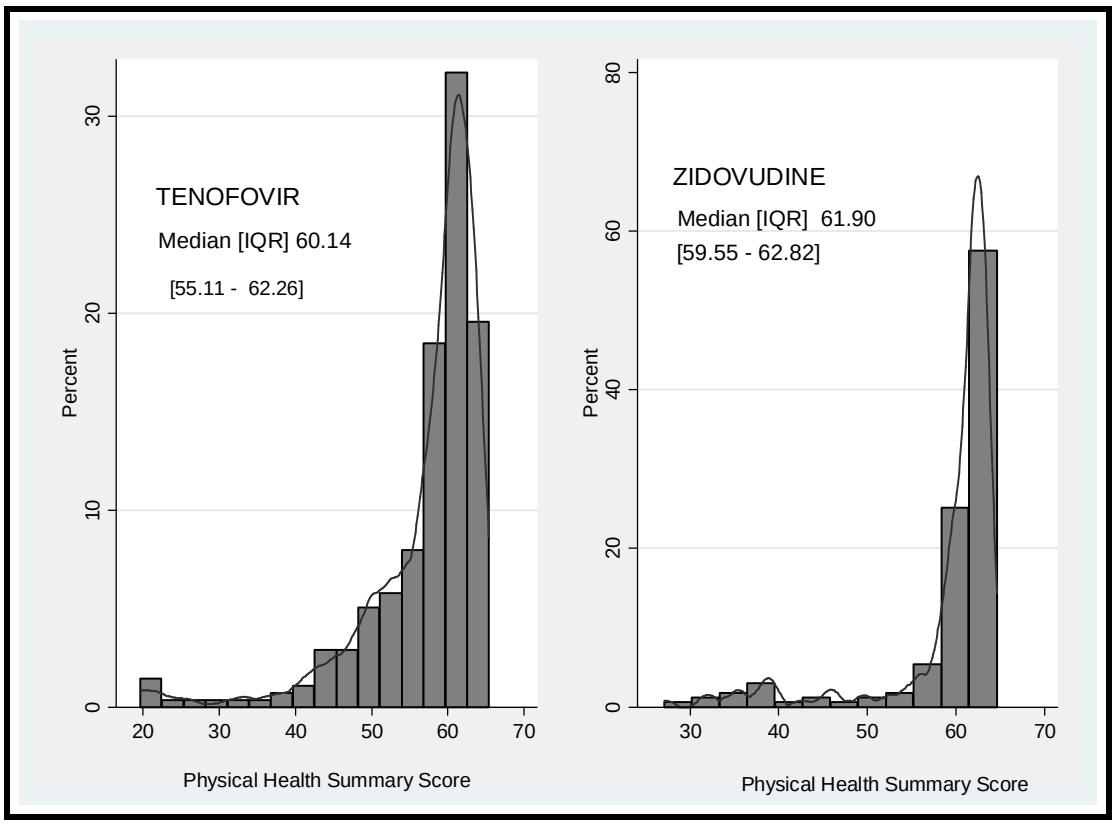

Figure 4.4: Comparison of Physical Health Summary scores for participants on zidovudine versus tenofovir based regimens

Figure 4.4 demonstrated that participants on the zidovudine based arm had a higher median 61.90 IQR [59.55, 62.82] Physical Health Summary score compared to those on the tenofovir based regimens median 60.14 IQR [55.11, 62.26].

4.10 Comparison of the Physical Health Summary score in participants on tenofovir and zidovudine across socio-demographic characteristics

The socio-demographic determinants of Physical Health Summary score of study participants are summarized in **Table 4.9**. These were obtained by summary statistics as median, interquartile range. The p-value was obtained by two-sample Mann-Whitney test.

Table 4.9: Socio-demographic determinants of Physical Health Summary scores for participants on tenofovir versus zidovudine based regimens

Variables	Tenofovir (median, n)	Zidovudine (median, n)	Total (median, n)
Sex n=441			
Male	61.28, [58.29, 62.55] [n=80]	62.07, [60.44, 62.88] [n=54]	61.74, [58.64, 62.74] [n=134]
Female	59.29, [53.69, 62.08] [n=194]	61.79, [59.39, 62.81] [n=113]	60.46, [55.69, 62.43] [n=307]
			P = 0.004
Age – group n=442			
18-35	59.93, [55.23, 62.41] [n=60]	61.03, [59.18, 62.82] [n = 41]	60.37, [56.87, 62.55] [n=101]
36-45	60.21, [54.01, 62.17] [n=117]	62.06, [60.54, 62.94] [n = 75]	61.24, [57.70, 62.51] [n=192]
46-64	60.26, [55.62, 62.46] [n=95]	61.90, [58.48, 62.81] [n = 50]	60.90, [56.73, 62.48] [n=145]
≥65	58.17, [47.82, 61.31] [n=3]	62.67, [62.67, 62.67] [n = 1]	59.74, [52.99, 61.99] [n=4]
			P = 0.851
Religious belief n=438			
Yes	60.14, [55.08, 62.26] [n=270]	61.85, [59.52, 62.82] [n=164]	60.90, [57.10, 62.51] [n=434]
No	56.52, [43.38, 57.24] [n =3]	64.05, [64.05, 64.05] [n=1]	56.88, [49.95, 60.64] [n= 4]
			P = 0.407
Education level n=439			
No education	60.13, [59.27, 61.57] [n=6]	50.89, [39.11, 62.67] [n=2]	60.13, [59.09, 62.12] [n=8]
Primary	57.40, [50.02, 62.06] [n=50]	61.64, [59.78, 62.84] [n=39]	60.54, [54.01, 62.40] [n=89]
Secondary	60.59, [56.52, 62.24] [n=129]	62.04, [59.49, 62.90] [n=74]	61.18, [57.85, 62.54] [n=203]
Tertiary university	60.35, [56.17, 62.51] [n=89]	62.08, [59.99, 62.67] [n=48]	60.91, [58.17, 62.61] [n=137]
Others	-	49.89, [39.48, 60.29] [n=2]	49.89, [39.48, 60.29] [n=2]
			P = 0.368
Disclosure Status n=443			
Yes	60.32, [55.39, 62.24] [n=213]	61.90, [59.89, 62.83] [n=136]	61.01, [57.76, 62.54] [n=349]
No	59.75, [52.90, 62.44] [n=62]	61.64, [59.18, 62.67] [n=29]	60.70, [51.60, 62.52] [n=91]
			P = 0.329
Regions of Origin n=439			
Nyanza	60.62, [57.02, 62.28] [n=70]	61.23, [59.36, 62.54] [n=29]	60.77, [57.76, 62.45] [n=99]
Western	60.10, [55.50, 62.29] [n=44]	62.46, [61.45, 63.20] [n=23]	61.35, [57.80, 62.84] [n=67]
Rift Valley	58.57, [52.47, 62.40] [n=13]	62.61, [58.41, 63.25] [n=9]	61.09, [52.47, 62.90] [n=22]
Nairobi	59.53, [57.73, 62.47] [n=5]	57.59, [55.50, 61.78] [n=4]	59.39, [56.89, 62.47] [n=9]
Central	59.47, [54.49, 62.22] [n=82]	61.77, [60.29, 62.67] [n=54]	60.83, [58.36, 62.51] [n=136]
Eastern	60.84, [53.87, 62.21] [n=52]	61.90, [58.53, 62.89] [n=40]	61.26, [56.79, 62.48] [n=92]
North Eastern	58.74, [52.29, 64.42] [n=4]	62.41, [39.11, 63.03] [n=3]	62.41, [50.57, 63.46] [n=7]
Coast	60.22, [55.72, 61.30] [n=4]	62.51, [56.59, 64.48] [n= 3]	60.90, [56.59, 62.51] [n=7]
			P = 0.993
Has regular source of income n=436			
Yes	60.48, [55.75, 62.28] [n=217]	61.89, [59.93, 62.83] [n=132]	61.07, [57.92, 62.54] [n=349]
No	59.16, [52.33, 62.17] [n=57]	62.04, [52.46, 62.74] [n=30]	59.63, [52.32, 62.38] [n=87]
			P = **0.046**
Marital Status n=443			
Married	60.90, [57.18, 62.42] [n=144]	62.02, [59.55, 62.88] [n=93]	61.37, [58.47, 62.56] [n=237]
Living together	58.60, [58.60, 58.60] [n=1]	61.06, [47.42, 62.78] [n=4]	59.86, [58.60, 62.26] [n =5]
Single	58.66, [54.60, 62.22] [n=57]	61.23, [59.78, 62.51] [n=25]	59.87, [56.52, 62.51] [n=82]
Widowed	59.23, [49.36, 61.46] [n=44]	61.55, [52.19, 62.55] [n=20]	59.56, [49.39, 62.09] [n=64]
Divorced	60.32, [54.01, 62.16] n=30]	62.14, [60.19, 62.96] [n=25]	61.18, [57.73, 62.91] [n=55]
			P = **0.017**

n= Represents the number of participants who gave a response for a particular variable

Gender (p=0.004), source of income (p=0.046) and marital status (p=0.017) were significantly associated with the PHS. There was no difference across most of the socio-demographic variables except for sex where males gave a higher median score of 61.74 compared to females 60.46. The males were more optimistic. This difference was statistically significant (p=0.004). When assessed across the two arms on variable sex, participants on zidovudine performed better than those on tenofovir based regimens. Participants who practiced religion (median 60.90) scored higher than those without religious belief. Participants with unspecified level of education had the lowest Physical Health Summary score, while those who had attained secondary and tertiary university had almost the same median score 61.18 and 60.91 respectively p=0.368).

