PREDICTORS OF LOSS TO FOLLOW UP AMONG ADULT PATIENTS INITIATED ON ANTIRETROVIRAL THERAPY IN NAKURU WEST SUB-COUNTY HEALTH FACILITIES, KENYA

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DECLARATION

This thesis is my original work and has not been presented for a degree or an award in any other university.

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DEDICATION

I dedicate this thesis to my husband Charles Chepkewel Kapkwang for his tireless assistance in molding this research, my children: Prudence, Doreen, Maureen, Faith, and Abraham who learned to keep off mum's work. Not forgetting my mother Esther Chirchir for her unwavering support during this Master's program and above all, the Almighty God to whom the glory belongs now and forever more. Amen.

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ABSTRACT

The loss to follow up (LTFU) has reversed the successful strengthening of antiretroviral therapy (ART) programmes globally. The factors associated with the LTFU still remain a challenge to many countries, becoming a critical barrier to effective scale-up of HIV services. Kenya is one of the four HIV high burden countries in Africa (alongside Mozambique and Uganda) with the retention rate of about 81% which is below the set 90%. The HIV prevalence in the country is at 5.9% with 29% adult HIV co-morbidities overburdening the health care system and economy. UNAIDS targeted to achieve 90% in three key areas of HIV: identification in HIV positive patients; prompt linkage to treatment; and viral suppression by the year 2020. The second and third strategy has not been met in Nakuru West Sub-County. The Sub-County has had increasing incidences of HIV and AIDS co-morbidities with drug resistance. This study aimed at determining predictors of LTFU among adult patients initiated on ART in Nakuru County health facilities. A retrospective cohort study design was employed and 1131 participants enrolled/initiated on ART within 1st January 2016 to 31st December 2018 in the County Referral hospital, Kapkures and Rhonda health centers were examined to determine their outcomes. Baseline patient records were extracted from Electronic Master Facility and ART Cohort registers. Survival data analysis was done using cox regression analysis besides to the descriptive statistics. Kaplan Meier (KM) curves were drawn to estimate the probability of LTFU and proportionality hazards assumption was checked for covariates intended to be included in the final cox mode. A total of 9 Key informants from identified CCC/HIV clinics were interviewed. The written interviews were analyzed using standard qualitative method, to identify content and themes where the researcher made claims on evidence in the data provided. From the results, a total of 1131 participants contributed to 2094.6 PYs of follow up time with an overall LTFU incidence rate of 161.1 (95%CI: 144-7 – 179.2) per 1000 PYs (337/1131). Four predictive variables were statistically identified as significant to LTFU in the final Cox Regression model: Low BMI of 18.4, (AHR = 1.88; 95%CI: 1.40 – 2.54; $p < 0.0001$); attending rural facility (AHR: 0.58; 95%CI: 0.36 – 0.76); $p < 0.0001$); IPT users (AHR:1.34; 95%CI: 0.84 – 1.57); $p < 0.0001$) and high VL (AHR: 0.59: 95%CI: 0.17 – 1.00); $p < 0.0001$). In addition, the key informants identified the following factors that contributed to LTFU: wrong documentation; long waiting time; inappropriate implementation of the HIV and AIDS management policies and inadequate funds. To minimize LTFU and realize the second and third UNAIDS/WHO HIV implementation strategies, interventions should be geared towards, close supervision all HIV adults with: CD4 <200 cells/mm^3, high VL, attending rural facility and IPT-users. This study also recommends that, the Ministry of Health, County government and all other stakeholders should build capacity of health care personnel to improve provision of HIV care services; they also need to address availability of resources and challenges that impede the implementation of HIV and AIDS management policies. This will, in turn, curb LTFU, enhance patient retention, patient survival and improve quality of life.

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LIST OF ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ATV/r	Atazanavir/ ritonavir
AZT	Zidovudine
BMI	Body Mass Index
CCC	Comprehensive Care Clinic
CD4	Cluster of Differentiation 4
CHV	Community Health Volunteer
d4T	Stavudine
ddl	Didanosine
DHIS	District Health Information System
DTG	Dolutegravir
EVF	Efavirenz
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IBM	Information Motivation Behavior Model
IPT	Isonized Prophylaxis Therapy
KASF	Kenya aids strategic framework
LDL	Low detectable levels
LTFU	Loss to Follow-Up
MFL	Master Facility List

MOH Ministry of Health

NACC National Aids Control Council

NASCOP National AIDS and STI Control Programme

NRTIs Nucleosides Reverse Transcriptase Inhibitors

NNRTIs Non- Nucleosides Reverse Transcriptase Inhibitors

NVP Nevirapine

OIs Opportunistic Infections

PIs Protease Inhibitors

PLHIV People Living with HIV

SCMOH Sub-county Medical Officer of Health

SDG(s) Sustainable Development Goals

SSA Sub-Saharan Africa

STF Suspected Treatment Failure

TB Tuberculosis

TFV Tenofovir

UNAIDS Joint United Nations Program on HIV and AIDS

VL Viral Load

WHO World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Overview

The following has been presented in this chapter: background information, statement of the problem, justification, research objectives (broad and specific objectives), hypothesis, study limitations, the operational definition of terms and conceptual framework.

1.2 Background to the study

There has been a growing concern on the increasing rates of LTFU globally, among people already on treatment (Tadesse & Haile, 2014) ranging from, 0.3 to 50% (Agwu, *et al.,* 2016) and (Meloni, *et al.,* 2014). LTFU, compromises the long-term success of ART worldwide (Berheto, *et al.*, 2014) and patients' survival (Saumu, 2017). Those affected, may increase the risk of HIV transmissions and deteriorating their health condition due to unchecked HIV status (Meloni, *et al.*, 2014). The United Nations Program on HIV and AIDS (UNAIDS) three targeted strategies of HIV, is to achieve 90% in: identification in HIV positive patients; prompt linkage to treatment; and viral suppression by the year 2020 (UNAIDS, 2018). In order to realise the 3 targets, improvement in ART management as well as close follow up of patients is essential (Yehia, *et al.*, 2015 and Tweya, Obono & Gugsa, 2018).

Failure to observe the appointment dates, leads to unscheduled visits (Ministry of Health (MOH)/NASCOP, 2016), and subsequently loss to follow up (LTFU). LTFU is defined as failure to attend clinic for three months for ART refill and not yet classified as 'dead' or 'transferred-out' (Megerso, *et al.*, 2016; Berheto, *et al.*, 2014

In Africa, it has been observed that the successful scale-up of ART coverage (Saumu, 2017) has vastly changed the outcomes of HIV, shifting the disease from once uni-

formly fatal to a chronic disease (Meloni *et al.,* 2014). But LTFU cases have been identified as a critical barrier to effective scale-up of HIV programme (Hassan, *et al.*, 2012; Saumu, 2017). Sub-Sahara Africa (SSA) studies revealed that, the incidence of attrition after ART initiation at 6 months, is about 20% to 87% and it increases with time (Honge, *et al.,* 2013). LTFU has negatively impacted on the immunological benefit of ART, leading to drug toxicity, treatment failure and drug resistance starring increased AIDS-related morbidity, mortality, and hospitalizations (Berheto, *et al.,* 2014). The factors associated with LTFU still remain a challenge in many countries (Mehari, *et al.,* 2017), although age, gender, and clinical factors have some association (Eguzo, *et al.,* 2015).

Kenya is one of the four HIV high burden countries in Africa (alongside Mozambique and Uganda) (Kimani, 2013). There has been rapid scale-up of ART services evidenced by an increase in treatment sites NASCOP/MOH, 2018; Saumu, 2017). The HIV prevalence in the country is at 5.9% with 29% adult HIV co-morbidities overburdening the health care system and economy (NASCOP, 2016). The retention rate is at 81% (DHIS, 2018) short of 90% as recommended by UNAIDS/WHO (NASCOP, 2014).

Nakuru County among the 47 Counties has been ranked number nine nationally, with an estimated 37,324 HIV positives adults on ART amounting to 76%, and HIV related deaths at 1204 (MOH/NACC, 2016; NASCOP, 2016). By 2018, the HIV prevalence rate had declined from 6.3 to 5.6% (County Government of Nakuru, 2018). Upon researcher's observation and evaluation of ART cohort register, the approximated percentage of patients who were LTFU in Kapkures health centre is at 30%, viral suppression as low as 27% and retention rate of about 50%

(MOH/NASCOP, 2016), which is below the national rate of 80% (District Health Information System {DHIS}, 2018). The county has had increasing incidences of HIV and AIDS co- morbidities with drug resistance leading to many patients being substituted to second-line drug regimen (County Government of Nakuru, 2018).

The prevalence and predictors of LTFU after initiation on ART among adult HIV patients have been investigated in Kilifi, Kisumu, Machakos, and Nairobi. Little information is available on the incidence and predictors of LFTU in Nakuru County. Therefore, this study sought to determine, predictors of LTFU among adult patients initiated on ART in Nakuru west sub-county health facilities. The study will contribute in identifying factors that would help in improving retention rate to the recommended 90% by UNAIDS and reduce negative consequences of LTFU among people with HIV/AIDS in the study area and the country in general.

1.3 Statement of the problem

The successful implementation of ART globally has long been reversed by LTFU (Berheto, *et al.*, 2014). Similarly to SSA, the growing rate of LTFU in ART programs is overwhelming (Saumu, 2017). The factors associated with LTFU still remains a challenge in many countries of SSA (Mehari, *et al.*, 2017), becoming a critical barrier to effective scale-up of HIV services (Hassan, *et al.*, 2012; Saumu, 2017).

Kenya is one of the four HIV high burden countries in Africa (alongside Mozambique and Uganda) (Kimani, 2013). Despite the successful implementation of ART, the retention rate is at 81% (County Government of Nakuru, 2018) below the WHO recommendation of 90%. Without being retained in care, ART patients are susceptible to HIV-related morbidity and mortality as well as at risk of transmitting drug-

resistant strains of the virus. Outcomes from such research could determine ways to improve practice and could ultimately determine best practice in curbing LTFU

A preliminary analysis of the 2016 data by NASCOP indicated that, ART coverage in Nakuru County is at 76%, the viral suppression rate at 33% which was very low compared to other counties nationally, with that fairly good ART coverage (NASCOP, 2016). In addition, the patients currently on ART by the end of December 2018 were 11896, from the fourteen health facilities offering CCC services, where 93% are adult patients. The Nakuru County Government using the policy Kenya aids strategic framework (KASF) 2014/15-2018/19 had put their focus on UNAIDS implementation program, which aimed at identifying: HIV positive patients; prompt linkage to treatment care and viral suppression, scaling them up to 90% (NASCOP, 2014). The first UNAIDS implementation cascade on the identification of HIV positive is well addressed in the county running to 95%, but the second and third (linkage to treatment and viral suppression) are far below 90%. This was evidenced by the rates of high drop out rates among patients initiated on ART (County Government of Nakuru, 2018).

From the 11896, about 50% of the patients had defaulted treatment since it opened its doors to cater for ART in the County. Among the Sub-Counties in Nakuru County, it has been observed that Nakuru West is experiencing higher numbers of drop-out rate among adults initiated on ART leading to rising rates of LTFU, compared to other Sub-County where the retention rates were above 50% (County Government of Nakuru, 2018; MOH/NASCOP, 2016). Regrettably, there has been an increasing rate of HIV and AIDS co-morbidities and mortalities among adults, some developing drug resistance ending up with substitution or switching the drug regimen to the second line/ third line of which are very costly even unavailable (County Government

of Nakuru, 2018; MOH/NASCOP, 2016) raising a lot of concern among ART co-ordinators.

APHIA PLUS in collaboration with MOH made some follow up policy guidelines, to ensure patient retention hence curbing LTFU. Their contributions to the facilities included provisions of resources (personnel and supplies) to enable continuity of services and scaling up of the ART services. However, despite these efforts, it has been evident that patients get lost of treatment for unknown contributing factors (County Government of Nakuru, 2018).

Owing to lack of information on precise data about the incidence of LTFU as well as clinical and health system factors that may influence the follow up outcome, appropriate interventions to increase ART adherence cannot be designed and implemented. Therefore, conducting research aimed at determining predictors of LTFU among adult patients initiated on ART in the study area is extremely vital.

1.4 Objectives of the study

1.4.1 Broad objective

To determine the predictors of LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.

1.4.2 Specific objectives

i. To determine the incidence rate and the socio-demographic predictors of LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.
ii. To analyze the clinical predictors associated with LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.

iii. To evaluate the health system factors associated with LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.

1.5 Research hypothesis

There is no association between the predictors and LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities. Alternatively, there is an association between predictors and LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.