Participants from the North Eastern part of Kenya had the highest Physical Health Summary score (median 62.41). People with origins in Nairobi had the lowest Physical Health Summary score median (59.39).

Participants with unclear explanation of the source of income (neither regular source nor no regular source of income) had the highest Physical Health Summary score (median 61.80). People without a regular source of income had the least Physical Health Summary score of 59.63 IQR [52.32, 62.38]. When the participants on the two arms were assessed by source of income participants on zidovudine perfomed better than those on tenofovir. However it should be noted that participants without a source of income and were on zidovudine reported the highest PHS but this group had only 30 participants compared to 132 who had a source of income.

Married people and those who were divorced had a slight lead in the Physical Health Summary score compared to the other marital categories. The widowed had the least score. Marital status was a key determinant of the Physical Health Summary score (p=0.017). Participants on zidovudine performed better than those on tenofovir based regimens when assessed by marital status.

4.11 Comparison of the Physical Health Summary score of participants across medical characteristics

The comparison of Physical Health Summary Score across medical determinants of study participants are presented in **Table 4.10**

Table 4.10: Medical determinants of Physical Health Summary Score for participants on tenofovir versus zidovudine based regimens

Variables	Tenofovir (median, IQR, n)	Zidovudine (median, IQR, n)	Total (median, IQR, n)
Duration HIV in years (n=443)			
≤ 2.0	60.18, [55.43, 62.75] [n=32]	39.30, [35.39, 50.81] [n=4]	59.71, [51.95, 62.55] [n=36]
2.1-5.0	59.79, [54.27, 62.42] [n=64]	62.26, [59.40, 62.94] [n=40]	60.95, [56.98, 62.74] [n=104]
5.1-10.0	60.26, [54.98, 62.16] [n=115]	62.01, [60.16, 62.90] [n=92]	61.26, [58.28, 62.54] [n=207]
10.1-15.0	59.54, [54.01, 62.17] [n=47]	61.84, [59.36, 62.34] [n=22]	60.58, [55.75, 62.22] [n=69]
>15	60.56, [57.80, 61.53] [n=18]	59.78, [54.85, 61.79] [n=9]	60.37, [57.73, 61.79] [n=27]
			P = 0.321
Duration on ART in years (n=443)			
< 1.0	58.66, [52.77, 61.71] [n=29]	62.14, [31.68, 62.61] [n=3]	58.91, [52.51, 62.24] [n=32]
1.1 -2.0	58.99, [56.87, 62.94] [n=27]	60.38, [39.48, 61.45] [n=6]	59.63, [56.87, 62.51] [n=33]
2.1 -5.0	60.73, [54.99, 62.48] [n=74]	61.54, [58.77, 62.90] [n=51]	61.07, [57.55, 62.72] [n=125]
5.1 -10	60.35, [54.98, 62.14] [n=115]	62.01, [60.30, 62.83] [n=92]	61.31, [57.85, 62.54] [n=207]
>10	59.88, [56.59, 61.70] [n=31]	61.23, [59.39, 62.34] [n=15]	60.51, [58.41, 62.22] [n=46]
			P = 0.201
Presence of any Symptom of disease or side effects (n=443)			
Yes	55.54, [48.91, 59.12] [n=54]	59.24, [48.76 ,61.28] [n=16]	55.96, [48.91, 60.29] [n=70]
No	60.88, [57.07, 62.44] [n=221]	62.04, [60.03 ,62.82] [n=149]	61.35, [58.57, 62.61] [n=370
Missing	63.28, [63.28, 63.28] [n=1]	62.55,[61.83, 63.28] [n=2]	63.28, [61.83, 63.28] [n=3]
			P < 0.001
Missed taking drugs (n=443)			
Yes	59.36, [54.05, 62.19] [n=89]	61.90, [58.28, 62.54] [n=47]	60.45, [55.15, 62.44] [n=136]
No	60.43, [55.75, 62.31] [n=182]	61.87, [60.00, 62.84] [n=119]	61.03, [58.22, 62.55] [n=301]
Missing	58.61, [58.44, 59.27] [n=5]	62.61, [62.61, 62.61] [n=1]	58.94, [58.44, 61.94] [n=6]
			P = 0.217
Recent CD_4 Count cells/mm^3 (n=425)			
<250	59.19, [51.87, 62.54] [n=38]	61.80, [58.99, 62.88] [n= 32]	60.84, [57.63, 62.67] [n=70]
250-499	58.99, [53.69, 61.89] [n=99]	62.18, [61.16, 62.98] [n=59]	61.04, [56.73, 62.54] [n=158]
500-999	60.33, [56.59, 62.25] [n=118]	61.12, [58.51, 62.55] [n=60]	60.62, [57.76, 62.40] [n=178]
≥1000	61.12, [52.55, 62.58] [n=12]	62.72, [60.00, 63.20] [n=7]	61.37, [52.77, 62.96] [n=19]
			P = 0.797
Recent Viral Load copies per ml (n=139)			
≤ 0.01	60.86, [58.57, 62.88] [n=55]	61.90, [60.57, 62.91] [n=37]	61.45, [58.82, 62.89] [n=92]
1-1000		61.65, [60.73, 63.18] [n=6]	61.18, [55.69, 62.61] [n=19]
>1000		60.55, [58.99, 62.44] [n=16]	59.31, [52.78, 62.03] [n=28]
			P = 0.032
Satisfaction with service provision (n=443)			
Very good	60.58, [56.52, 62.34] [n=181]	62.12, [60.12, 62.88] [n=115]	61.32, [58.41, 62.61] [n=296]
Good	59.05, [52.33, 62.13] [n=86]	61.42, [58.99, 62.56] [n=44]	60.13, [54.32, 62.42] [n=130]
Fair	58.85, [53.40, 61.00] [n=8]	60.57, [58.41, 61,87] [n=7]	59.11, [55.48, 61.87] [n=15]
Bad	62.26, [62.26, 62.26] [n=1]	59.95, [59.95, 59.95] [n=1]	61.11, [59.95, 62.26] [n=2]
			P = 0.098
Ability to Cope with HIV (443)			
Excellent	60.89, [57.36, 62.69] [n=96]	62.48, [60.81, 62.91] [n=45]	61.69, [58.99, 62.84] [n=141]
Very good	60.21, [56.17, 62.24] [n=81]	61.81, [59.36, 62.74] [n=69]	61.00, [57.76, 62.55] [n=150]
Good	59.12, [51.83, 61.66] [n=85]	61.15, [58.56, 62.61] [n=48]	60.59, [54.05, 62.26] [n=133]
Fair	57.92, [49.90, 59.27] [n=11]	61.99, [58.41, 62.67] [n=5]	58.50, [50.61, 59.56] [n=16]
Poor	49.05, [25.57, 62.34] [n=3]	-	49.05, [25.57, 62.34] [n=3]
			P < 0.001
Alcoholism/substance dependence (n=437)			
Use alcohol	60.32, [56.17, 61.94] [n=79]	62.14, [59.95, 62.61] [n=46]	61.07, [57.85, 62.43] [n=125]
Hard drugs	60.26, [58.44, 60.79] [n=5]	59.55, [55.79, 62.98] [n=3]	59.91, [57.12, 61.88] [n=8]
No drugs	59.96, [54.00, 62.39] [n=188]	61.82, [59.64, 62.84] [n=116]	60.88, [56.97, 62.56] [n=304]
			P = 0.901

A long duration of HIV infection did not have an effect on Physical Health Summary score. However those that had been sero-positive for less than 2 years gave the lowest score. Similarly longer duration of ART treatment did not seem to affect the physical health score but notably those who had been on treatment for less than two years gave the lowest score of less than 60. The only clinical or medical variables that had an effect on Physical Health Summary score were: presence of a symptom of illness and the viral load. Study participants who had any medical symptom at the time of the study had a median physical score of 56 IQR [48.91, 60.29] which were about 5 units lower than those who had no symptom. The difference was statistically significant ($p<0.001$).

Participants who reported that they were able to cope with disease very well gave the highest score of about 60 compared to those who were unable to cope 49.05 IQR [25.57, 62.34] ($p<0.001$). Similarly study participants with very high viral loads gave lower scores compared to those with undetectable viral loads ($P = 0.032$).

Participants who reported no symptom of disease/side effects reported better Physical Health Summary Score compared to those who had symptom of disease/side effects. Those on zidovudine had better scores when compared to those on tenofovir. Equally participants who had a viral load of less or equal to 0.01 and were on zidovudine based regimens reported better Physical Health Summary Score compared to those on tenofovir based regimens.

4.12 Regression analysis for factors associated with the Physical Health Summary scores

Regression analysis was performed to establish factors that are associated with the Physical Health Summary score. The results are presented in **Table 4.11**.