1.6 Justification of the study

Identifying the predictors, those influencing LTFU, will aid in making recommendations to the health authorities, using them in planning for intervention strategies to curb LTFU, aiming at retaining patients in care. This will help in attaining the 90% in second and third, (treatment and viral suppression) UNAIDS strategy on HIV and AIDS. Thence, realizing the WHO goal standard and aiming at achieving the 5^{th} Sustainable Development Goals (SDGs) on compacting HIV and AIDS, Malaria and Tuberculosis by 2030.

Implementation of HIV care by the: National, County Governments, NGOs, Faith-based Organizations, etc. have been seen using massive resources. But, good fight against HIV, delivery of quality care and retention of patients in care still unmet. The study findings will assist the health authorities, to identify who is ‘true LTFU' hence will be helpful in making recommendations for the health data collection systems, to be integrative as much as possible so as to minimize duplication of efforts and wastage of scarce resource (MOH/NASCOP, 2016). Also, findings will be used as the baseline for other studies related to HIV and AIDS.

Lastly, it will help in ensuring sustainability of patients to the program leading to improvement of the quality of life and prolonging life and in turn patient retention.

1.7 Limitation of this study

The study had several limitations. First and foremost, the researcher utilized already collected data used for routine patient management in CCC. Notably such data have a lot of gaps and may not be up to the required standards expected for research purposes as the centers are not part of well-known research sites in the country. However, the researcher a lot of effort was put in adhering to data validation rules within the database and daily data cleaning conducted to guarantee a certain degree of data correction and collation. Secondly, it was realized that the centers have passively follow up their patients from the time of enrollment into the programme. Therefore, there could have been possibilities of having considered some patients as having been lost to follow up when they were actually in the programme and receiving treatment somewhere else. This therefore, might have resulted in some over-estimation of the cumulative incidence rates of LTFU in our study. Such possibilities were, however, minimized by the researcher conducting contact tracing for clients who missed clinic appointments. This helped minimize possible misclassification. Lastly, the variables of interest that were collected were limited. Some of the many health system (human resource, distance) and socio-economic (type of work, socio contacts, HIV disclosure) factors known to affect LTFU were not studied. The effect of such possible determinants under the current study settings remained unknown. Future studies examine these additional factors to better inform ART programing and policies towards boosting retention. Despite this study's limitations, the findings are likely to be generalizable to HIV positive patients who start ART in Nakuru County and other areas with similar settings. Our study cohort was derived from a regional referral CCC, it

is highly possible that a wide scope of HIV patients with different background characteristics were studied.

1.8 Conceptual framework

The researcher opted to adapt and modify the Information Motivation Behavior skill (IMB) model as a guide in the study. The "health-related information, motivation, and behavioral skills interact to give the performance of health outcomes". The researcher agrees that "if individuals are well informed, motivated to act, and possess the requisite behavioral skills for effective action, they will be likely to initiate and maintain health-promoting behaviors and to experience positive health outcomes and vice versa (Fisher., Fisher and Harman, 2003).

In this study, motivation becomes the independent variable. They are the predictors of LTFU to include: socio-demographic predictors (age, sex, residence etc.), clinical predictors such as all the immunologic and clinical characteristics (Baseline & subsequent CD4 counts, BMI (height, weight), TB status, viral load count, WHO staging, treatment duration, and IPT prophylaxis) and health facility-related factors, all influence patient outcome (LTFU). Information/knowledge and behavioral skills are the intervening variables, meaning that they mediate between the independent and dependent variable. The information received on drug interaction, importance of adherence and severity of HIV and AIDS, forms the information part and on behavioral skills includes: self-efficacy objective (ART time fashion & appropriate storing**,** adhere to treatment**,** while incorporating treatment into daily life**,** avoiding and minimizing side effects and joining social support) may influence the behavioral outcome (LTFU) as illustrated below.

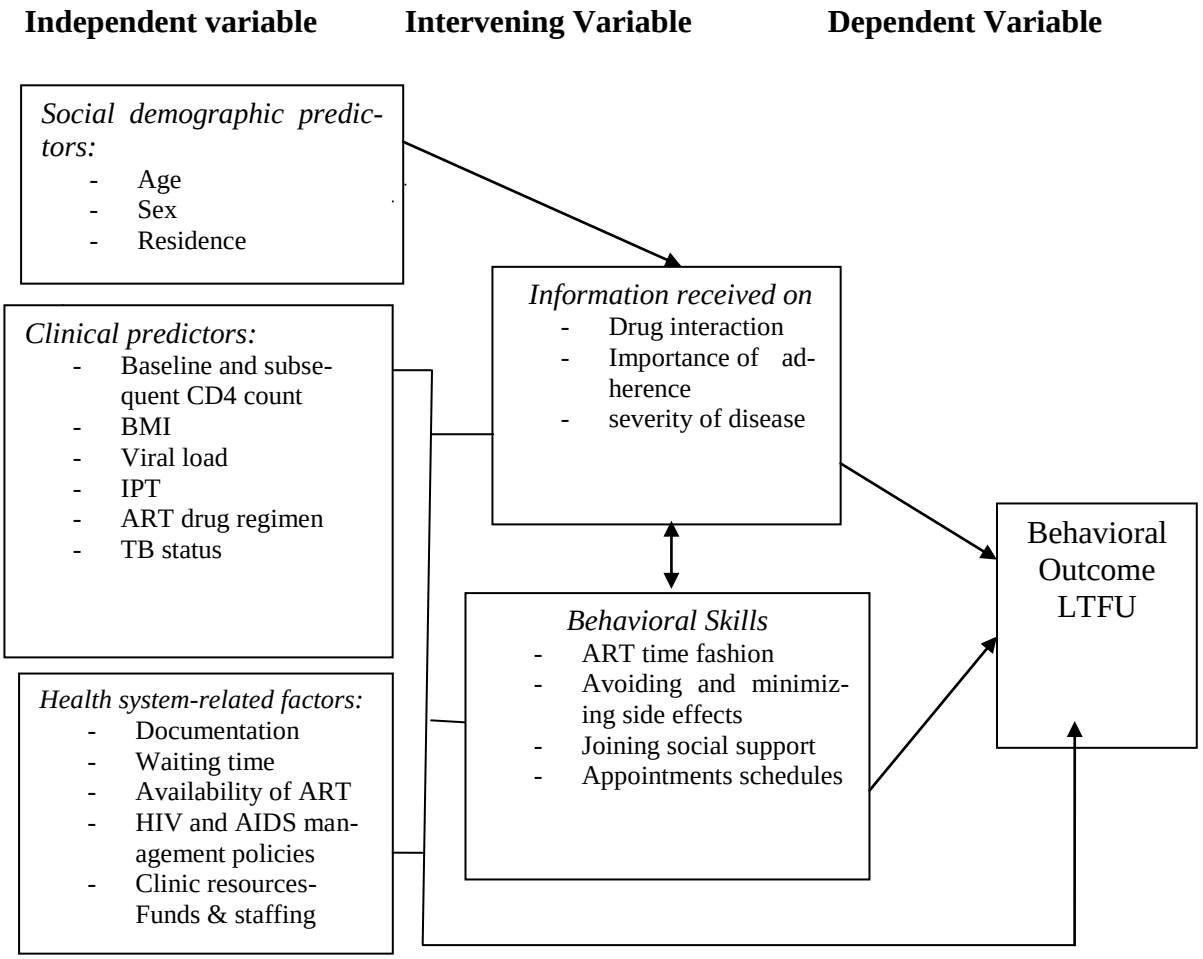

Figure 1. 1: Conceptual Framework

1.9 Operationalization of terms

Clinical predictors– are the patient clinical outcomes, depending on direct observation and laboratory findings. In this study they will include; BMI, CD4 Count, WHO Staging IPT, TB status and Viral load.

Date started/ initiated on ART- this is the date when the client/ patient was initiated/ commenced on ART.

Incidence rate- reflects the time until a participant has an event of interest (LTFU), calculated in person months/ or person-years.

LTFU - More than 90 days from the missed clinical or drug pick-up appointment without follow-up contact.

Predictors – Factors that determine LTFU in ART. They are the information that supports a probabilistic estimate of future events.

Retention rate – In the study is the percentage of patients who are still active on treatment minus loss to follow up, transfer out or dead.

WHO staging - It is how the patient clinically presents prior to ART commencement. The WHO clinical staging increases with severity of opportunistic infections that are; stage 1, stage 2, stage 3 and then stage 4- AID stage.

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview

This section provides the literature on the epidemiology of HIV and AIDS; mode of transmission; signs and symptoms; diagnosis, management and preventive measures of HIV/AIDS, incidence rate, socio-demographic, clinical, health systems predictors of LTFU and summary.

2.2 Epidemiology of HIV and AIDS

HIV is the virus that causes AIDS (Mathebula, 2014). Once a person is infected with HIV, he or she is permanently infected (Salema, 2015). Australia Federation of AIDS Organisations, (2017) reported that "HIV infects the immune system (T-cells)**,** which help fight diseases, attaching to T-cells then multiplying, destroying the cells thus weakening the immune system. Eventually, the person's immune system can no longer effectively fight off diseases (Pietrangelo & Murrell (Ed.), 2018).

U.S Department of Health & Human Services, (2018), documented that, "typically, the adult's CD4 count is 500 to 1,500 cells/mm^3, but as HIV lowers the CD4 cell count, the immune system also weakens" and that if CD4 count falls below 200 cells/mm^3 a person then is considered to have AIDS. This can last up to a decade before advancing to AIDS without treatment, where at that point, the immune system is too weak to fight off other diseases and infection, having a life expectancy of about three years (Mathebula, 2014). A person can also be diagnosed with AIDS if they have HIV and develop an opportunistic infection (pneumonia) or cancer that's rare in people who don't have HIV (Tina Shahian, 2018). However, treatment with an-

tiretroviral drugs can prevent AIDS from developing (Pietrangelo & Murrell (Ed.), 2018).

2.3 Mode of transmission

According to Hoque, (2015), HIV and AIDS is transmitted mainly by having sexual intercourse with an infected person or by sharing sharp instruments which are contaminated with infected blood and blood products or by receiving contaminated blood (blood transfusion). It can be a transmission from an infected mother to the child via trans-placental during pregnancy, contaminated delivery or during breast-feeding (Selema, 2018). Although, the use of ART in pregnancy can reduce the mother-to-child transmission rate to less than 1% (Fettig, 2016). In addition, occupational hazards among nurses, doctors, and scientists who have frequent contact with human bodily fluids are considered high-risk. For example, an accidental needle prick while treating an infected patient can transmit HIV to the caregiver (U.S Department of Health & Human Services, 2018).

2.4 Signs and symptoms

Sometimes infection with HIV does not produce symptoms until the disease has progressed to AIDS; this could take ten years for some people. Symptoms vary highly from one person to the next and depend on the stage of infection (Nordqvist, 2018).

Early stage infection typically produces flu-like symptoms that appear within 2-4 weeks of infection. The body's viral load (number of virus particles) is especially high at this stage and the test is recommended. The symptoms include fever, headaches, muscle pain and fatigue, sore throat, swollen glands and rash (Mathebula, 2014).

During the *clinical latency stage* the virus “hides” in the immune cells and is minimally active. Although symptoms tend to disappear and viral load is low during latency, it is still possible to transmit HIV (Tina Shahian, 2018). The latency stage may last up to ten years without treatment, or for many decades with treatment (Nordqvist, 2018).

In addition, the U.S Department of Health & Human Services, (2018), reported that during the *late stage* (AIDS), symptoms for secondary infections or other complications appear. They include significant weight loss; fever and night sweat extreme fatigue, chronic diarrhea, sores in the mouth or genital areas, swelling of the lymph glands, *Pneumocystis carinii* Pneumonia, red/brown/purple blotches on the skin and neurological disorders (e.g. depression and memory loss).

2.5 Diagnosis of HIV

Diagnosis is made through a blood test that screens specifically for the virus (Hoque, 2015). Before the procedure is carried out in a patient the following steps are involved: *Pre-test session* -where basic HIV information is given to the client then opportunity to sign the consent, *HIV test*- should follow the current HIV test standard operating procedures (SOPs) (MOH/ NASCOP, 2015). If HIV has been found, the test result is "positive." The blood is re-tested before a positive result is given (Centre for Disease Control and Prevention [CDC], 2017). The earlier HIV is detected, the more likely the treatment will be successful (Mayo Clinic, 2018). According to Mathebula, (2014) *post-test session* is done with the goal to achieve counseling for both HIV positive and negative results. Then the next step of action which is the final is *Referral and linkage* to other appropriate health services (Mitsuyasu, 2015). These four elements make up the minimum service package of HTC, which is aimed at en-

abling the clients to understand their HIV risk, take the HIV test, come up with a risk reduction plan, and take up appropriate referrals (MOH/NASCOP, 2016).

2.6 HIV and AIDS management/ treatment

There's no cure for HIV and AIDS, but many different drugs are available to control the virus. Such treatment is called ART (Australia Federation of AIDS Organisations, 2017). In Kenya, strategies to reduce HIV infection and management of the infected and affected have been scaling up since the declaration of the pandemic as a National disaster in 1999 (Kimani, 2013). ART services were first introduced into the public sector in Kenya in 2003 with only less than 10 health facilities providing treatment**.** The number of facilities increased since then, to 1,405 facilities (including 1,242 public sector facilities) by 2011 (Adido, 2016). The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels and ultimately reduce HIV transmission and to minimize the adverse reactions (NASCOP, 2016).

Care and treatment by use of Antiretroviral (ARV), the medicines often called "HAART" suppresses HIV replication, help prevent new HIV infections, save lives, and provide hope to people and countries as a whole crippled with HIV and AIDS (CDC, 2013). Standard ART, consists of a combination of ARV drugs used to maximally suppress the HIV virus and stop the progression of HIV disease the AIDS (Chigova, 2016). The timing and method of treatment are decided based on the patient's test results (CD4 count, VL and drug resistance) and other existing conditions) (Shahian, 2018). Three years following the introduction of effective ART, mortality, AIDS, AIDS-defining diagnoses, and hospitalizations all decreased by 60 to 80%. But without treatment, the life expectancy of an HIV-infected individual is 9-11 years (Sax, Hirsch & Bloom (Eds), 2018).

All individuals with confirmed HIV infection are eligible to start ART (preferably within 2 weeks of confirmation of HIV status), regardless of their status example: CD4 levels, WHO/clinical stage, age…. or any other criteria provided that the individual is willing and ready to take ART and adhere to follow-up recommendations (MOH/NASCOP, 2016).

2.6.1 Treatment regimen

There are different classes of ART and they act at different stages of the HIV life cycle (Australia Federation of AIDS Organisations, 2017). Each class works at a different stage of the life cycle of HIV infection (Mitsuyasu, 2015). According to (Pietrangelo & Murrell (Ed.), 2018), a national report on HIV/AIDS, "of those people who were on treatment in 2015, 64% were virally suppressed, which equated to 51% of all people in Kenya living with HIV".

2.6.2 Classification of antiretroviral drugs

According to Mitsuyasu, (2015), the classes of anti-HIV drugs include: *Non-nucleoside reverse transcriptase inhibitors (NNRTIs)* turn off a protein needed by HIV to make copies of it. Examples include efavirenz (Sustiva), etravirine (Intelence) and nevirapine (Viramune)***;*** according to Mayo Clinic, (2018); *Nucleoside or nucleotide reverse transcriptase inhibitors (NRTIs)* are faulty versions of the building blocks that HIV needs to make copies of itself. Examples include Abacavir (Ziagen), and the combination drugs emtricitabine/tenofovir (Truvada), Descovy (tenofovir alafenamide/emtricitabine), and lamivudine-zidovudine (Combivir); *Protease inhibitors (PIs)* inactivate HIV protease, another protein that HIV needs to make copies of it. Examples include atazanavir (Reyataz), darunavir (Prezista), fosamprenavir (Lexiva) and indinavir (Crixivan) U.S Department of Health & Human Services, 2018; last but not least, *Entry or fusion inhibitors*, they block the

HIV's entry into CD4 T cells. Examples include enfuvirtide (Fuzeon) and maraviroc (Selzentry) (Tina Shahian, 2018); lastly, *Integrase inhibitors* work by disabling a protein called integrase, which HIV uses to insert its genetic material into CD4 T cells. Examples include raltegravir (Isentress) and dolutegravir (Tivicay) (Australia Federation of AIDS Organisations, 2017).

2.6.2.1 Adult ART first-line regimen

Since the introduction of potent ARV therapy, all preferred regimens, had a combination of: two NRTIs and one NNRTI drug (NASCOP, 2016 and Tsegaye, Wubshet, Awoke &Alene, 2015).

According to Mitsuyasu, (2015) factors to be considered in choosing first-line therapy included: patient willingness to commit to therapy; baseline resistance; efficacy data; tolerability; convenience; co-morbid conditions and consequences of failure (resistance).

Table 2. 1: Recommended first-line adult ART

No.	ART Codes	Drug Regimen Combination (Symbols)
1	AF1A	AZT+3TC+NVP
2	AF1B	AZT+3TC+EFV
3	AF2A	TDF+3TC+NVP
4	AF2B	TDF+3TC+EFV
5	AF3A	d4T+3TC+NVP
6	AF3B	d4T+3TC+EFV
7	AF2E	TDF+3TC+DTG

Source: (MOH/NASCOP, ART Cohort Register: MOH 361B, 2016)

Despite the above drug combinations, a study by Grimsrud, (2015), revealed that, patients using d4T in their drug regimen are at increased risk of LTFU due to the

high rates of side effects. Baseline (first line) ART regimen of patients was also found to be one of the independent predictors of LTFU (Tadesse & Haile, 2014).

2.6.2.2 Adult ART second-line regimen

Second-line drug regimens are ART combination given to patients due to the following reasons: confirmed clinical treatment failure; immunological failure; virologic failure, a new drug available; drug out of stock and other reason. Also, reasons for changing drugs (substitution) includes toxicity, pregnancy, the risk of pregnancy, due to new TB; new drug available; drug out of stock and other reasons (MOH/NASCOP, ART Cohort Register: MOH 361B, 2016).

If in case the first-line treatment failure occurs, a second-line treatment is implemented, utilizing, the two NRTIs not previously used in first-line treatment, as well as one additional protease inhibitor (PI) (Tsegaye, *et al.*, 2015).

Table 2. 2: Recommended second-line adult ART

No.	ART Codes	Drug Regimen Combination (Symbols)
1	AS1A	AZT+3TC+LPV/r
2	AS1B	AZT+ddl+LPV/r
3	AS1C	AZT+3TC+ABC
4	AS2A	TDF+3TC+LPV/r
5	AS2B	TDF+3TC+ABC
6	AS2C	TDF+3TC+AZT
7	AS2D	TDF+ABC+LPV/r
8	AS2E	TDF+AZT+LPV/r
9	AS3A	ABC+ddl+LPV/r
10	AS4A	d4T+3TC+LPV/r
11	AS4B	d4T+3TC+ABC
12	AS5A	ATV+3TC+AZT

Source: (MOH/NASCOP, ART Cohort Register: MOH 361B, 2016)

Table 2. 3: Other adult ART regimen

1	AQ1A	ABC+3TC+NPV
2	AQ1B	ABC+3TC+EFV
3	AQ1C	ABC+3TC+LPV/r

Source: (MOH/NASCOP, ART Cohort Register: MOH 361B, 2016)

2.6.2.3 Adult ART third-line regimen

Clinical Guideline, (2015) reported that "The third line drug regimen was often associated with cumulative toxicity, their maintenance in third-line ART may not be optimal and may involve increased pill burden and risk of drug interactions a major contributing factor of LTFU. The drugs in this class combination include:

AT1A=RAL + 3TC + DRV + RTV (Raltegravir + Lamivudine + Darunavir + Ritonavir) AT1B=RAL + 3TC + DRV + RTV + AZT (Raltegravir + Lamivudine + Darunavir + Ritonavir + Zidovudine).

AT1C=RAL + 3TC + DRV + RTV+TDF (Raltegravir + Lamivudine + Darunavir + Ritonavir + Tenofovir)

AT2A=ETV + 3TC + DRV + RTV (Etravirine + Lamivudine + Darunavir + Ritonavir) AT2X=All other 3rd line Adult regimens (all other Adult patients on 3rd line regimens not listed above (coded and un-coded) (MOH/NASCOP, 2016).

Regimen substitutions either to second or third line during the follow-up period, has been seen to contribute a lot to LTFU and the reason provided for substitution includes; adverse drug reactions as patients become concerned about side effects and the effectiveness of new medication, causing to seek other treatment options (Berheto, *et al.,* 2014)**.**

2.6.3 Importance of treatment

It is important to get on and stay on HIV treatment in order to protect own health (Mehari, *et al.,* 2017). HIV treatment is important because it helps your body fight HIV, and it will be achieved only with good adherence, which means staying on your

treatment plan (Sax, *et al.*, 2018). Most people living with HIV who don't get treatment eventually develop AIDS (Pietrangelo & Murrell (Ed.), 2018). If left untreated, HIV attacks your immune system and can allow different types of life-threatening infections and cancers to develop especially if the CD4 cell count falls below a certain level (CDC, 2017).

According to Clinical Guideline, (2015) monitoring people on ART is important to ensure successful treatment, identify adherence problems and determine whether ART regimens should be switched in case of treatment failure thus, reducing the accumulations of drug resistance mutations and improving clinical outcomes.

2.6.4 Adherence to ART

Adherence to ART is critical if patients are to achieve and maintain undetectable VL and avoid preventable opportunistic infections (Susich, *et al.,* 2016). According to NASCOP/MOH, (2018), before initiating therapy, adherence must be made part of the patient's routine care. This will enable one to learn about patient's health history, beliefs and attitudes on HIV, which may be potential barriers to compliance (Mayo Clinic, 2018). This is because the virus has a very high replication and mutation rate; NNRTI has broad class resistance: when resistance to one drug develops; often resistance is developed to all the drugs in that class; PI can retain activity to other drugs within the class following failure depending on how long the patient remains on the failing PI-containing regime (Jamaica Ministry of Health, 2017). Meloni et. al, (2014), reported that, multiple studies previously used Prescription refill timeliness as a measurement of adherence and proven to be a strong surrogate to HIV care.

On the other hand, non-adherence to ART could result in adverse events and enormous costs for healthcare delivery systems (Thompson, *et al.,* 2012). Also, the report further indicates that, a significant proportion of all hospital admissions among

PLWHA were due to drug non-adherence (Ibid). Therefore, promoting optimal adherence to ART and optimal treatment regimens is critical to maintaining virological suppression and thereby ensuring the global success of ART.

2.6.5 Side effects of antiretroviral

People who use ARV might have side effects such: high blood sugar; nausea; high cholesterol; liver or kidney damage; anemia….and rash (Australia Federa as tion of AIDS Organisations, 2017). Another possible side effect is resistance to medication, which means the medication isn't working as well as it should (Mitsuyasu, 2015). Resistance comes as a result of not retaining the patient in care attributed by LTFU (WHO, 2014). Lowering the chance of resistance to medication, by not missing doses and by using a combination of medications instead of just one (Pietrangelo & Murrell (Ed.), 2018)

2.7 Preventive measures of HIV

There are several measures that one has to take into account to prevent self from getting infected. They include: *Getting tested and knowing your partner's HIV status*- talking to your partner about HIV testing and get tested before you have sex (Pietrangelo & Murrell (Ed.), 2018; the Federal Democratic Republic of Ethiopia, (2014) reported that *having less risky sex* is a preventive measure for HIV transmission. This is because HIV is mainly spread by having anal or vaginal sex without a condom or without taking medicines to prevent or treat HIV; *use of condoms*- it should be worn correctly every time you have sex…(ibid); *limiting the numbers of sexual partners*- because the more partners you have, the more likely that you are to have a partner with HIV whose HIV is not well controlled or to have a partner with a sexually transmitted disease (STD). Both of these factors can increase the risk of

HIV transmission. If you have more than one sexual partner, get tested for HIV regularly (U.S Department of Health & Human Services, 2018); Saumu, (2017) *getting tested and treated for STD*- insist that your partners get tested and treated too. Having an STD can increase your risk of becoming infected**;** *pre-exposure prophylaxis (PrEP)* - PrEP is an HIV prevention option for people who don't have HIV but who are at high risk of becoming infected with HIV. PrEP involves taking a specific HIV medicine every day (CDC, 2017); *do not inject drugs*- but if you do, use only sterile drug injection equipment and water and never share your equipment with o with HIV or spreading it to others; *talking to your health care provider about Post*-exposure prophylaxis (PEP) - it is the use of HIV medicines to reduce the risk of HIV infection soon after a possible exposure to HIV. PEP may be used, for example, after a person has sex without a condom with a person who has HIV or after a health care worker is accidentally exposed to HIV in the workplace. To be effective, PEP must be started within 3 days after the possible exposure to HIV. PEP involves taking HIV medicines each day for 28 days in *Prevention of mother-to-child transmission of HIV (PMTCT)* **(**Gomez, & Kouzouian, 2018). According to CDC, (2017), women with HIV take HIV medicines during pregnancy and childbirth, to reduce the risk of passing HIV to their babies. Their newborn babies also receive HIV medicine for 4 to 6 weeks after birth. It should be noted that adherence to ART= viral suppression and in turn less risk of HIV transmission. Finally, protection against HIV and other STIs for the unmarried is to abstain from sexual intercourse until the marriage to one uninfected partner; therefore, getting tested for HIV before marriage is a must (Kimani, 2013).