Table 4.11: Regression analysis of determinants of Physical Health Summary score

Variables	Crude beta co efficient (95 C.I)	P-value	Adjusted beta coefficient (95 % CI)	P-Value
ART regimen	2.04 (0.58,3.50)	**0.006**	-	
Sex	-2.04 (-3.46, -0.62)	**0.005**	-1.986 (-3.460,-0.511)	**0.008**
Age	-0.05 (-0.13,0.03)	0.223	-	
Age above 40	-1.46 (-2.83,-0.08)	**0.038**	-1.782 (-3.202,-0.361)	**0.014**
Religious belief	2.62 (-4.78,10.03)	0.487	-	
Education level	0.55 (-0.47,1.56)	0.294	-	
Status disclosure	1.93 (-0.24,4.10)	0.081	-	
Region	-0.03 (-0.37,0.31)	0.856	-	
Has regular source of income	3.07 (0.75,5.39)	**0.010**	2.617 (0.456,4.778)	**0.018**
Marital status	-0.54 (-1.01,0.07)	**0.025**	-	
HIV duration	0.04 (-0.13,0.21)	0.617	-	
ART duration	0.10 (-0.12,0.31)	0.380	-	
Presence of any symptom	-6.57 (-9.35,-3.79)	**<0.001**	-5.581 (-8.072,-3.091)	**<0.001**
Satisfaction with service provision	-0.89 (-2.08,0.29)	0.140	-	
Inability to cope with HIV	-1.92 (-2.79,-1.05)	**<0.001**	-1.813 (-2.562,-1.064)	**<0.001**
Missed drugs intake	-1.39 (-3.04,0.27)	0.100	-	
Alcoholism/substance dependence	-0.22 (-0.75,0.31)	0.411	-	
Recent CD4 cells/mm^3	0.003 (-0.0003,0.006)	0.079	-	
Recent viral load copies/ml	7.99e-08 (-5.80e-07,7.40e-07)	0.811	-	
Zidovudine	2.025 (0.564,3.485)	**0.007**	1.329 (0.002,2.657)	**0.050**
Tenofovir	-2.025 (_3.485,0.564)	**0.007**	-	
Nevirapine	0.48 (-1.037,1.996)	0.534	-	
Efavirenz	0.78 (-0.739,2.298)	0.314	-	
Lopinavir/ritonavir	-4.30 (-8.194,-0.403)	**0.031**	-3.773 (-7.418,-0.129)	**0.042**
Atazanavir/ritonavir	-0.26 (-6.4,5.87)	0.932	-	
First line	3.64 (0.205,7.074)	**0.038**	-	
Second line	-3.64 (-7.074,-0.205)	**0.038**	-	
Type of weight disorder	-1.53 (-3.941,0.881)	0.213	-	
Has skin disorder	-1.94 (-6.325,2.446)	0.388	-	
Has weight disorder	-4.154 (-9.751,1.444)	0.145	-	
Has pain disorder	-8.802 (-13.994,-3.610)	**0.001**	-	

Factors that had effect on the PHS on regression analysis were: sex (p=0.008), age above 40 (p=0.014), having a regular source of income (p=0.018), presence of any symptom that compromised the quality of life (p<0.001), inability to cope with HIV (p<0.001), treatment with Lopinavir/ritonavir (p=0.042) and being on zidovudine (p=0.050).

Having a regular source of income increased the score by 2.62 units 95% CI (0.456, 4.778). Being on zidovudine instead of tenofovir based regimens improved the Physical Health

Summary score by 1.33 units 95% CI (0.002, 2.66). Regular source of income was a key factor that increased the Physical Health Summary score.

Having a symptom that compromises the quality of life greatly reduced the PHS by -5.58 95% CI (-8.072, -3.091). Other factors that were negatively associated with the Physical Health Summary score were being female gender -1.99 units 95% CI (-3.46, - 0.51), age above 40 -1.78 95% CI (-3.20, -0.36), inability to cope with HIV -1.81 95% CI (-2.56, -1.064) and being on Lopinavir/ritonavir -3.77 95% CI (-7.418, -0.129).

4.13: Determinants of the Mental Health Score

This was a measure of freedom from mental limitations.

4.13.1 Summary Mental Health Summary score of the study participants

Figure 4.5 presents a histogram of the Mental Health Summary score for study participants for the whole cohort.

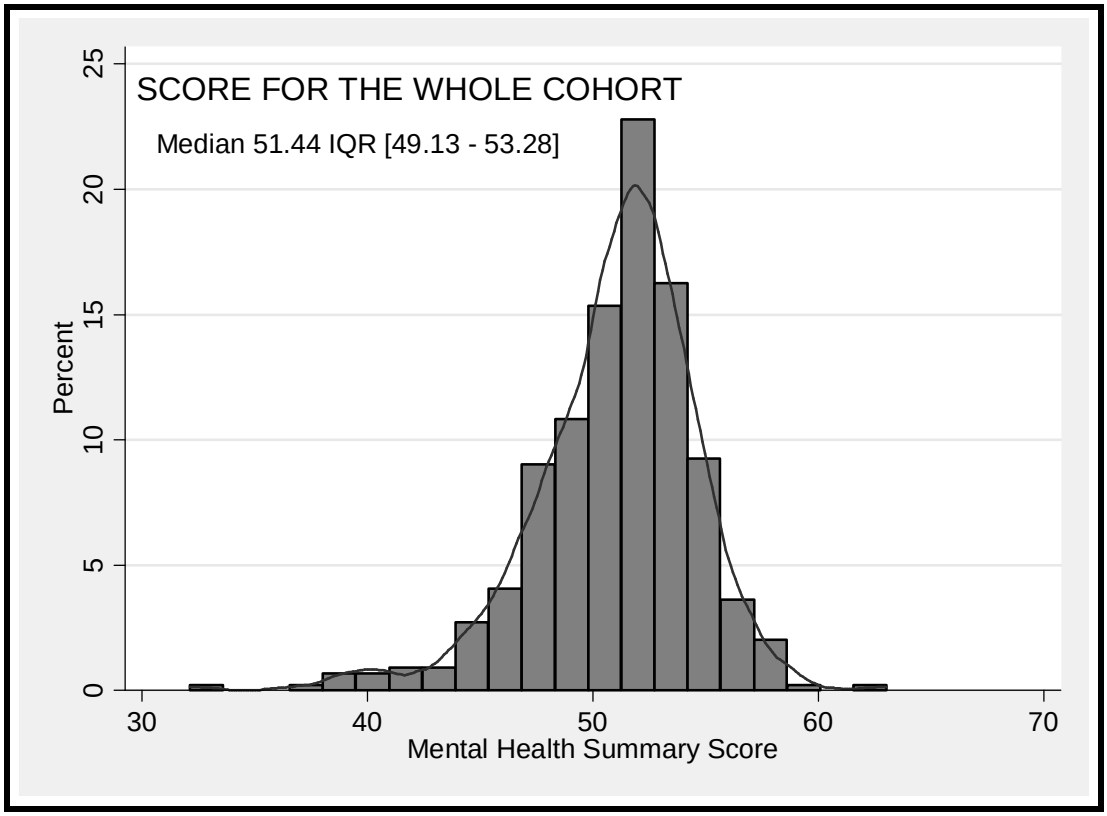

Figure 4.5: Summary score of mental health status for the study participants

The participants in this study had an average Mental Health Summary score with a median of 51.44 [49.13, 53.28] as demonstrated in **Figure 4.5**. The data was normally distributed with less tailing compared to Physical Health Summary score.

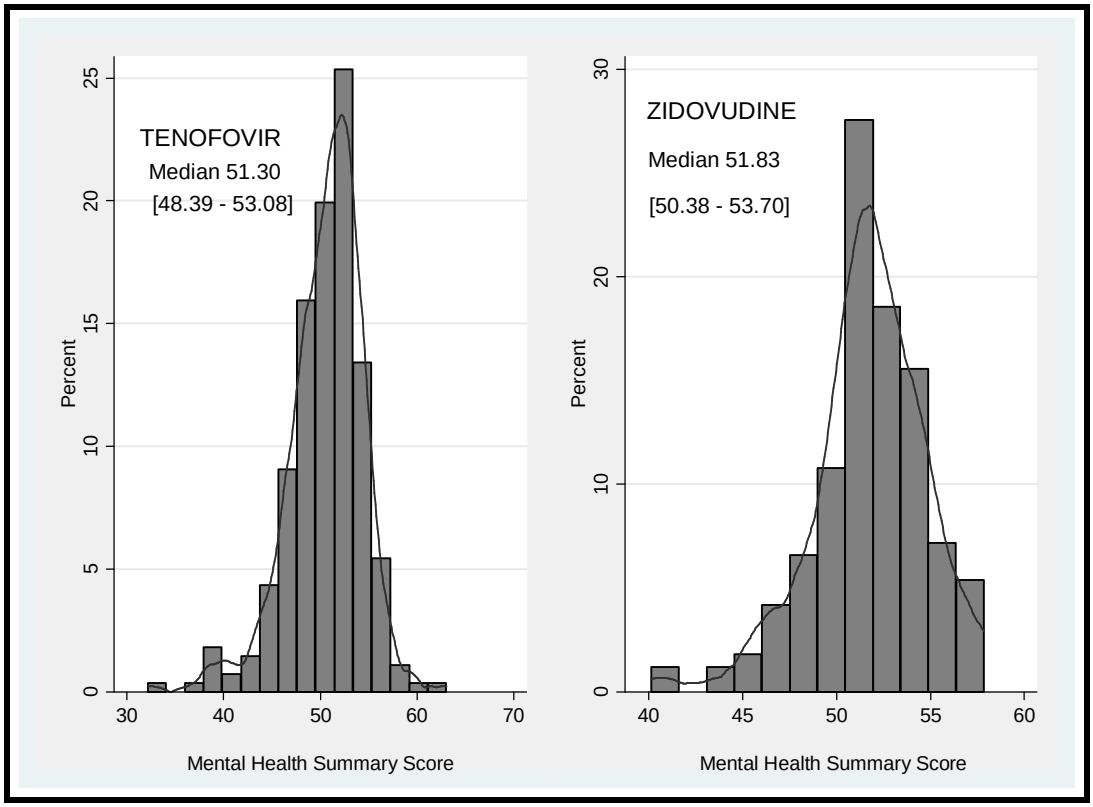

Figure 4.6: Comparison of Mental Health Summary scores for participants on zidovudine versus tenofovir based regimens

Comparing the histograms in **Figure 4.6**, participants on zidovudine based regimens had a higher MHS median 51.83 IQR [50.38, 53.70] compared to a median score of 51.30 of those on the tenofovir based arm. More participants on zidovudine based regimens had values great than the median when compared to those on tenofovir based regimens.

4.14 Comparison of the Mental Health Summary score across socio-demographic characteristics

The comparison of Mental Health Summary score across the socio-demographic characteristics is shown in **Table 4.12.**

Table 4.12: Comparison of Mental Health Summary Scores across social-demographic characteristics for participants on zidovudine versus tenofovir based regimens

Variables	Tenofovir (median, IQR, n)	Zidovudine (median, IQR, n)	Total(median, IQR, n)
Sex (n=441)			
Male	51.41,[49.29, 53.71] [n=80]	51.80, [50.65, 53.28] [n=54]	51.58, [49.79, 53.35] [n=134]
Female	51.21,[48.08, 52.93] [n=194]	51.85, [50.09, 53.95] [n=113]	51.34, [48.81, 53.26] [n=307]
			P = 0.190
Age Group (n=442)			
18-35	51.51, [47.82, 52.81] [n=60]	51.52, [49.47, 53.88] [n=41]	51.51, [48.75, 53.06] [n=101]
36-45	51.17, [48.10, 52.93] [n=117]	51.85, [50.75, 53.42] [n=75]	51.40, [49.10, 53.24] [n=192]
46-64	51.32, [49.36, 53.61] [n=95]	51.77, [49.34, 53.95] [n=50]	51.50, [49.36, 53.61] [n=145]
≥65	48.12, [43.98, 53.69] [n=3]	56.32, [56.32, 56.32] [n=1]	50.91, [46.05, 55.00] [n=4]
			P = 0.694
Religious Belief (n=443)			
Yes	51.30, [48.36, 53.06] [n=270]	51.80, [50.37, 53.68] [n=164]	51.43, [49.13, 53,26] [n=434]
No	49.42, [48.14, 56.38] [n=3]	51.01, [51.01, 51.01] [n=1]	50.22, [48.78, 53.69] [n=4]
			P = 0.800
Education Level (n=439)			
No education	51.57, [48.08, 53.23] [n=6]	54.87, [53.42, 56.32] [n=2]	53.08, [49.15, 54.77] [n=8]
Primary	50.51, [47.78, 52.85] [n=50]	52.05, [51.04, 54.00] [n=39]	51.50, [49.13, 53.62] [n=89]
Secondary	51.25, [48.14, 53.05] [n=129]	51.71, [50.11, 53.47] [n=74]	51.36, [49.06, 53.26] [n=203]
Tertiary	51.44, [49.35,53.06] [n=89]	51.65, [50.01, 53.38] [n=48]	51.50, [49.49, 53.09] [n=137]
university	-	49.30, [47.19, 51.40] [n=2]	49.30, [47.19, 51.40] [n=2]
Others			P = 0.793
Status Disclosure (n=443)			
No	50.95, [48.22,52.90] [n=62]	51.30, [50.52, 53.41] [n=29]	51.11, [49.43, 53.19] [n=91]
Yes	51.30, [48.41, 53.12] [n=213]	51.86, [50.32, 53.77] [n=136]	51.50, [49.11, 53.29] [n=349]
			P = 0.569
Regions of Origin (n=439)			
Nyanza	51.35, [49.06, 52.90] [n=70]	51.11, [49.47, 52.48] [n=29]	51.32, [49.27, 52.90] [n=99]
Western	51.32, [47.96, 53.07] [n=44]	51.78, [51.11, 54.28] [n=23]	51.68, [49.35, 53.29] [n=67]
Rift Valley	51.30, [47.04, 53.09] [n=13]	51.11, [49.13, 52.64] [n=9]	51.20, [47.04, 53.09] [n=22]
Nairobi	52.71, [52.47,53.21] [n=5]	52.37, [49.92, 54.80] [n=4]	52.71, [50.74, 54.00] [n=9]
Central	50.26, [47.28, 52.90] [n=82]	51.96, [50.59, 53.46] [n=54]	51.29, [48.95, 53.22] [n=136]
Eastern	51.05, [49.31, 53.44] [n=52]	52.11, [50.56, 53.95] [n=40]	51.87, [49.53, 53.81] [n=92]
North Eastern	53.14, [50.19, 54.78] [n=4]	53.42, [49.86, 55.41] [n=3]	53.41, [49.86, 55.41] [n=7]
Coast	52.09, [49.96, 52.75] [n=4]	51.85, [48.69, 56.71] [n=3]	51.91, [48.69, 53.23] [n=7]
			P = 0.484
Has regular source of Income (n=443)			
Yes	51.30, [48.74, 52.99] [n=217]	51.85, [50.56, 53.68] [n=132]	51.45, [49.34, 53.22] [n=349]
No	51.51, [48.59, 53.61] [n=57]	51.15, [49.43, 53.42] [n=30]	51.30, [48.81, 53.61] [n=87]
			P = 0.917
Marital status (n=443)			
Married	51.35, [48.61, 53.38] [n=144]	51.97, [50.59, 53.47] [n=93]	51.62, [49.36, 53.46] [n=237]
Living together	49.49, [49.49, 49.49] [n=1]	51.14, [49.61, 53.69] [n=4]	50.40, [49.49, 51.87] [n=5]
Single	50.93, [48.87, 52.97] [n=57]	51.42, [49.47, 52.05] [n=25]	51.20, [49.28, 52.78] [n=82]
Widowed	50.51, [47.96, 52.87] [n=44]	53.81, [48.31, 54.25] [n=20]	50.95, [47.96, 53.83] [n=64]
Divorced	51.67, [49.06, 53.05] [n=30]	51.30, [50.56, 53.13] [n=25]	51.51, [49.34, 53.09] [n=55]
			P = 0.609

n= Represents the number of participants who gave a response for a particular variable

None of the socio-demographic characteristics showed any statistical significance when compared the Mental Health Summary scores.

Table 4.13: Comparison of Mental Health Summary scores across medical variables for participants on zidovudine versus tenofovir based regimens