2.8 Loss to follow up (LTFU) on ART

According to NASCOP, (2016), follow-up of patients on ART, is determined by the duration the patient is on treatment, how well they understood the treatment and their response to ART. A reasonable follow-up schedule for most patients was: 2 weeks and 4 weeks after ART initiation, then monthly until viral suppression is confirmed… (Ibid). Those who follow the treatment schedule, taking their daily ART medications to the later, have successfully achieved their viral suppression and their quality of lives have been improved reaching the WHO goal standard and aiming at achieving the SDGs on compacting HIV and AIDS, Malaria and Tuberculosis by 2030 (NASCOP/MOH, 2018). Failure to observe the appointment dates as stated or as provided by the caregiver, will lead to unscheduled visits (MOH/NASCOP, 2016), and subsequently may lead to LTFU.

According to Berheto, *et al.*, (2014), the time to LTFU was calculated in months by time interval between the dates of ART initiation to drop out, (a period exceeding three months or longer from the last attendance when the patient did not return to the facilities for the usual refill and not yet classified as 'dead' or 'transferred-out'). This definition also used by WHO & NASCOP, therefore in this study; the researcher will adopt this definition of LTFU.

The LTFU patients are those patients who cannot be easily reached out in most of the cases, because they may have decided to be out of care, either voluntarily or involuntarily (Berheto, *et al.,* 2014). Providers typically do not know whether a lost patient has died, transferred to a new treatment site or unable to stay in care due to various unknown reasons (Seifu, *et al.*, 2018).

Unstable patients require closer follow-up to address whichever issues are leading them to be categorized as unstable. They have any of the following: On their current

ART regimen for < 12 months; any active OIs (including TB) in the previous 6 months; poor or questionable adherence to scheduled clinic visits in the previous 6 months; most recent VL ≥ 1,000 copies/ml; has not completed 6 months of IPT; Pregnant or breastfeeding; BMI < 18.5; While *Stable patients,* require less frequent facility follow-up, with up to six months between clinic appointments. They must have achieved ALL of the following: On their current ART regimen for ≥ 12 months; no active OIs (including TB) in the previous 6 months; adherent to scheduled clinic visits for the previous 6 months; most recent VL < 1,000 copies/ml; has completed 6 months of IPT; non-pregnant/not breastfeeding; BMI ≥ 18.5 and/or age ≥ 20 years (National AIDS & STI control program, 2016).

2.9 Incidence rate of LTFU

According to Tadesse & Haile, (2014), the time event of LTFU increases as the time spent on ART increases. The average duration of LTFU in a study conducted at Coe d'Ivoire was 466 days with a standard deviation of 279 days (Kan, *et al.*, 2014). Berheto, *et al.*, (2014), revealed that, the cumulative incidence of LTFU was 8.8 (8.1-9.6) per 1000 person-months. While, Grimsrud, (2015) found out that, the over-all LTFU rate in South Africa was 7.9 per 100 person-years, while in Kisumu-Kenya Ojwang', *et al.*, (2016), reported an overall incidence rate of LTFU of 52.9 per 100 person-years which was much higher. A study in South Africa also revealed that the risk of LTFU is usually highest during the first 6 months after starting ART (Honge, *et al.*, 2013 and Berheto, *et al.*, 2014). The later author giving an explanation that there was inadequate counseling and tracing of patient's also limited coverage of network and a higher cost of calling.

2.10 Predictive factors of LTFU in ART

Studies conducted on Predictors of LTFU in ART, have documented the following predictors: Socio-demographic predictors; clinico -immunologic predictors and health system-related factors to be significantly associated with LTFU.

2.10.1 Socio-demographic predictors

The following are some of the socio-demographic predictors found to be statistically significant to LTFU: age; gender and residence.

2.10.1.1 Age

Age at ART initiation is reported to be a significant factor of LTFU. De La Mata, *et al.,* (2018) reported that, patients aged 50 years and above were less likely to be LTFU compared to younger age (30 years or below). According to Megerso, *et al.,* (2016) and Eguzo, *et al.,* (2015), patients who were below 25 years old, were more likely to be LTFU compared to older generation. These findings were also similar to that of Mugisha, *et al.*, (2014); Clouse, *et al.,* (2014) and Agwu, *et al.,* (2016), where they reported some associations between younger age and LTFU. The explanation provided was that, this group experience fear of stigma and discrimination, and dependent on others, where being independent members could make them be more mobile as compared to the older population (Dewi, *et al.,* 2015).

2.10.1.2 Gender

A study by Megerso, *et al.,* (2016) and Clouse, *et al.,* (2014) reported significant association between gender and LTFU among adults on ART. Tadesse & Haile, (2014) and Arnesen, *et al.,* (2017) stated that, men's nature of work, involves traveling, sometimes for long distances which keeps them away from their home. In addition, male patients drop out either because of the history of high viral load, hab-

its like drinking alcohol, smoking, and over-representation, which is dominance (Magala, Tapati, & Nalubega, 2018).

On the other hand, Tweya, *et al.,* (2018) and Eguzo, *et al.,* (2015) pointed out that, females were at higher risk of LTFU than their counterpart but no explanation was provided for the same. But Berheto, *et al.,* (2014) found equal chances between male and female.

2.10.1.3 Residence

Various studies conducted in various parts of the continent, identified different residential settings to be associated with LTFU. Salema, (2015) revealed that, LTFU occurs mainly in clinics with many patients compared to clinics with fewer patients. Dessalegn, Tsadik, & Lemma, (2015) and Mecha, *et al.,* (2016) reported that patients' residing in urban areas had a higher chance of becoming LTFU compared to their counterparts but no explanation was given.

In addition, receiving HIV care in a rural setting was associated with increased risk of LTFU among ART patients (Tweya, *et al.,* 2018 and Megerso, *et al.,* 2016). This was because, rural setting commonly experiences poor patient tracing as a result of not reporting the risk of death events, was a major contributor of LTFU (Berheto, *et al.,* 2014). Similally, Megerso, *et al.,* (2016), reported that, rural residents could get lost to treatment, due to various factors such as level of patient's awareness of the treatment schedules, and social stigma". This finding was also supported by (Tweya, *et al.,* 2018) that, poor adherence to clinic appointments and receiving HIV care in rural facilities were associated with increased risk of LTFU among ART patients.

2.10.2 Clinico-immunologic predictors

Saumu, (2013) reported several clinico-immunological factors to have contributed to LTFU in ART. These include: CD4 count; Viral load count; WHO staging; Isoniazid prophylaxis therapy (IPT); TB co-infection; body mass index and ART regimen

2.10.2.1 CD4 count

The highest rates of LTFU were observed in patients initiating on ART with a CD4 cell count below 200 cells/mm^3 (Grimsrud, 2015), this was as a result of the advancement in disease, that could have ended up to death (Megerso, *et al.*, 2016). In addition, Arnesen, *et al.*, (2017) reported that "Lack of clinical response to treatment may reinforce stoppage of ART, further decreasing the effectiveness of therapy and resulting in a poor clinical response including LTFU.

Whereas patients with higher CD4 cell counts at a different setting, are more likely to early disengagement from care and risk of LTFU, if they do not directly experienced the benefits of ART on their personal health (Grimsrud, 2015 and Mecha, *et al.*, 2016).

2.10.2.2 VL count

According to Arnesen, *et al.*, (2017) a patient with VL of above 1000 (STF) were more likely to LTFU. While, Meloni., *et al.*, (2014) reported significant assocation between viral suppression (LDL), with retention in care. In addition, a study conducted by Agwu, *et al.*, (2016), reported some associations between higher VL (STF) with LTFU but no explanation was provided.

2.10.2.3 WHO staging

According to Saumu, (2013), patients in WHO stage 3 or stage 4, were more likely to be LTFU than those who were WHO stage 1. This finding was similar to the study conducted in Ethiopia by Megerso, *et al.*, (2016), but no definite reason was provided. Patients at stage 2 of the WHO classification were significantly associated with LTFU (Kan, *et al.*, 2014), while majority with WHO stage I, were reported LTFU by Grimsrud, (2015). Contrary to the above, patients in WHO stage 3 or 4, had a better chance of retention, due to their increased health-seeking behavior (Berheto, *et al.*,

2014). Unlike Mugisha., *et al.*, (2014), reported no association between WHO staging and LTFU.

2.10.2.4 Isoniazid prophylaxis therapy (IPT)

Patients, who are non-IPT users, were more likely to be LTFU than their counterparts because IPT users benefit from reinforced counseling hence better follow-up (Berheto, *et al.*, 2014 and Dessalegn, *et al.*, 2015). Contrary to those findings, Assemie, *et al.*, (2018), reported some association between IPT and LTFU, but no justification was provided.

2.10.2.5 TB co-infection

A TB positive patient is at higher risk of LTFU than a TB negative patient, either due to, overlapping toxicity in using any multidrug therapy (Tadesse & Haile, 2014). But according to Berheto, *et al.*, (2014), there was no association between TB and LTFU.

2.10.2.6 Body mass index

The rate of LTFU was significantly associated with a baseline body weight of patients as provided by other studies. A patient with weight above 60 kilograms at baseline had a lower risk of LTFU than one below 40 kilograms, because patients with normal weight would like to maintain their good wellbeing (Tadesse& Haile, 2014). Contrary, patients with no weight gain at six months were more likely to discontinue treatment compared to those with weight gain (Kan, *et al.*, 2014). But, those patients with BMI less than or equal to 18.4 at ART initiation were significantly associated with LTFU (Tweya, *et al.*, 2018).

2.10.2.7 ART regimen

A study conducted by Tadesse & Haile, (2014) reported that, the baseline ART regimen of patient is an independent predictor of LTFU. The study further revealed that, patients who take AFIA (AZT+3TC+NVP) regimen had a higher chance of LTFU compared to those individuals using AF3A (d4t +3TC+NVP). There was also an

increased risk of LTFU among patients on d4T in their drug regimens, due to the high rates of side effects Grimsrud, 2015). With no explanations, patients who take AF2B (TDF+3TC+EFV) were more likely to be LTFU in ART compared to those who take AF1A (AZT+3TC+NVP) (Megerso, *et al.*, 2016).

2.10.3 Health system related factors associated with LTFU

According to Tuhadeleni, (2016), health care workers (HCW) perceptions play a role in LTFU. Megerso, *et al.*, (2016) pointed out that, practitioners' work overload, contributed a lot to: suboptimal quality of health care; poor documentation; record keeping problems which have been identified to accelerate LTFU.

A study conducted by Saumu, (2017) suggested that, missing patient records and poor defaulter tracing systems, may misclassify some patients as LTFU when in fact they were not. In addition, inadequate staffing, stigma and inadequate funding to facilitate physical tracing, contributed to LTFU. This finding was supported by Seifu, *et al.*, (2018) suggesting that patients who did not disclose their HIV/AIDS status more likely to withdraw from the treatment program as compared to their counterparts. In addition, poor adherence to clinic appointments by patients due to poor or wrong documentations was some reasons for increased cases of LTFU (Tweya, *et al.*, 2018).

Without a proper recording of the next appointment visit, leads to increased likelihood of patients becoming LTFU compared to their counterpart. This was supported by studies conducted in Northwest Ethiopia, Malawi and Kenya, which reported that LTFU happens because a clinician fails to record the next appointment date on the patient's card. In addition, health provider might forget to provide written or verbal information for the patient about the specific date of the next visit and other related

messages as well, hence the probability of returning back to the ART clinic for such kind of patients' will be unlikely (Seifu, *et al.,* 2018).

2.11 Summary of literature review

The frequent increasing rate of LTFU in Nakuru County Referral-RVPGH and rural facilities as documented in the EMR and ART cohort registers, needs to be identified and discern the "*true*" LTFU. This is because, we do not know whether the patient documented as LTFU in those facilities, end up to be transferred-in in the same facility or other facilities or not. Therefore, this study will try confirming out the "true LTFU" and also identifying the characteristics (predictors) of those patients who were LTFU. Identifying those predictive factors of LTFU would give better knowledge and understanding that will aid in making recommendations to the health authorities of Nakuru County, help them in finding and planning for innovative remedy to curb LTFU. Consequently, increase retention rate on care, which will help in improving the patient outcomes (quality of life and patient longevity) and lastly achieving the second and third UNAIDS implementation strategies.

CHAPTER THREE

METHODOLOGY

3.1 Overview

Methodology chapter has been organized in the following subtopics: research design, study area, study population, inclusion and exclusion criteria, sampling methods, data collection, ethical consideration, and data analysis.

3.2 Study design

This was a retrospective cross-sectional study involving analysis of extracted routine CCC data on patients who were on ART and conducting interviews with heads of departments. Thus, mixed methods were used for data collection.