Variables	Tenofovir (median, IQR, n)	Zidovudine (median, IQR, n)	Total (median, IQR, n)
Duration HIV in years n=443			
≤ 2.0	51.88, [49.04, 53.03] [n=32]	51.87, [49.51, 52.67] [n=4]	51.88, [49.04, 53.03] [n=36]
2.1 -5.0	51.36, [47.89, 53.11] [n=64]	51.61, [50.39, 54.49] [n=40]	51.44, [49.29, 53.73] [n=104]
5.1-10.0	50.84, [48.22, 52.80] [n=115]	51.98, [50.87, 53.59] [n=92]	51.44, [49.58, 53.28] [n=207]
10.1-15.0	50.76, [48.87, 53.44] [n=47]	50.07, [48.28, 52.55] [n=22]	50.37, [48.87, 53.13] [n=69]
>15	51.94, [49.28, 54.09] [n=18]	51.71, [49.11, 52.05] [n=9]	51.71, [49.11,54.10] [n=27]
			P = 0.57
Duration of ART in years n=443			
≤ 1.0	51.59, [47.81, 52.97] [n=29]	51.83, [51.11, 51.92] [n=3]	51.70, [49.04,52.80] [n=32]
1.1 -2.0	52.18, [49.28, 53.62] [n=27]	52.47, [47.19, 56.71] [n=6]	52.18, [49.28, 53.62] [n=33]
2.1-5.0	51.30, [47.91, 53.62] [n=74]	51.85, [50.27, 54.47] [n=51]	51.38, [49.35, 53.88] [n=125]
5.1-10	50.61, [48.59, 52.76] [n=115]	51.92, [50.66, 53.46] [n=92]	51.40, [49.34, 53.21] [n=207]
>10	51.17, [48.80, 53.16] [n=31]	49.77, [48.90, 52.55] [n=15]	50.32, [48.87, 52.55] [n=46]
			P = 0.50
Presence of any Symptom n= 443			
Yes	49.17, [46.91, 51.50] [n=54]	50.98, [46.40, 54.17] [n=16]	49.49, [46.89, 52.60] [n=70]
No	51.51, [49.26, 53.19] [n=221]	51.85, [50.56, 53.65] [n=149	51.63, [49.64,53.31] [n=370]
			53.47, [52.27,57.83] [n=3]
			P < 0.001
Missed taking drugs n= 443			
Yes	51.52, [49.06, 53.05] [n=89]	51.52, [48.90, 53.41] [n=47]	51.52, [49.10, 53.21] [n=136]
No	51.24, [48.25, 53.16] [n=182]	51.97, [50.59, 53.95] [n=119]	51.45, [49.34, 53.33] [n=301]
Missing	49.36, [48.80, 49.84] [n=5]	51.11, [51.11, 51.11] [n=1]	49.60, [48.80, 51.11] [n=6]
			P = 0.162
Recent CD_4 Count cells/mm^3 $_{n= 425}$			
<250	51.23, [47.78, 52.90] [n=38]	51.75, [50.12, 52.67] [n=32]	51.35, [49.49, 52.68] [n=70]
250-499	50.22, [47.78, 52.78] [n=99]	51.87, [50.76, 53.47] [n=59]	51.30, [48.59, 53.25] [n=158]
500-999	51.60, [49.31, 53.21] [n=118]	51.41, [49.83, 53.68] [n=60]	51.52, [49.35, 53.26] [n=178]
≥1000	51.79, [49.76, 53.72] [n=12]	52.71, [50.74, 54.49] [n=7]	52.42, [50.14,54.12] [n=19]
			P = 0.413
Recent viral load copies per ml n= 139			
0.01	51.50, [49.13, 54.07] [n=55]	52.00, [50.81, 53.28] [n=37]	51.60,[50. 18,53.76] [n=92]
1-1000	-	51.86, [51.28, 54.00] [n=6]	51.42, [47.78, 52.64] [n=19]
>1000	-	51.80, [49.66, 54.96] [n=16]	51.27, [48. 37,54.53] [n=28]
			P = 0.440
Satisfaction with service provision n= 443			
Very good	51.42, [49.26, 53.32] [n=181]	51.92, [50.66, 54.00] [n=115]	51.71, [49.82,53.55] [n=296]
Good	50.51, [47.83, 52.60] [n=86]	51.62, [49.80, 53.06] [n=44]	51.00, [48.75, 52.68] [n=130]
Fair	48.29, [45.73, 51.92] [n=8]	49.47, [47.77, 53.04] [n=7]	49.47, [46.60, 52.47] [n=15]
Bad	55.83, [55.83, 55.83] [n=1]	46.50, [46.50, 46.50] [n=1]	51.16, [46.50, 55.83] [n=2]
			P = 0.010
Inability to cope with HIV n= 443			
Excellent	51.44, [49.43, 53.31] [n=96]	53.04, [51.78, 54.49] [n=45]	52.05, [49.98, 54.90] [n=141]
Very good	51.44, [49.13, 53.22] [n=81]	51.30, [50.11, 53.35] [n=69]	51.39, [49.77, 53.28] [n=150]
Good	50.75, [47.54, 52.78] [n=85]	51.11, [49.41, 52.67] [n=48]	51.01, [48.10, 52.71] [n=133]
Fair	46.46, [42.33, 48.01] [n=11]	52.45, [48.75, 52.87] [n=5]	47.10, [45.29, 52.39] [n=16]
Poor	46.01, [32.14, 52.63] [n=3]	-	46.01, [32.14, 52.63] [n=3]
			P < 0.001
Alcoholism/substance dependence n= 437			
Use alcohol	51.18, [49.06, 52.90] [n=79]	51.78, [50.56, 53.32] [n=46]	51.44, [49.34, 52.90] [n=125]
Hard drugs	49.84, [47.49, 50.01] [n=5]	55.60, [49.77, 56.52] [n=3]	49.93, [48.63,54.21] [n=8]
No drugs	51.31, [48.24, 53.19] [n=188]	51.87, [50.39, 53.91] [n=116	51.50,[49.12,53.38] [n=304]
			P = 0.757

In the analysis of the effect of medical variables on Mental Health Summary score, the participants who had a symptom that compromised the quality of life scored the least (median 49.49 (p=0.001)), while participants who were satisfied with service provision scored the highest (51.71 p=0.010). Good coping ability with HIV status improved Mental Health Summary score. Participants on zidovudine based regimens reported a higher score in Mental Health Summary compared to those on tenofovir across 12 out of 16 variables as illustrated in **Table 4.12** and **Table 4.13**.

Table 4.14: Bi-variable regression analysis-determinants of Mental Health Summary Score for participants on zidovudine versus tenofovir based regimens

Variable	Crude beta Coefficient 95 C. l	P-value
Patient regimen	1.12 (0.47,1.76)	**0.001**
Sex	-0.58 (-1.28,0.13)	0.111
Age	0.03 (-0.01,0.07)	0.148
Religious belief	-0.24 (-3.35,2.87)	0.877
Education Level	-0.04 (-0.47,0.39)	0.859
Status disclosure	0.4 (-0.46,1.26)	0.360
Region	-0.01 (-0.17,0.15)	0.895
Has regular source of income	0.42 (-0.58,1.43)	0.410
Marital status	-0.16 (-0.39,0.06)	0.159
Married	-	-
HIV duration	-0.02 (-0.10,0.06)	0.616
ART duration	-0.04 (-0.14,0.06)	0.467
Any symptom	-2.0 (-3.13,-0.85)	**0.001**
Satisfaction with service provision.	-0.89 (-1.49,-0.29)	**0.004**
Inability to cope with HIV	-1.12 (-1.58,-0.66)	**<0.001**
Missed drugs intake	-0.26 (-1.0,0.48)	0.486
Alcoholism/substance dependence	0.075 (-0.16,0.31)	0.528
Recent CD4 cells/mm^3	0.001 (-0.001,0.002)	0.308
Recent viral load copies/ml	2.93e-07(1.60e-07,4.24e-07)	**<0.001**
Zidovudine	1.063(0.417,1.710)	**0.001**
Tenofovir	-1.063 (-1.710,-0.417)	**0.001**
Nevirapine	0.394 (-0.306,1.093)	0.269
Efavirenz	-0.121 (-0.793,0.552)	0.725
Lopinavir/ritonavir	-0.739 (-1.971,0.493)	0.239
Atazanavir/ritonavir	-4.437 (-2.325,1.451)	0.649
First line	0.701 (-0.384,1.786)	0.205
Second line	-0.701 (-1.786,0.384)	0.205
Type of skin disorder	-0.264 (-0.557,0.030)	0.078
Type of weight disorder	-1.401 ((-2.152,-0.650)	**<0.001**
Type of pain	-1.144 (-1.721,-0.568)	**<0.001**
Regimen	-0.261 (-0.410,-0.111)	**0.001**
Has pain	-3.77(-6.481,-1.052)	**0.007**
Has weight	-2.76(-4.126,-1.39)	**<0.001**
Has skin problem	-1.087 (-3.499,1.324)	0.376

Bi-variable regression analysis of determinants of Mental Health Summary Score showed that ART regimen (p=0.001), having any symptom that compromises the quality of life (p<0.001), satisfaction with service provision (p=0.004), inability to cope with HIV (p<0.001), availability of recent viral load data (p<0.001) were the statistically significant factors that affected the Mental Health Summary score. Presence of any symptom that compromised the quality of life was negatively related to the mental health score by (β -1.85, 95% CI; -2.72, -0.98; p<0.001). The participants' stated inability to cope with HIV was attributed to reduction in the Mental Health score by -1.011 (95% CI; -1.37, -0.66; p<0.001).

Table 4.15: Parsimonious models of the Mental Health Summary score for participants on zidovudine versus tenofovir based regimens

Variable	Most parsimonious model	Parsimonious model in which regimen is replaced by AZT	Model adjusted for duration of ART use
Stated inability to cope with HIV	-0.999 (-1.411, -0.588)	-0.995 (-1.407, -0.582)	-1.029 (-1.441, -0.617)
Score on absence of pain	0.413 (0.152, 0.674)	0.413 (0.152, 0.674)	0.414 (0.154, 0.675)
Presence of any symptom of illness	-1.240 (-2.253, -0.226)	-1.28 (-2.293, -0.266)	-1.238 (-2.246, -0.230)
Types of ART Regimen	-0.187 (-0.330, -0.045)	-	-0.205 (-0.346, -0.063)
If patient was on AZT	-	0.738 (0.127, 1.349)	-
Duration of ART use	-	-	-0.081 (-0.179, 0.017)

The parsimonious models of the Mental Health Summary score of study participants are presented in **Table 4.15.** The key determinants that reduced the Mental Health Summary score on adjusting for the duration of ART use were: stated inability to cope with HIV (β -1.029, 95% CI; -1.441, -0.617), presence of symptoms of illness (β -1.238, 95% CI; 95 % CI; -2.246, -0.230), type of ART combination regimens (β -0.205, 95% CI; -0.346, -0.063) and duration of ART use (β -0.081, 95% CI; -0.179, 0.017). The presence of any symptom reduced the mental health score by 1.24 units (95% CI; -2.253, -0.226) before adjusting for confounding. This association remained significant even after adjusting for confounding by duration of ART use.

The absence of pain score increased the mental health score by 0.413 units and this association was not confounded by duration of therapy and being on zidovudine. Being on zidovudine based regimens as opposed to tenofovir based was associated with improved mental health with a beta coefficient of 0.738 (95% CI; 0.127, 1.349).

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

This study was designed to establish whether there was difference in HRQoL of participants on tenofovir based regimens versus zidovudine based regimens. Secondly factors that determine HRQoL, prevalence and risk factors for presence of symptoms of illness/side effects and coping strategies adopted by participants were to be evaluated.

5.1 Characteristics of the study participants

The majority of participants were aged 36-45 years and the proportion of females was higher than that of men in both treatment arms. This could be as a result of better health seeking behavior of females when compared to men. Similarly the current HIV prevalence in Kenya tends to be higher in women as compared to men. The findings are consistent with a number of studies that reports higher prevalence of HIV in women than in men (8,37,48). A study conducted in Kisumu, Kenya and Ndola, Zambia found that the prevalence of HIV in females was greater than in men. This varied depending on the age group (49).

Participants on zidovudine based regimens had been on treatment for a longer duration compared to those on tefonovir based. This is because those participants that were earlier initiated on zidovudine and performed well on the regimen before the change of the treatment guidelines were retained on it while those that were initiated on stavudine were switched to tenofovir (13). This explains why participants on the zidovudine based regimens had been on treatment for a longer duration compared to those on tenofovir based regimens.

The bigger population of participants was on first line antiretroviral, and most of the patients were on TDF/3TC/EFV combination. Most participants on tenofovir based regimens were on efavirenz as opposed to zidovudine based arm where most participants were on nevirapine. This is likely as a result of the respective combinations being available as fixed dose combinations. Administration of fixed dose combination ARVs is highly recommended in order to improve treatment adherence. The majority of participants on second line drugs were on zidovudine based regimens.

The study participants reported the various coping mechanisms adopted to deal with their HIV status. These were; acceptance of their HIV status, sharing, support groups; spiritual support and other unspecified coping mechanisms. About 35.4% of the participants adopted sharing as the main coping mechanism while 30.8% had accepted their HIV status. Sharing

was highly embraced coping style by the participants. There was variation of coping a cross the regimens in that most of participants on tenofovir accepted their HIV status while majority on the zidovudine were comfortable with sharing.

5.2 Scores on individual domains of health

Participants in this group generally had good quality of life when assessed across the domains of health. The least median score across the domains of health was 75%. Ability to function physically, absence of pain, scores on intellectual skills, ability to do day to day activities, functioning socially reported 100% score. This might be as a result of the benefit associated with antiretroviral therapy on quality of life. When compared across the regimens participants on zidovudine based regimens reported higher scores compared to those on the tenofovir based arm. A study on clinical outcomes of tenofovir versus zidovudine demonstrated the survival benefit of tenofovir based regimens was similar to zidovudine based regimen and therefore can be used as an alternative for HIV/AIDS patients in resource limited set ups (30,50). The difference was significant with regard to the following domains: general health perception, quality of life, energy levels, ability to function physically, absence of pain, scores on intellectual skills, ability to function mentally and health transition.

5.3 Prevalence of symptoms of disease or side effects

Though HAART has been attributed to improved quality of life and longer life expectancy, long-term use has been associated with toxicity (30). The potential of adverse side effects of antiretroviral is well demonstrated in literature (51–53). The prevalence of symptoms in this study was found to be 15.37% (77/501). The participants on tenofovir based regimens had a higher prevalence of side effects (19.27% compared to those on zidovudine based regimens 9.5%). Though not directly related to our study, a study conducted in Kenyatta National Hospital on the prevalence of opportunistic infections among HIV positive adults found a prevalence of 14% (54). A similar study of prevalence of opportunistic infections in Kenyatta National Hospital amongst children living with HIV found a prevalence of 14.3% (55).

A hospital based study in Central Kenya at Kiambu sub-County established a prevalence of 65.2% of symptoms suggestive of ADRs. In the Kiambu study, the most common reported symptom was peripheral neuropathy while hepatotoxicity was the least common. The Kiambu study highlighted the fact that most of the patients were not well informed of how to

identify the ADRs (56). In our study the most common symptoms experienced by participants were pain followed by weight related disorders.

The Kiambu study recommended the need for patient centered health education programs which should include counseling, detection and reporting of ADRs. A comparative study in Mbeya Region, Tanzania found better safety profile for zidovudine/lamivudine/nevirapine over zidovudine/lamivudine/efavirenz (57).

The symptoms reported by the participants in the current study included; skin disorders, pain, weight disorders, physiological problems, liver and musculoskeletal disorders. Other symptoms cited by participants were bad breath, stroke, blindness, colds and eye problems. Studies have been conducted on side effects, pharmacovigilance of patients on tenofovir and ADRs in developing countries that have reported side effects associated with tenofovir (51–53). Other rare symptoms experienced by the participants' included swollen legs, yellow eyes. There was significant difference in the presence of pain and weight across the two regimens. This study did not however differentiate disease related symptoms/side effects from drug related symptoms/side effects.

5.4 Factors associated with occurrence of any symptom of illness or side effects

This study demonstrated that the risk factors for the presence of a symptom were being on tenofovir based regimens or being on second line regimens. Other individual antiretroviral drugs the participants were on were not risk factors for presence of symptom of illness/side effects as analyzed by regression analysis as showed **Figure 4.8.** Out of 47 people on the second line regimen 29 were on zidovudine while 18 were on tenofovir.

5.5 Determinants of the physical health score

Majority of participants in this study had a high Physical Health Summary score when compared to the Mental Health Summary score. This is mainly as a result of the psychological burden associated with HIV that influences the mental health. Participants on zidovudine based regimens had higher Physical Health Summary score compared to those on tenofovir based regimens. A comparative outcomes study of tenofovir- and zidovudine-based antiretroviral therapy regimens in Zambia concluded that TDF+3TC+NVP were associated with higher mortality when compared with ZDV+3TC+NVP (27). Similarly a study in a large Nigerian cohort on superior effectiveness of zidovudine compared with tenofovir when combined with nevirapine based antiretroviral therapy concluded that tenofovir-lamivudine

or emtricitabine in combination with nevirapine was a strong predictor of virologic failure (41). However our findings are in contrary with a number of studies that usually report tenofovir to have better outcomes when compared to zidovudine (58).

Being a man improved the Physical Health Summary score. There was positive correlation between regular source of income and improved Physical Health Summary score. This is similar to a number of studies that illustrates HRQoL to be positively related to source of income (38,59). This finding illustrates that apart from the clinical interventions additional intergraded efforts should be put in programs in order to achieve improved quality of life in HIV positive patients.

Factors that decreased the score on physical health included having age above 40, presence of a symptom that compromised the quality of life, inability to cope with HIV and being on Lopinavir/ritonavir. Among the variables that decreased the Physical Health Summary score presence of a symptom had the greatest negative impact.

Participants on zidovudine based regimens had a higher median Physical Health Summary score than those on tenofovir based regimens. The findings were statistically significant. We however did not find a study that compared tenofivir to zidovudine across the physical health aspect.

Sex, regular source of income and marital status were key socio-demographic determinants of Physical health across the two regimens. Presence of any symptom of disease or side effects, recent viral load and ability to cope with HIV were the medical characteristics that affected the Physical Health Summary score.

Sex, age above 40, presence of any symptoms, inability to cope with HIV and being on Lopinavir/ritonavir were the key factors that were associated with reduced Physical Health Summary score on regression analysis. Having any symptom that compromises the quality of life greatly reduced the Physical Health Summary score by -5.6 units. Having a regular source of income and being on zidovudine were positively attributed to increased Physical Health Summary score.

5.6 Determinants of the Mental Health Score

Study participants in this population generally had lower mental quality of life when compared to their physical health. Participants on zidovudine based regimens reported a

better Mental Health Summary score when compared to those on tenofovir based regimens. They had better mental health score performance in 12 out of 16 variables when compared to those on tenofovir based regimens. Inability to cope with HIV, presence of a symptom, type of combinations of regimens patients were on and duration of ART use reduced the mental health score.

Previous studies have reported HIV related symptoms to be associated with poor HRQoL. In our study participants on tenofovir based regimens had a higher prevalence of symptoms when compared to those on zidovudine based regimens. Consequently participants on tenofovir based regimens reported poorer PHS and MHS when compared to those on zidovudine based regimens. The effect of presence of a symptom was more on the Physical Health Summary score compared to the Mental Health Summary score. This is in concordant with other studies that report the presence of a symptom to have more effect on the physical health when compared to the mental health. Analysis of other individual antiretroviral drugs the participants were on, showed that they did not affect both Physical Health Summary score and Mental Health Summary score as showed in **Table 4.11** and **Table 4.14**.

All the measured aspects in this study namely domains of health, Physical and mental health reported better performance of participants on zidovudine based regimens when compared to those on tenofovir. This study reports better Health Related Quality of Life of participants on zidovudine compared to those on tenofovir. On the contrary numerous studies that assessed the two drugs across safety and clinical outcomes, reported better outcomes of the tenofovir arm. It should however be noted that though the findings appear different the current study assessed the quality of life of study participants while the other studies looked in to the tolerability and clinical outcomes profile comparing the two drugs. A systemic review and meta-analysis head to head comparison of efficacy and tolerability of TDV/3TC/EFV and ZDV/3TC/EFV was done in Ethopia. The study reported better outcomes of TDV/3TC/EFV when compared to ZDV/3TC/EFV (5). Another prospective cohort study in resource limited setting reported better performance of tenofovir as opposed to zidovudine and stavudine when assessed across the clinical outcomes (58).