3.3 Study area

This study was conducted in Nakuru County, which is one of the 47 Counties in the Republic of Kenya lying within the Great Rift Valley and borders eight other counties namely: Kericho and Bomet to the west, Baringo and Laikipia to the north, Nyandarua to the east, Narok to the southwest and Kajiado and Kiambu to the south. It covers an area of about 7,495.1 Km² and is located between Longitudes 35.41 º East or 35º 24’ 36” East and 36.6 ºEast or 36º 36’ 0” East and Latitude 0.23º North or 0º 13’ 48” North and 1.16º South or 1º 9`36” South (Courtesy of County Meteorological Office). The County headquarters is Nakuru Town and has 11 Sub-counties (Constituencies) namely; Nakuru East, Nakuru West, Nakuru North, Subukia, Naivasha, Gilgil, Molo, Njoro, Kuresoi North, Kuresoi South, and Rongai, with an estimated population of 2,162,202 people as in the year 2019.

The population served by the county health system is more than the estimated the neighboring counties, seek health care services in the county's health facilities. The

county currently has a total of 674 Health facilities, including; 26 hospitals, 630 primary care facilities and 2 community health units (County Government of Nakuru, 2018). The study was conducted in the RVPGH and two rural public health facilities (Kapkures and Rhonda Health Centres) of Nakuru West Sub-County.

3.4 Study population and target population

The study populations were the records of HIV and AIDS positive patients who were initiated on ART at CCC/HIV clinics within Nakuru West Sub-County MOH facilities. The patients currently on ART by the end of December 2018 were 11896, from the fourteen health facilities offering CCC services, where 93% are adult patients, and over 80% of the patients were attending CCC clinic at County Referral Hospital-RVPGH (County Government of Nakuru, 2018). The researcher concentrated on County Referral hospital and the rural facilities. The target population were records of HIV and AIDS patients aged 15 years and above in the selected facilities and who were initiated on ART between 1st January 2016 to 31st December 2018, where they were followed up for three years to determining their outcomes. In addition, the key informants, at the CCC/HIV clinic were also included for an interview.

3.5 Inclusion and exclusion criteria

3.5.1 Inclusion criteria

- Records of all Patients who were initiated on ART, aged 15 years and above, attending CCC clinic in the selected facilities of Nakuru West Sub-County.
- The in-charges of different departments of the CCC/HIV clinic in the selected facilities.

3.5.2 Exclusion criteria

- All the records of patients who transferred out and continued ART elsewhere.
- Those patients whose files indicate they were enrolled but died.

- Those patients whose required data's are missing in the file e.g. the age and year of ART initiation.

3.6 Sampling method

3.6.1 Sampling technique

Initially, the study used purpose sampling whereby Nakuru County was selected due to its decreasing rates of viral suppressions in the County. Then, multi-stage sampling method was used to group the facilities offering CCC services according to MOH public service delivery both urban and rural. Purposely, the RVPGH was identified, to represent urban facilities because of its high volume of patients (over 80% of all HIV patients) on ART in the county and the only two rural facilities (Kapkures and Rhonda health centers), for they had high records of patient drop-out rates (County Government of Nakuru, 2018). The researcher then analyzed the records by filtering the ART cohort register first and patients' file according to their entry time to the follow-up. Next, the researcher using age as eligibility criteria later entered the data in the prepared Excel spread-sheet. In addition, the researcher used census inquiry method whereby all the records of patients who had passed the eligibility criterion and those who successfully traced from LTFU, including all the key informants were included in the study. The outcome variable was LTFU.

3.6.2 Sample size

The researcher utilized 1131 study participants extracted from EMR, ART cohort register and patients' records including 9 staffs working at the CCC/HIV clinic. Census inquiry technique was used, where all the eligible subjects were included in the study. Table 3.1, illustrates how the target population was identified.

Table 3. 1: Nakuru West identified public health facilities offering CCC services

3.7 Data collection tool

Facilities	Data collection tool	Target population
Nakuru County referral hospital (RVPGH)	Data abstraction form Key informant interview guide	Patients review 768 CCC In-charge (I/C) 1 Defaulter tracer I/C 1 Adherence counselor I/C 1
Rural facilities Kapkures Health Center	Data abstraction form Key informant interview guide	Patient review 202 CCC I/C 1 Defaulter tracer I/C 1 Adherence counselor I/C 1
Rhonda Health Center	Data abstraction form Key informant interview guide	Patient review 161 CCC I/C 1 Defaulter tracer I/C 1 Adherence counselor I/C 1
Total patient reviewed Key informants		1131 9
GRAND TOTAL		**1140**

Mixed method of data collection (quantitative and qualitative approach) was used to identify the predictors of LTFU among all patients who were initiated on ART with the aid of the key informant guide to explore the perception of the key informants, regarding the main barriers, preventing patients from attending follow-up visits for HIV care.

3.7.1 Development of the tool

An abstraction checklist form was used for recording information extracted from the ART register. The form was modified from the existing national standardized ART

Cohort register employed by the ART clinic (MOH/NASCOP, 2016). The tool was used to monitor the socio-demographic and clinical characteristic of all the records of patients: age; sex; residence; ART regimen received and reason of substitution; base-line and subsequent CD4 counts; VL count; WHO stage; TB status and lastly patient outcome. Occupation, education and marital status as a socio-demographic characteristic were excluded in the study since the ART register does not cover/capture the above information.

During interview session, modified pre-structured questions were used as a guiding tool to interview the key informants. The tool was derived from the Kone consultings, (2017), which was used to interview key persons taking care of brain injury patients. It was then adapted and modified by the researcher to suit the study.

3.7.2 Data collection procedure

The researcher employed three research assistants comprising of one nurse, one clinical officer, and one records officer, working in CCC/HIV clinic. They assisted in collecting the data by filling in the data abstraction form in the EXCEL spread-sheet and taking notes during the key informant interview session for one month (May 2019). They were trained for a minimum of two days on; the scope of the study, use of data abstraction form in the EXCEL using ART cohort register following the inclusion criterion, and the ethical aspects of the research. The researcher supervised the entire processes. The data obtained was subjected for analysis and the results generated were used to meet the objectives; one, two and three.

3.8 Data Management

Before the data entry was conducted, verification and validation of data was done regularly and at the end of the process with was then resolved with the researcher and

research assistants. The information obtained were treated as confidential where password only known by the researcher.

3.9 Data analysis

First, data were entered, and then exported in SPSS version 21.0. Data were cleaned and categorical variables were labeled prior to data analysis. Survival data analysis was done using cox regression analysis. Kaplan Meier (KM) curves were drawn to estimate the probability of LTFU and proportionality hazards assumption was checked for covariates intended to be included in the final cox model. Log rank test was used to select categorical predictors. Decision was based on a p-value of 0.07 in univariate analysis for potential candidate variables selection to be considered in the final model. Variables with a p-value of less than 0.05 (5%) were considered as statistically significant predictors of LTFU after interaction effects and model diagnostics checked. Finally, the Adjusted Hazard Ratio and 95% CI were interpreted for the statistically significant predictors of LTFU in the final cox model.

The written interviews were analyzed using standard qualitative method, to identify content and themes. This process included presumptive focused coding where central concepts and categories were identified and the researcher made claims on evidence in the data following important theme identified.

3.10 Ethical consideration

The study proposal was approved and cleared by Masinde Muliro University of science and technology (MMUST) institutional ethics review committee (IERC). A research authorization permit was obtained from National Commission for Science and Technology (NACOSTI) and an official data collection permission letter was ob-

tained from the Chief Officer of Health (COH) Nakuru County through IERC and study facilities.

The research was guided by the ethical principles throughout the study period to include;

Respect of persons- where the written informed consent was obtained voluntarily from the key informants upon consenting and ensuring anonymity of their data during interview with no linkage to information provided.

Beneficence- the researcher was at all-time practicing to do well and maximize all the data obtained

Maleficence-Rights to withdraw from the interview were explained with no punishment/penalty in mind.

Justice-the researcher ensured reasonable non exploitative and carefully considered procedures with fairness as well as treating all data as private and confidential, in addition all the data were to be stored safely. Debriefing was done before and after data was collected.

CHAPTER FOUR

RESULTS

4.1 Overview

The results chapter is organized and presented as per the objective of the study. The study aimed at investigating the predictors of LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities.

4.2 Baseline Socio-demographic characteristics/ incidence rate of LTFU

4.2.1 Baseline Socio-demographic characteristics of study participants

Table 4.1 shows the characteristics of patients followed up at the Comprehensive Care Centers in Nakuru west Sub-County. A total of 1,131 cases, were reviewed over three years study period in the three health facilities. The total number of years of follow-up was 2092.4 with LTFU incidence rate of 161.1 (95%CI: 144.7 – 179.2) per 1000 PYs. Among 1131 patients followed, majority were females 810 (71.6%) compared to their counterparts. Cases of LTFU were 337 (29.8%) out of 1131 patients. Most of the LTFU (36.5%) among the males were aged 35 – 44 years while the age groups among females experiencing higher LTFU (46.8%) were younger and aged between 25 – 34 years. Median age for male was higher (39.5 years) than that of females (33.0 years). A comparatively higher proportion of females who were LTFU (43.4%) visited rural facilities than males (37.7%). On the contrary there were more males LTFU cases (30.1%) than females (21.7%) who visited urban facility.

Table 4. 1: Baseline Socio-demographic characteristics of patients

Variables	Male		Female	
	LTFU	Non-LTFU	LTFU	Non-LTFU
Age group in years	n (%)	n (%)	n (%)	n (%)
15 – 24	5 (4.8)	12 (5.5	28 (12.0)	54 (9.4)
25 – 34	31 (29.8)	57 (26.3)	**109 (46.8)**	**222 (38.5)**
35 – 44	**38 (36.5)**	**79 (36.4)**	61 (26.2	192 (33.3)
45 – 54	18 (17.3)	50 (23.0)	30 (12.9)	66 (11.4)
≥55	12 (11.5	19 (8.8)	5 (2.2)	43 (7.5)
Median age (Range)	**39.5** (16.0 - 70.0)	40.0 (15.0 – 73.0)	33.0 (18.0 – 62.0)	35.0 (15.0 – 76.0)
Facility Type				
Urban	**67(30.1)**	156 (69.9)	118 (21.3)	427 (78.7)
Rural	37(37.7)	61 (62.3)	**115 (43.4)**	150 (56.6)

4.2.2 Incidence rate of LTFU among adult patients on ART

Table 4.2 shows the distribution of incidence rate per follow-up person years of LTFU patients. The overall incidence rate of LTFU among 337/1131 patients confirmed LTFU, was 161.1 (95%Cl: 144.7 – 179.2). Within the first year of ART initiation, 259/337 (76.9%) patients were LTFU contributing to an incidence rate of 418.7 (95%Cl: 370.6 – 472) per years of follow-up, suggesting a greater fallout rate of patient in our selected facilities soon after ART initiation. The proportion of LTFU declined with time in ART.

Table 4. 2: LTFU person-years of follow-up by year

Year	N	LTFU Rate per 1000 PYs	95%CI
1	259	418.7	370.6 – 472.9
2	47	30.6	23.0 – 40.8
3	31	1.3	0.9 – 1.9
Overall LFTU	337	161.1	144.7 – 179.2

From figure 4.1, the overall survival probability of ART patients during the start of ART in the study period was equal to 1. The figure shows a drastic fall of survival probability of patients within the first month and by the end of 3 months, 50% of them had experienced an event (LTFU). There was a decline in LTFU in the subsequent months reaching the lowest point a survival probability of 0.06.

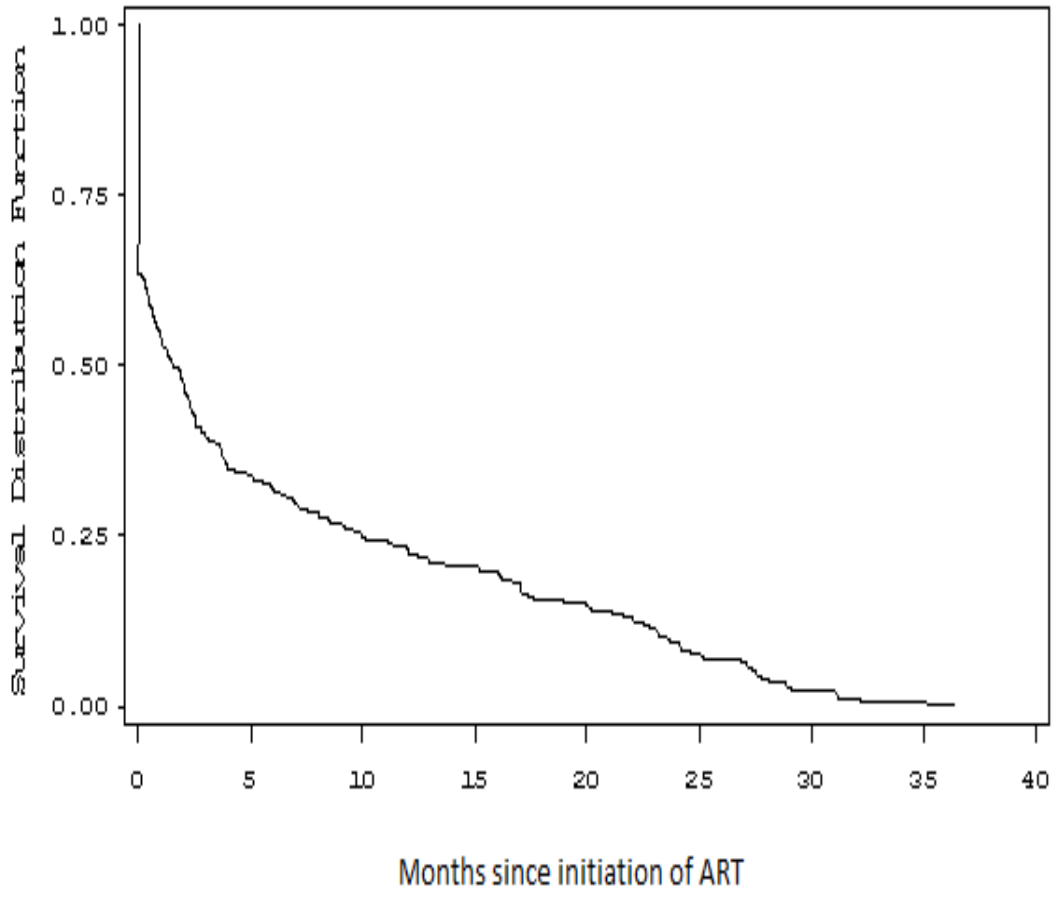

Figure 4. 1: Overall Survival probability of patients initiated on ART and the event of occurrence

4.2.2.1 LTFU person-years of follow up

Table 4.3 presents the incidence rate of LTFU per person's years of follow-up in relation to different variables. The age group with the highest incidence rate was 25 – 34 years with 192.5 new cases per 1000 person years. The incidence rate by gender was higher among males (184.0 per 1000 person years) compared to females (152.6 per 1000 person years). Results also show lower incidence rate for urban patients (122.0 per person years) versus rural patients (264.0 per 1000 person years).

Equally, a higher incidence rate was posted among patients with WHO stage 3 and 4 (239.9 per 1000 person years) in contrast to those in stage 1 and 2. With regard to IPT, patients who were non-IPT register a higher incidence rate (413.3 per 1000 years) than their counterparts on IPT (31.1 per 1000 person years). Patients with TB co-infection compared with those who had no TB were leading in LTFU incidence rate (206.2 per 1000 person years). Incidence rates for cases with low CD4 counts (225.8 per 1000 person years) or those who were on AF2B (TDF+3TC+EFV) ART regimen (182.2 per 1000 person years) were higher than those of their counterparts. Conversely, incidence rates for cases with low BMI (124.4 per 1000 person years) or low VL (79.7 per 1000 person years) were lower than their counterparts.

Table 4. 3: LTFU person-years of follow-up

Variable	N	LTFU Rate per 1000 PYs	95% CI	
			Minimum	Maximum
All cases of LTFU	337	161.1	144.7	179.2
Age groups				
15 – 24	33	181.1	128.8	254.8
25 – 34	**140**	**192.5**	163.1	227.2
35 – 44	99	141.0	115.8	171.7
45 – 54	48	152.9	115.3	203.0
≥55	17	101.7	63.2	163.6
Gender				
Male	104	**184.0**	151.8	223.0
Female	**233**	152.6	134.2	173.5
Facility Type				
Urban	**185**	122.0	105.6	140.9
Rural	152	**264.0**	225.2	309.4
WHO Staging				
III & IV	73	**239.88**	190.71	301.73
I & II	**264**	147.64	130.86	166.57
IPT				
Yes	43	31.1	23.1	42.0
No	**294**	**413.3**	368.7	463.4
TB Status				
Yes	13	**206.2**	119.7	355.1
No	**324**	159.6	143.2	178.0
BMI				
< 18.4	106	124.4	102.8	150.5
≥ 18.4	**231**	**186.3**	163.7	211.9
CD4 Count				
< 200	**249**	**225.8**	199.5	255.7
≥ 200	88	88.9	72.1	109.6
VL				
Low	109	79.7	66.0	96.1
High	**228**	**314.8**	276.5	358.4
ART Regimen				
AF2B	**305**	182.2	162.9	203.8
AF2E	11	34.1	18.9	61.51
Other	21	**219.6**	143.2	336.8

4.2.3 True LTFU patients traced from the documented LTFU

Overall, 1131 patients were enrolled and started on ART at the County Referral Hospital and the two rural facilities (Kapkures and Rhonda health center's) during the study period. Upon reviewing the Electronic Master facility and ART Cohort Registers, 407 patients were registered has LTFU. This means that, they were not able to be tracked by any means. The researcher tried to confirm the actual, "True" LTFU through telephone calling and the findings obtained were as presented in figure 4.2. The researcher then used the actual "true" LTFU during data analysis.

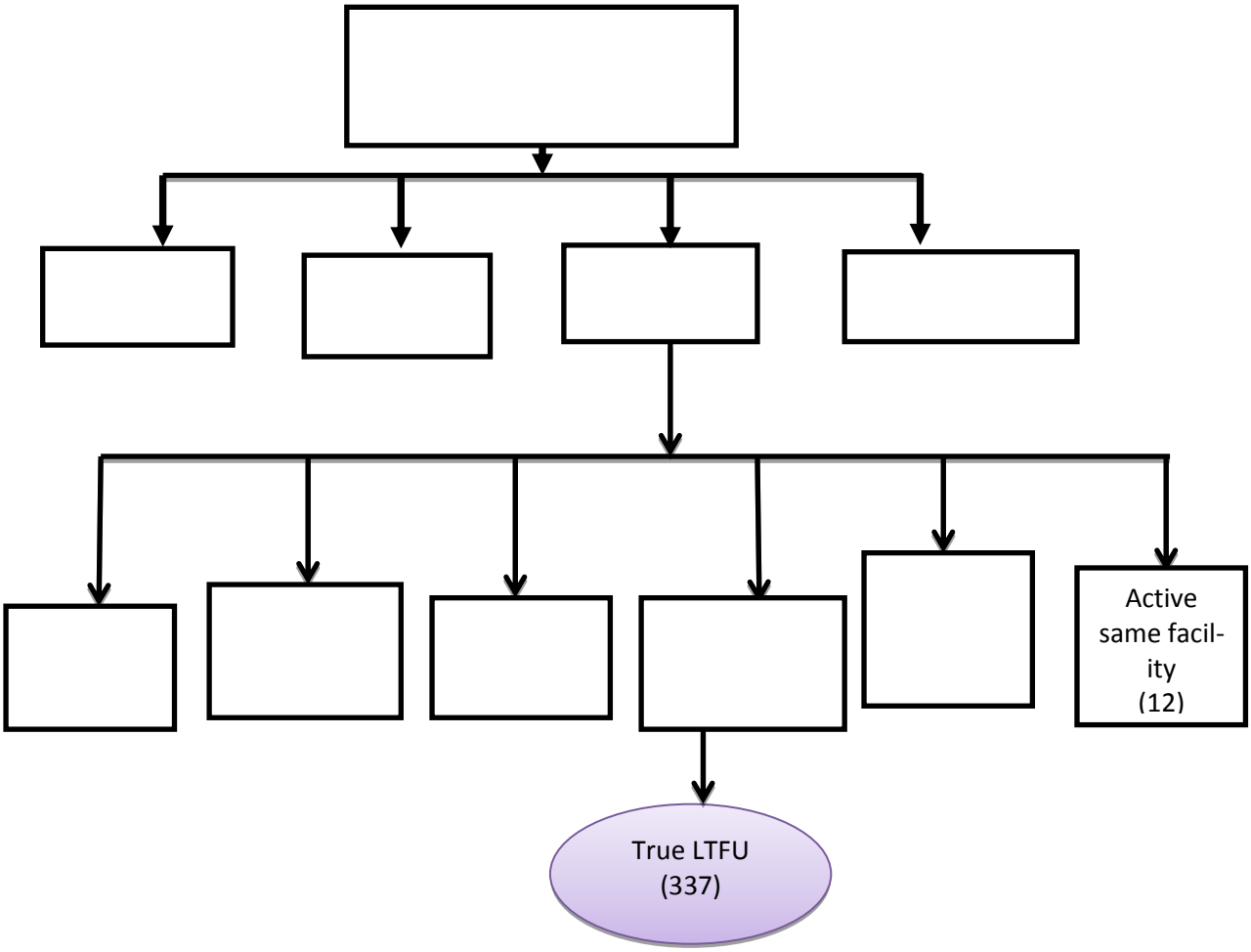

Figure 4. 2: Flow diagram on patients outcomes, documented vs actual (true LTFU)

4.2.4 Patient factors influencing LTFU

The median LTFU time in study participants aged less than 35 years is 0.15 (95%CI: 0.08 – 0.23) compared to those aged 35 years and above with median LTFU time of 0.11 (95%CI: 0.03 – 0.19) as presented in Table 4.4. Log rank test for a difference in the survival curves of the two age groups has an associated p value of 0.49. This suggests that there is no evidence that difference in the LTFU time experience of the two age groups is significantly different.

There was a significant association between gender and LTFU. More females (n=233) than males (n=104) experienced LTFU. For males LTFU median time was 0.06 (95%CI: 0.00 – 0.16) compared with females with a corresponding value of 0.18 (95%CI: 0.08 – 0.25) and a p value of 0.02 confirming significant differences in hazard ratios.

A comparison on LTFU between urban and rural facilities was made as illustrated in table 4.3. Results show a significant difference in LTFU median time experienced by patients in urban facilities (AHR: 0.02; 95%CI: 0.00 – 0.05) and rural facilities (AHR: 0.58; 95%CI: 0.36 – 0.76). Urban facilities reported more case of LTFU (n=185) as opposed to rural facilities (n=152). LTFU median time was significantly different between the two groups ($p < 0.0001$).

Table 4. 4: Adjusted Hazard ratios of study participants

Variable	N	Adjusted Hazard ratio	95%CI	P value
Age groups				
<35	173	0.15	0.08 – 0.23	0.49*
≥35	**164**	0.11	0.03 – 0.19	
Gender				
Female	**233**	0.18	0.08 – 0.25	0.02
Male	104	0.06	0.00 – 0.16	
Facility Type				
Urban	**185**	0.02	0.00 – 0.05	**<0.0001**
Rural	152	0.58	0.36 – 0.76	

*Log Rank Test

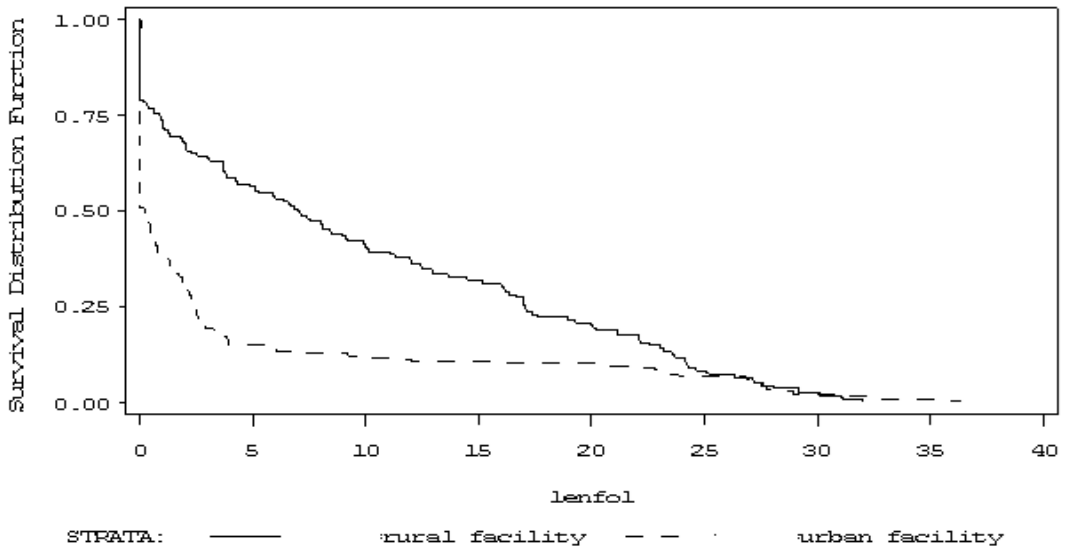

Figure 4. 3: Survival probability of LTFU patients in the urban versus rural facilities

From the above figure, the survival probability of patients from the urban and rural facilities is comparable. Soon after ART initiation at month zero, all the patients from the selected facilities had an equal chance of survival (equal to 1). Meaning all the case had an equal chance of survival (an event to occur). But as observed, within the first month (normally 2 weeks) of ART initiation 25% of patients from rural facilities and 50% of the patients from the urban facility had disengaged from treatment that is, did not returned to care in the subsequent appointment. From the key informants, the test and treat policy proves to be a bigger challenge, and was associated with LTFU among patients. This was justified by the fact that, not all patients were ready to be started on ART and that most had self-stigma. This sediment was supported by finding from the key informant that;

> *"Most of the patients, who end up in our clinic, did not come voluntarily to be tested for HIV, but because it was a requirement before clients get other services. So when the results are positive and they were not prepared for such a shock they take the drugs but may not turn for the next appointment" Clinician 1*

In addition, the urban facility have had drastic fall as illustrated in the survival distribution function curve to about 0.25 by the fifth month and continues to stagnates for some time, unlike for the rural where the clients continues to deteriorate with time in care. By the end of first year more than 194 cases of LTFU (75%) were reported and the trend however continued declining in the next 2 years of ART care.