5.7 Conclusion

In summary the findings of this study provided evidence that participants on zidovudine based regimens had a better HRQoL scores compared to those on tenofovir based regimens. Participants in aggregate had a better Physical Health Summary score when compared to the Mental Health Summary score. This highlights the need for monitoring the mental health

even when the physical health seems to be well. Generally participants in this group reported a better HRQoL as the least reported median score was 75 IQR (50,100) and 5 domains reported a median score of 100 when measured across the domains of health. This is evidence of better quality of life attributed to antiretroviral.

Pain and weight related disorders were the most reported symptoms by the participants with those on tenofovir based regimens reporting higher numbers. It was especially evident that sex, regular source of income and marital status were positively associated with the Physical Health Summary score.
The factors that decreased the Physical Health Summary score were age above 40, presence of a symptom, inability to cope with HIV and being on Lopinavir/ritonavir.

5.8 Strengths and limitations of this study

Our study highlights the need to evaluate the patients' rating of their own health because in any case the interventions are usually geared at making the patient life better. This can only be obtained by getting the patient reported outcomes. The study ventured into the key components of health that is the physical health and mental health as perceived by patients. The current study adopted the use of standardized widely used disease specific MOS-HIV questionnaire which enables the obtained findings comparable to other findings where similar questionnaire has been used.

This study however had its limitations. Firstly, the subjective nature of the questionnaire. The study did not clearly differentiate the symptoms of the disease with those ones as a result of side effects of the drugs. As much as possible similar studies that highlight the disease symptoms and the side effects should be conducted to ascertain the different prevalence. By default the numbers of participants on tenofovir based regimens were more than those on the zidovudine based regimens. This was as a result of the hospital having more participants on tenofovir as opposed to zidovudine.

There could have been non-response bias since some of the questions in the MOS-HIV questionnaire are almost similar, some participants did not answer all the questions thinking that it was repetition this explains why the number of responders was not equal across the variables. It should be pointed out that the participants could have been taking other drugs or

had other co-morbidities that were not controlled for in this study. The possibility of drug-drug interactions the participants could have had were not controlled for in this study.

5.9 Policy implication of the study

The study works as an outcome measure of the impact of ARVs on the patients as well as satisfaction with service delivery. This when implemented evaluates patients' progress and creates room for improvement in service delivery.

5.10 Recommendations

5.10.1 Recommendations for policy

Since quality of life improvement is one of the objectives of ART its measure should be embraced in routine practice just as other clinical and laboratory measures in HIV management.

There is need for more awareness and dissemination of information about the HRQoL among the health care providers for evaluation purposes on the impact of interventions in health care on the patients' quality of life.

This study found the prevalence of symptoms/side effects was higher in patients on tenofovir compared to those on zidovudine. It is therefore essential that patients on tenofovir should be closely monitored for symptoms of disease/side effects.

It's recommended that the Kenya National AIDS Control Council (NACC) and National AIDS and STI Control Programme (NASCOP) in its effort to combat the severity of HIV should adopt more of patient centered approach as part of outcome measure on interventions already in place for people living with HIV.

We recommend that the Pharmacy and Poisons Board to sensitize both the health care workers and patients on identification, assessment, reporting of side effects for patients on HAART.

5.10.1 Recommendations for future research

We recommend further study on HRQoL on patients treated with tenofovir versus zidovudine based regimens to be conducted to confirm the findings.

In the current study convenient sampling was used, we therefore recommend a randomized head to head HRQoL study of patients on tenofovir versus zidovudine based regimens for comparison purposes.

We recommend a review on questions in the MOS-HIV questionnaire which though they measure different aspects of quality of life they appear similar to make it simpler for the patients to understand.

More studies focusing on the prevalence and type of symptoms/side effects reported by HIV patients should be carried out since some can be life threatening.

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APPENDICES

APPENDIX 1: LETTER OF ETHICAL APPROVAL

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

11 NOV 2015

Ref: KNH-ERC/A/467

11th November 2015

Dr. Jilian Oranga Etenyi
U51/75501/2014
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Dr. Etenyi

Research proposal: Comparison of Health related quality of life of adult HIV positive patients on Tenofovir and Zidovudine based regimens at Kenyatta National Hospital (P675/10/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval periods are 11th November 2015 – 10th November 2016.

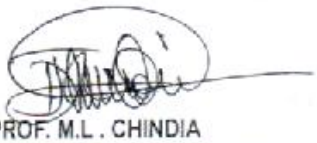
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

Protect to Discover

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

Yours sincerely,



PROF. M.L . CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy,UoN
The Chair, Dept.of Pharmacology and Pharmacognosy,UoN
Supervisor: Dr.S.A. Opanga, Dr.K.A. Sinei, Dr. G.O.Osanjo

APPENDIX 2: LETTER OF ETHICAL APPROVAL RENEWAL

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

Ref. No.KNH/ERC/R/52

March 7 2018

Jilian Oranga Etenyi
U51/75501/2016
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Jilian

Re: Approval of Annual Renewal – Health related quality of life of adult patients on Tenofovir versus Zidovudine based regimens at Kenyatta National Hospital, Kenya (P675/10/2015)

Refer to your comrnunication dated February 8, 2018.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethical research protocol P675/10/2015.

The approval dates are 11th November 2017 – 10th November 2018.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH- UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH- UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN-Ethics & Research Committee for each batch of shipment.

g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

Ensure that the ethical renewal is renewed timely as per KNH-UoN ERC requirements.

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH-UoN ERC
The Dean, School of Pharmacy, UoN
Supervisors: Prof.Faith A.Okalebo, Dr.Sylvia A.Opanga,Dr. Kipruto A.Sinei, Prof.George O.Osanjo

APPENDIX 3: CONSENT FORM

To be read in a language that the respondent is fluent in.

Title of the study: Health Related Quality of Life of adult patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy,

University of Nairobi, P.O BOX 30197-00400, Nairobi

Investigator: Jilian Oranga Etenyi P.O BOX 150, Malava

Supervisors: Prof. Faith A. Okalebo, Department of Pharmacology and Pharmacognosy

Dr. Sylvia A. Opanga, Department of Pharmaceutics and Pharmacy practice

Dr. K.A. Sinei, Department of Pharmacology and Pharmacognosy

Prof. George. O. Osanjo, Department of Pharmacology and Pharmacognosy

Ethical Approval

Kenyatta National Hospital/University of Nairobi Ethical and Research Committee, P.O BOX 20723-00100, Nairobi Tel 2726300/2716450 Ext 44102

Permission is requested from you to enroll in this medical research study. You should understand the following general principals which apply to all participants in a medical research:

Introduction: In this study lam comparing the Health Related Quality Of Life of HIV positive adults age 18 and above who are on tenofovir and zidovudine based regimen at Kenyatta National Hospital. One of the objectives of being put on ARVS is to improve the quality of life among other benefits. The study therefore seeks to find out whether your quality of life has improved after being on the drugs for some time. You will be requested to fill a structured questionnaire that informs ten aspects of your quality of life. The questionnaire will take around 10-20 minutes. The information obtained from you will then be aggregated to inform about your overall quality of life. Factors that contribute to Health Related Quality of life will also be determined.

Purpose of the study: The main objective of the study is to compare the Health Related Quality of Life of adults who are on tenofovir versus zidovudine based regimens and identify factors that contribute to their HRQoL.

Procedure to be followed: With your permission, I will administer a questionnaire seeking to find out your demography and Health Related Quality of Life. All information obtained will be handled with confidentiality.

Risks: There will be no risk involved in this study as there is no new intervention given to you apart from the questionnaire.

Benefits: There will be no direct benefits to you but the findings will be useful in improving the quality of service offered to you as it will inform the Quality of life of different patients based on the regimen the patients are on. These will inform policy.

Assurance of Confidentiality: All information obtained from you will be kept in confidence. At no point will your name be used or mentioned during data handling or in any resulting publications. Serial numbers will be used instead.

Your rights as a participant

1. Your agreement to participate in this study is voluntary.
2. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
3. After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Contacts

In case you need to contact me, my academic department or the Kenyatta National Hospital/University of Nairobi Ethics and research Committee concerning this study use the contacts provided below:

Jilian Oranga Etenyi,
Department of Pharmacology and Pharmacognosy
School of Pharmacy, University of Nairobi
P.O Box, 151- Malava. Tel: 0725-620126

Dr. Sylvia Opanga,
Department of Pharmacology and Pharmacognosy
School of Pharmacy, University of Nairobi
P.O Box, 19676- Nairobi. Tel: 0721-296448

The Chairperson,
The Kenyatta National Hospital/University of Nairobi Research and Ethics Committee,
P.O Box, 19676- Nairobi. Tel: 020-2726300 Ext 44102
I now request you to fill the attached consent form.

CONSENT FORM

HEALTH RELATED QUALITY OF LIFE OF ADULT PATIENTS ON TENOFOVIR VERSUS ZIDOVUDINE BASED REGIMENS AT KENYATTA NATIONAL HOSPITAL

I……..give consent to the investigators to interview me and use the information obtained in her study. The nature of the study has been explained to me by Jilian Oranga Etenyi.