4.3 Clinico-immunologic predictors of LTFU

The following presents the baseline clinical characteristics and the clinic-immunologic factors associated with LTFU

4.3.1 Baseline clinical characteristics of study participants

Table 4.5 shows the baseline clinical characteristics of study participants in line with LTFU as per the gender. Notably, most of cases of LTFU among males (62.5%) and females (66.1%) were in Stage 1 of WHO classification. Majority of males (88.5%) and females (86.7%) who were LTFU were non-IPT users. The same was true of LTFU cases that did not have TB where 95.2% of males and 96.5% of the females were LTFU. The results also show that a higher proportion of males (56.7%) and females (73.8%) who had higher BMI were cases of LTFU. A higher proportion of males (69.2%) and females (76.0%) with less than 200 CD4 count were also LTFU. Further analysis shows that, more males (75.0%) and females (64.4%) with higher VL were cases of LTFU in contrast to those with low VL in the same gender category. Majority of males (93.3%) and females (89.3%) who were cases of LTFU were on AF2B.

Table 4. 5: Baseline Clinical characteristics of study participants

Variables	Male		Female	
	LTFU	Non- LTFU	LTFU	Non-LTFU
WHO Staging				
I	65 (62.5)	153 (70.5)	154 (66.1)	419 (72.6)
II	13 (12.5)	27 (12.4)	32 (13.7)	77 (13.3)
III	20 (19.2)	33 (15.2)	41 (17.6)	63 (10.9)
IV	6 (5.8)	4 (1.8)	6 (2.6)	18 (3.1)
IPT				
Yes	12 (11.5)	154 (71.0)	31 (13.3)	363 (62.9)
No	92 (88.5)	63 (29.0)	202 (86.7)	214 (37.1)
TB Status				
Yes	5 (4.8)	7 (3.2)	8 (3.5)	20 (3.5)
No	99 (95.2)	210 (96.8)	221 (96.5)	556 (96.5)
BMI				
< 18.4	45 (43.3)	105 (48.4)	61 (26.2)	217 (37.6)
≥ 18.4	59 (56.7)	112 (51.6)	172 (73.8)	360 (62.4)
CD4 Count				
< 200	72 (69.2)	117 (53.9)	177 (76.0)	314 (54.4)
≥ 200	32 (30.8)	100 (46.1)	56 (24.0)	263 (45.6)
VL				
Low	26 (25.0)	145 (66.8)	83 (35.6)	358 (62.1)
High	78 (75.0)	72 (33.2)	150 (64.4)	219 (37.9)
ART Regimen				
AF2B	97 (93.3)	124 (57.1)	208 (89.3)	514 (89.1)
AF2E	4 (3.8)	87 (40.1)	7 (3.0)	37 (6.4)
Other	3 (2.9)	6 (2.8)	18 (7.7)	26 (4.5)

4.3.2 Baseline clinical factors influencing LTFU

The hazard rates for WHO staging was statistically significantly different in terms of LTFU median time for the two categories. The median LTFU time in study participants with Stage 1 and 2 was 0.17 (95%CI: 0.08 – 0.24) in contrast to participants in stage 3 and 4 (AHR: 0.04; 95%CI: 0.00 – 0.16) and a p value of 0.05 **β.**

LTFU median time was 1.34 (95%CI: 0.84 – 1.57) for patients on IPT was significantly different median time for those who were not on IPT (AHR: 0.07; 95% CI: 0.04 – 0.13), significantly different (p = 0.0004). A comparison of LTFU median time for patients with TB (AHR: 0.00: 95%CI: 0.00 – 0.13) versus those without TB (AHR: 0.16; 95%CI: 0.08 – 0.19) shows a statistically significant difference (p = 0.0016).

The LTFU median time for patients with BMI of 18.4 and below (AHR: 0.17: 95%CI: 0.08 – 0.23) was significantly different from that of patients with higher BMI (AHR: 0.04: 95%CI: 0.00 – 0.15) suggesting that, patients with higher BMI stayed in ART programme for a longer time compared with those with lower BMI (p = 0.0014). There is a difference between the two groups in the probability of LTFU at any point during the study. Further analysis shows a significant difference between LTFU median time for patients with higher VL (AHR: 0.59: 95%CI: 0.17 – 1.00) compared with their counterparts who had lower VL (AHR: 0.06: 95%CI: 0.03 – 0.14) and a p value of <0.0001. Time to LTFU was significantly different for the two groups of CD4 count (<200 & >200 cell/mm^3). ART regimen showed no significant difference in LTFU median time experienced by the patients with low versus higher CD4 counts and patients on AF2B drugs compared with those on other ARVs.

Table 4. 6: Adjusted Hazard ratios of baseline clinical characteristics of study participants from LTFU

Variables	N	AHR	95%Cl	p-value
WHO Staging				
III & IV	73	0.17	0.00 – 0.16	0.05β
I & II	264	0.04	0.08 - 0.24	
IPT				
Yes	43	**1.34**	0.84 – 1.57	**0.0004**
No	294	0.07	0.04 – 0.13	
TB Status				
Yes	**13**	0.00	0.00 – 0.13	0.0016
No	324	0.16	0.08 – 0.19	
BMI				
< 18.4	62	0.17	0.08 – 0.23	0.0014
≥ 18.4	**275**	0.04	0.00 – 0.15	
CD4 Count				
< 200	**249**	0.17	**0.07 – 0.19**	0.8309
≥ 200	88	0.11	0.04 – 0.21	
VL				
Low	109	0.59	0.17 – 1.00	**<0.0001**
High	**228**	**0.06**	0.03 – 0.14	
ART Regimen				
AF2B	305	0.16	0.08 – 0.19	0.597
Other ARTs	32	0.08	0.00 – 0.35	

β Wilcoxon test

4.4 Health system-related factors associated with LTFU in ART

In depth interview with the aid of key informant interview guide was used to evaluate the health system-related factors associated with LTFU, where the 9 Key informants working at CCC/HIV clinic were identified from the selected urban and rural facilities. The variables below were evaluated: documentation/waiting time; availability of ART; HIV and AIDS management policies and clinic resources as shown in appendix IV**.**

4.4.1 Documentation

Poor documentation led some patients to be incorrectly labeled as LTFU yet they were not. The researcher, made some confirmations by calling all the reachable LTFU patients to ascertain their whereabouts. Out of 407 LTFU cases identified and documented in the ART cohort register and the master electronic ART register, only

337 cases were confirmed "true" LTFU after mobile phone conversations with the patients/care supporters has justified on figure 4.2. The researcher opted to use this number during the analysis, for it gave the real picture on the ground. Key informers also supported the fact that wrong documentation could lead to LTFU. For example;

> *"Rural facilities in the study sites operates during week days only, if the dates provided do not fall in the working days, patients tend to miss the appointments and later become LTFU"* Clinician 2

4.4.2 Waiting time

In this study, the key informants agreed that, unscheduled appointment made by patients, contributed to LTFU because it initiates long waiting time as suggested.

> *"Patients who do not follow their appointment visit end up increasing workload, promoting delays hence demoralized scheduled patient…. relaxed and skip subsequent appointments"* clinician 2.

4.4.3 HIV and AIDS management policies

The policies include: "test and treat" and follow up –defaulter tracing.

4.4.3.1 Test and treat policy challenges

The entire key informant believed that, the test and treat policy was the biggest contributor of LTFU. This is because some patients experienced self-stigma also that, not all patients might declare not to be ready to start ART. This was supported by what the key informant narrated.

> *"Most of the patients end up to be LTFU because, HIV test is a mandatory and a gateway to other services…ending up with results plus treatment, when not fully prepared but for the sake of accomplishing their mission"* Clinician 1

4.4.3.2 The defaulter tracing policy challenges

All the key informants admitted that, the policy regarding defaulter tracing was in place, but the implementation part was a bigger challenge. This was as a result of inadequate provision of funds to support the full implementation. Patients' factor has seen to be another contributor to non-implementation of this policy. Especially when

patients provide wrong contacts location and/or mobile numbers, or even do not provide any, hence making too hard to trace them eventually becomes LTFU. One of the key informants said;

> "*Patients do not provide their true mobile phone numbers, and has we insist, they provide them but immediately they change the sim card, later we cannot trace them"* Defaulter tracer 2.

4.4.4 Availability of ART

All the key informants revealed that, they had adequate supply of ART drugs in the facilities. The most commonly reported cause of LTFU in relation to ART, was the side effects of AF2B combination regimen. This was supported by the quantitative finding results that 97 (93.3%) of LTFU male, were on AF2B as compared to those who were on other regimen (AF1A). In addition, 208 (89.3%) of LTFU female were also using AF2B the remainder fraction being other regimen.

4.4.5 Clinic resources (staffs, support groups)

Another variable the researcher used to evaluate the health systems-related factor of LTFU was the clinic resources (in terms of staffing, support groups-funding).

4.4.5.1 Availability of staffs

All the key informants admitted that, most of the CCC/HIV clinic health care practitioners were employed on contract by APHIA PLUS- NYOTA, where majority often are equipped with knowledge and updates on management of HIV and AIDS unlike the MOH staff. But when their contract ends, the MOH staffs are left to handle the patients with limited experience.

4.4.5.2 Availability of funds/ support groups

When the funds provided are inadequate to carry out planned activities, the implementation part becomes inactive. The key informants mentioned that, they experience problems of coordinating support groups, despite the fact that it has contributed

enormously in reduction of patients' stigma and promote retention. Also another barrier they experience is inadequate funds to sustain the defaulter tracing policy, where the key informants are required to call the patients and contact physical tracing, with the assistance of the CHVs. Even though, the CHVs work on voluntary basis they many need to engage some money to reach to LTFU patients. One of the key informant supported the idea that;

> *"For everything to be accomplished successfully, financial support will be necessary. Patients attending support groups, come from far places hence may need a motivator (transport reimbursement)"* Defaulter tracer 1

4.5 Summary of this chapter

The overall incidence rate of LTFU among 337/1131 patients confirmed LTFU, was 161.1 (95%Cl: 144.7 – 179.2) per 1000 person years of follow-up. Greater proportion of LTFU patients happened during the first year of ART initiation (76%) 259. Within the first month (2 weeks) after enrollment/starting ART, about 25% and 50% ended up as LTFU (after 3 months elapsed) in rural and urban facilities respectfully. Table 4.7 shows the summary of the four predictive variables, statistically significant to LTFU among adult's patients on ART by the final cox regression model: lower BMI of less than 18.4; attending rural facilities; high VL and not using IPT.

Table 4. 7: Predictors of LTFU among adults with HIV in the final cox model

Variable	Estimate	AHR	95%CI	p value
Male vs female	0.16	1.17	0.92 – 1.49	0.1952
Urban vs Rural	-0.31	0.73	0.58 – 0.92	**0.0081**
WHO stage III & IV vs I & II	-0.078	0.92	0.70 – 1.22	0.5798
On IPT vs No IPT	-2.19	0.11	0.08 – 0.16	**<.0001**
With TB vs No TB	-0.33	0.72	0.41 – 1.27	0.2537
BMI < 18.4 vs ≥ 18.4	0.63	1.88	1.40 – 2.54	**<.0001**
Low VL vs High VL	-1.11	0.33	0.26 – 0.42	**<.0001**

On the other hand the *'true'* LTFU confirmed through mobile phone calling, were 337 as opposed to 407 reviewed in the ART cohort register and in the electronic master facility register.

In addition, variables identified by the key informants, included: wrong documentation; long waiting time conformed by unscheduled visit; the implementation of the HIV and AIDS management policies- both: *"Test and Treat"* and *"defaulter tracing"* and finally inadequate funds to support staffing (CHVs & defaulter tracers to facilitate defaulter tracing system) and to manage support groups was crucial.

CHAPTER FIVE

DISCUSSION

5.1 Overview

This chapter discusses in detail the study findings. It presents brief findings followed by interpretations of the findings in support from existing and other related studies. The study was aimed at investigating the predictors of LTFU among adult patients initiated on ART in Nakuru West Sub-County health facilities. This study was initiated by the fact that, LTFU compromised the long-term success of ART, leading to deterioration of health condition of the infected person. This could be attributed by unchecked HIV status and consequently increases the risk of HIV transmissions (Meloni, *et al.*, 2014).