Signature……..Date…….
I confirm that I have explained the nature and effect of the study.

Signature……Date…….

APPENDIX 4: ELIGIBILITY CHECK LIST

All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application.

I. Study Information

Title:	Health Related Quality of Life of adult patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital
Protocol Number:	
Principal Investigator:	**JILIAN ORANGA ETENYI**

II. Subject Information:

Subject Name/ID:
Gender: ☐ Male ☐ Female

III. Inclusion/Exclusion Criteria

Inclusion Criteria	Yes	No
1. Is the patient HIV positive	☐	☐
2. Is the patient 18 years and above?	☐	☐
3. Is the patient either on Tenofovir or Zidovudine based regimen?	☐	☐
4. Is the patient enrolled at Kenyatta comprehensive care center clinic?	☐	☐

5. Has the patient been on either Tenofovir or Zidovudine based regimen for the past six months?	☐	☐
6. Has the patient consented to participate in the study?	☐	☐
Exclusion Criteria	**Yes**	**No**
1. Is the patient expectant?		
2. Does the patient fail to meet the inclusion procedure?		

All subject files must include supporting documentation to confirm subject eligibility. The method of confirmation can include, but is not limited to, laboratory test results, radiology test results, subject self-report, and medical record review.

IV. Statement of Eligibility

This subject is **[☐eligible** / **☐ineligible] for** participation in the study.

Signature:	Date:
Printed Name:	

APPENDIX 5: QUESTIONNAIRE

English version of the culturally adopted MOS-HIV tool

HEALTH RELATED QUALITY OF LIFE

I am from University of Nairobi School of Pharmacy and lam conducting a study to compare the health related quality of life among patients on tenofovir versus zidovudine based regimens at Kenyatta National Hospital. The information from this study will facilitate clinicians to improve on the provision of care and policy makers in their planning activities. Your participation in this study is voluntary and all the data provided will be treated as confidential and anonymous. You have a right to withdraw from the study anytime. Thank you.

Date:.....

Questionnaire number:.....

Name of Interviewer:.....

Clinic Number .....

Patient regimen

TENOFOR ☐ ZIDOVUDINE ☐

SECTION A

BASELINE CHARACTERISTICS

1. Sex ☐
2. What is your age in years? ☐
3. Do you have a religious belief?

   i.Yes ☐ ii. No ☐

4. What is the highest level of education you attained?

i. No education ☐ ii. Primary ☐

iii. Secondary ☐ iv. Tertiary University ☐

v. Others ☐

5. Have you ever disclosed to you partner about your HIV status

i. Yes ☐ ii. No ☐

6. From which part of Kenya do you come from?

i. Eastern ☐ ii. Western ☐ iii. North Eastern ☐ iv. Central ☐

v. Nairobi ☐ vi. Coast ☐ vii. Nyanza ☐ viii. Rift Valley ☐

7. Do you have a regular source of income or are you employed?

i. Yes ☐ ii. No ☐

8. What is your marital status?

i. Married ☐ ii. Living together ☐

iii. Single ☐ iv. Widowed ☐

v. Divorced ☐

9. How long have been with the HIV? ☐

10. How long have you been on ART? ☐

SECTION B

Now, I would like to ask you a few questions about your health.

I. In general, would you say your health is?

1. Excellent ☐ 2.Very good ☐

3. Good ☐ 4. Fair ☐

5. Poor ☐

II. How much bodily pain have you generally had during the past thirty days?

1. None ☐ 2. Mild ☐
3. Moderate ☐ 4. Severe ☐
5. Very Severe ☐

III. During the past thirty days, how much did pain interfere with your normal work, including both work outside the home and housework?

1. Not at all ☐ 2. Little bit ☐
3. Moderately ☐ 4. Quite a bit ☐
5. Extremely ☐

IV. The following questions are about activities that a person might do during a typical day. Does your health now limit you in the following activities? If so, how much?

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All

a) The kinds or amounts of vigorous activities you can do like, digging, fetching water from a well, carrying 10 kilograms of weight, splitting firewood.

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

b) The kinds or amounts of moderate activities you can do like washing clothes, moving a jerrican of water or moving a bundle of fire wood from one place to another.

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

c) Walking up hill, climbing stairs.

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

d) Bending, lifting light objects or kneeling

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

e) Walking one block

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

f) Eating, dressing, bathing or using the toilet

1. YES, Limited a Lot ☐
2. YES, Limited a Little ☐
3. NO, Not Limited at All ☐

V. Does your health keep you from working at a job, doing work around the house or attending school?

1. Yes ☐ 2. No ☐

VI. Have you been unable to do certain kinds or amounts of work, housework or schoolwork, because of your health?

1. Yes ☐ 2. No ☐

VII. For each of the following questions please tell me the answer that comes closest to the way you are feeling in the last thirty days

How much of the time, during the past 4 weeks, has your health limited your social activities (like visiting with friends or close relatives)?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A little of the Time ☐
6. None of the Time ☐

VIII. How much of the time, during the past thirty days:

a. Have you been a very nervous person?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

b. Have you felt calm and peaceful?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

c. Have you felt depressed?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

d. Have you been a happy person?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

e. Have you felt so depressed and nothing could cheer you up?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

IX. How often during the past thirty days:

a. Did you feel full of life and energy?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

b. Did you feel totally without energy?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

c. Did you feel tired?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

d. Did you have enough energy to do things you wanted to do?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

e. Did you feel weighed down by your health problems?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

f. Were you discouraged by your health problems?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

g. Did you feel despair over your health problems?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

h. Were you afraid because of your health?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

X. How often during the past thirty days:

a. Did you have difficulty reasoning and making decisions, for example, making plans or learning new things?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

b. Did you forget things that happened recently, for example, where you put things or when you had appointments?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

c. Did you have trouble keeping your attention on any activity for long?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

d. Did you have difficulty doing activities involving concentration and thinking?

1. All of the Time ☐
2. Most of the Time ☐
3. A Good Bit of the Time ☐
4. Some of the Time ☐
5. A Little of the Time ☐
6. None of the Time ☐

XI. Please tell me the answer that comes closest to describing whether the following statement is True or false for you. The answers are: [INTERVIEWER: READ RESPONSES BELOW].

1. Definitely True ☐
2. Mostly True ☐
3. Don't Know ☐
4. Mostly False ☐
5. Definitely False ☐

a. You are somewhat ill.

1. Definitely True ☐
2. Mostly True ☐
3. Don't Know ☐
4. Mostly False ☐
5. Definitely False ☐

b. You are as healthy as other people know you

1. Definitely True ☐
2. Mostly True ☐
3. Don't Know ☐
4. Mostly False ☐
5. Definitely False ☐

c. Your health is excellent.

1. Definitely True ☐
2. Mostly True ☐
3. Don't Know ☐
4. Mostly False ☐
5. Definitely False ☐

d. You have been feeling bad recently.

1. Definitely True ☐
2. Mostly True ☐
3. Don't Know ☐
4. Mostly False ☐
5. Definitely False ☐

XII. How has the quality of your life been during the past thirty days? That is, how have things been going for you?

1. Better ☐
2. Pretty good ☐
3. Good and bad parts about equal ☐
4. Pretty bad ☐
5. Very bad ☐
6. Be worse ☐

XIII. How would you rate your physical health and emotional condition now compared to thirty days ago?

1. Much better ☐
2. A little better ☐
3. A bout the same ☐
4. A little worse ☐
5. Much worse ☐

XIV. Do you have any symptom that compromise your Quality of life

1. Yes ☐ 2. No ☐

If yes, which one …….

XV. How satisfied are you with the services offered by the health care providers.

1. Very Good ☐
2. Good ☐
3. Fair ☐
4. Bad ☐

XVI. a. How do you rate your ability to cope with HIV?

1. Excellent ☐ 2. Very good ☐
3. Good ☐ 4. Fair ☐
5. Poor ☐

b. How do you manage to cope with your HIV status? (Tick what applies to you)

1. Acceptance ☐ 2. Sharing ☐

3. Joined Support group ☐ 4. Spiritual support ☐

Others .....

XVII. Have you ever missed taking your medication?

1. Yes ☐ 2. No ☐

Reason why .....

XVIII. Have you ever used the following; alcohol, hard drugs, smoking

Specify which ones .....

Medical record

XIX. Patient Clinical and Immunological Status as per the physician records

(a)Most recent CD4 counts (almost 3-4 months from the time of Interview) was

.....

(b)Most recent viral Load (almost 3-4 months from the time of Interview)

.....

THANK YOU

APPENDIX 6: FACTOR ANALYSIS: MOS-HIV SCALES

PRINCIPAL COMPONENT WITH ROCHE BASELINE DATA (44)

Scale	Factor 1: MHS	Factor 1: PHS
Mental1	0.31592	-0.13017
Distres1	0.27676	-0.07680
QOL1	0.21939	-0.00504
Cogn1	0.19615	0.01866
Energy1	0.16052	0.11785
Physical1	-0.06072	0.34370
Pain1	-0.08665	0.31854
Role1	-0.00325	0.29617
Social1	0.05690	0.22165
Ghealth1	0.10158	0.17829