5.2 Incidence rate/Socio-demographic characteristics of patients

5.2.1 Socio-demographic predictors of LTFU

This study utilized 1131 participants, where the findings demonstrated significant association between socio-demographic characteristics and LTFU. From the study, 69% of females experienced LTFU compared to their counterparts. This finding was comparable with the study findings conducted by Dessalegn, *et al.,* (2015), Tweya, *et al.,* (2018) and Eguzo, *et al.,* (2015). This was justified by the fact that, majority of women depended on men for their up keep and sustainability. Hence most of them would rely on them for making decisions and other assistance for they were needed to go for their due appointment where if it contravine the vice versa occurs.

In contrast, a comparatively higher proportion of males visiting urban facilities (42.9%) than females (27.6%) in the same settings were LTFU. Megerso, *et al.*, (2016) and Clouse, *et al.,* (2014), revealed that, male were significantly associated with LTFU compared to their counterpart, because of the men's nature of work, in-

volving traveling, sometimes for long distances which keeps them away from their home (Tadesse & Haile, (2014) and Arnesen, *et al.,* (2017). Lastly, male patients drop out either because of the history of high viral load and/or over-representation (Magala, *et al*., 2018) while, Berheto, *et al.,* (2014), reported equal chances of LTFU among both men and women.

Age at ART initiation; was also found to be a significant factor of LTFU in this study. This study enumerated majority of LTFU to be among 25-34 years 41.5% (140/337), and an incidence rate of 192.5 per 1000 person-years (95%Cl 163.1-227.2) of follow up time. This was attributed by the fact that majority of the patients registered in CCC/HIV clinic were young in age mostly in their reproductive age, as compared to their counterparts. Similar finding was obtained in studies conducted by, Mugisha, *et al.*, (2014) and Clouse, *et al.,* (2014), where they revealed that, patients who were younger in age were commonly linked to LTFU as opposed to senior age group with a justification that, these age-groups, experiences fear of stigma and dis-crimination. In addition, Megerso, *et al.,* (2016) and Eguzo, *et al.,* (2015) revealed that patients, who were below 25 years, were more likely to be LTFU compared to the older population due to their dependency Dewi, *et al.,* (2015). In addition, De La Mata, *et al.,* (2018) results was agreeable with our finding, that the older generation (above 50 years) were less likely to be LTFU compared to the younger generation (aged 30 or below). Recent evidence suggests that social factors, such as stability (income, education, occupation), are associated with LTFU, also that in Africa, both social and economic stability increases with age (Falagas, *et al.,* 2008). According to Krishnan, *et al.,* (2011), their findings shown that, there is a higher probability of being employed if older than when one is young.

Residential setting was found to be statistically significant factor of LTFU in this study. Results show higher proportions 42% (152/363) of patients were LTFU in rural compared to those attending urban facility 24% (185/768). Also, results show higher incidence rate of LTFU for rural facilities (264.0 per 1000 person years) than in urban patients (122.0 per person years). This finding was in line with Megerso, *et al.*, (2016) who pointed out that, LTFU occurs more commonly where people experience problems of infrastructure hence increased the chance of becoming LTFU. Berheto, *et al.*, (2014), reported that, rural setting experiences low chances of poor patient tracing as a result of not reporting the risk of death eventuality leading to LTFU. Contrast to those finding, Tweya, *et al.*, (2018) revealed a high patient turnover in urban clinics giving reasons that, increased patient-to-provider ratios attendance limits patient preparation before ART initiation. In addition, LTFU occurs mainly in clinics with many patients compared to those clinics with fewer patients. High volume clinic, experience between 30 and 40% cases of LTFU, Dessalegn, *et al.*, (2015). Moreso, Mecha, *et al.*, (2016) also suggested that, patients who reside in urban areas, were more likely to get lost in care compared to there counterpart but no explanation was given.

5.2.2 Incidence rate of LTFU of the study participants

This research study identified twenty nine point eight percent (337/1131) initiated on ART were confirmed and identified as "true" LTFU, by the end of the study period. This rate of LTFU was higher compared to other study findings and was within the global range of 0.3% to 50% (Agwu, *et al.*, 2016 and Meloni, *et al.*, 2014). Lower findings were revealed by Dessalegn, *et al.*, (2015) 11% and Mberi, *et al.*, (2015), reported 23.4% cases of LTFU. This higher rate may be explained by the variations

in time duration used to define LTFU, where some studies used 2 months, or 3 months and even others 4 months. This study opted to define LTFU using 3 months from the last date of drug refill. Also, different study settings can contribute to higher LTFU rates. Further analysis revealed that, within the first year of ART initiation, 259/337 (76.9%) patients were LTFU, suggesting a greater fallout rate soon after ART initiation but declined with time of follow-up. This finding was supported by what the key informant reported: most of the patients disengage in treatment probably due to the implementation of *test and treat policy* and self-stigma related.

This study results further revealed an overall LTFU incidence rate of 161.1 (95%CI: 144.7 – 179.2), where the first year recorded 418.7 (95%Cl: 370.6 – 472) per 1000 person-years of follow up time, which was must higher compared to other studies. A study conducted in South Africa by Mberi *et al.*, (2015), reported an overall incidence rate of LTFU of 109 per 1000 person-years (95%CI: 92–128) which was far much lower compared to your study findings. A study conducted at the University of Gondar Ethiopia, revealed the overall LTFU incidence rate of 12.3 per 100 person years (95%CI (10.61–14.18) and Berheto, *et al.*, (2014) reported 8.8 (8.1-9.6) per 1000 person-months of LTFU within the first 6 months of ART initiation which declined over time, relating it to inadequate counseling and high cost of calling the patients. In addition, a study conducted by Dewi et al., (2017)' in a private facility, a lower Cumulative rate of 18% of LTFU among HIV positive patients receiving antiretroviral therapy (ART) in Bali are reported compared to a public facility, which might be explained by the quality care they might be receiving due to decrease number of patients attentee compared to that of their counterparts.

5.3 Clinico-immunologic predictors of LTFU

Clinical and immunologic characteristics have been identified to have some associations with LTFU in this study. From the study finding, it was noted that, a higher proportion of patient 72/117 (69.2%) males and 177/314 (56.0%) female who were LTFU had a CD4 count >200 cells/mm^3. This could be explained by the fact that, the health care personnel, might not know the whereabouts of these patients because patients with lower CD4 cell counts may be too sick to continue on care, or self-transfer to the nearest clinics, or even they may have died (Ojwang' *et al.,* 2016). This results is in agreement with other study finding that shown association between low CD4 cell count of >200 cells/mm^3 during ART initiation and LTFU (Grimsrud, 2015 and Mberi, *et al.*, 2015).

Contrary to this finding, Grimsrud, (2015) had a conflicting results where apart from low CD4 associated with LTFU, some centres presented high CD4 with increased cases of LTFU and Mugisha, *et al.*, (2014), reported that, patients with higher CD4 cell counts were more likely to be LTFU compared to their counterparts because, these patients may not have directly experienced the benefits of ART on their personal health (Mecha, *et al.*, 2016). This was also noted by who reported associated between high CD4 count <350 cells/mm^3 with LTFU.

In addition, this study revealed the association between LTFU and detectable viral load (high). Further analysis shown significant difference between LTFU median time for patients with high VL (AHR: 0.59: 95%CI: 0.17 – 1.00) compared with their counterparts with lower VL (AHR: 0.06: 95%CI: 0.03 – 0.14) and a p value of <0.0001. A high VL in a person on treatment indicated either that the medication is not being taken properly or that the virus is becoming resistant to the medication (UNAIDS, 2016). This finding, was in line with that of, Arnesen, *et al.*, (2017) and

Agwu, *et al.*, (2016) suggested that patient with high/detectable VL, where more likely to disengage from treatment. Chendi, et al., (2019) gave an explanation that, poor adherence, treatment interruption due to dosage and the LTFU are factors reported most likely to influence virological failure responses.

Another clinical factor considered significant to LTFU was the WHO staging. This study revealed a higher incidence rate of LTFU amongst patients with WHO stage 3 and 4 (239.9 per 1000 person years) in contrast to those in stage 1 and 2, meaning that there was some association. This was because; patients, who start their treatment at this advanced WHO stage, were less likely to respond to treatment and had higher mortality rate compared to those who start their medication earlier as suggested by (Haskew, *et al.,* 2015). Moreso, the advancement of disease could have resulted in unreported death according to Megerso, *et al.*, (2016). Kan, *et al.*, (2014), found some relationship between WHO stage 2 and LTFU, while Grimsrud, (2015) reported likelyhood of LTFU in patient with WHO stage I could be mostly associated with LTFU. Contrary to the above findings, Berheto, *et al.,* (2014) reported that, patient with WHO Stage 3 and 4 had a better chance of retention in care, due to their increased health-seeking behavior. Lastly, Mugisha, *et al.*, (2014), reported no association between WHO staging and LTFU.

Our study results revealed that, majority of the patients who were LTFU, were non-IPT users, even though IPT protects against TB. This study concluded that those taking IPT were protected from LTFU. This was because of the increased reinforced counseling to patients taking IPT, contributing to better follow-up. These results were similar to that of Berheto, *et al.*, (2014) and Dessalegn, *et al.*, (2015) reported that the non-IPT users were more likely to be LTFU compared to their counterpart but no explanation was provided and were contrary with that of Assemie, *et al.*,

(2018), who established some association between patient IPT and LTFU, but no explanation was provided.

From the results, it was true that LTFU cases occur commonly to adults who had TB (AHR: 0.00: 95%CI: 0.00 – 0.13) versus those without TB (AHR: 0.16; 95%CI: 0.08 – 0.19) shows a statistically significant difference (p = 0.0016). According to this study, those using anti-TB, might have experienced increase in drug burden, discouraging them and later ending up to be LTFU. This finding was in line with the result presented by Tadesse & Haile, (2014), who presented that a TB positive patient had higher risk of LTFU than a TB negative patient, either due to overlapping toxicity in using any multidrug therapy. But according to Berheto, *et al.,* (2014), there was no association between TB and LTFU.

The results also identified lower BMI of less than 18.4 as a predictor of LTFU. This was justified by the fact that those with BMI <18.4, increased the risk of LTFU by almost two times compared to their counterparts. This finding was similar with that of Tweya, *et al.,* (2018) where they reported that, those patients with BMI less than 18.4 at ART initiation were associated with LTFU. Also, according to Kan, *et al.*, (2014), patients with no weight gain at six months were more likely to discontinue treatment compared to those who had weight gain. In addition, Tadesse & Haile, (2014), pointed out that, "the rate of LTFU was associated with a baseline body weight of patients" having weight more than 60 kg, lowers the risk of being LTFU compared to weigh less than 40 kg giving an explanation that, patients with normal weight would like to maintain their good wellbeing.

Visa Vis to that finding of Mukumbang, *et al.,* (2017) showing that, patients experience LTFU after they realize that they have started to look healthy and increase in body weight resulting from taking their ART.

5.4 Health systems related factors associated with LTFU

From the study finding, poor/wrong documentation was found to be a strong contributing factor of LTFU among adult patients initiated on ART. The key informants pointed out that, unclear dates or unjustified date provided, would influence LTFU. The finding was supported by studies conducted in Northwest Ethiopia, Malawi and other parts of the country, where they reported that "LTFU happens when a clinician fails to record the next appointment date on the patient's chart hence the probability of returning back to the ART clinic would be unlikely" (Seifu, *et al.,* 2018). The same finding was documented by Tweya, *et al.*, (2018) that, increased cases of LTFU occur due to poor adherence to clinic appointments, unclear or unjustified documentation.

This study finding established that, patients who come for unscheduled appointment creates additional patients to the queues and increasing waiting time upon the scheduled patients. This increases health care workers workload, hence discouraging the scheduled patients in the forthcoming visits and later leads to LTFU. This finding was supported by study conducted in Zambia by Mukumbang, *et al.,* (2017) who noted that, when ART center's experience high patient load, they are subjected to long waiting times and in turn call for high defaulter rates. The finding was also in line with that of Megerso, *et al.,* (2016) who reported that, practitioners' work overload attributed by increased clinic attendance, contributes to sub-optimal quality of health care to include problems in medical record.

Subjected HIV and AIDS management policies *(test & treat* and *follow up –defaulter tracing)* was also found to be associated with LTFU in terms of implementation. The key informants interviewed narrated that, they face great challenge using the "*test and treat*" policy because, newly diagnosed HIV positive patient were not ready to

start ART and even not open to declare. Even though this finding has not been shown in other studies, we found it as a relevant contributor, since majority of the patient default treatment soon after initiation. In addition, the key informants revealed that, the study facilities experiences inadequate funds to aid in the implementation of HIV and AIDS management policies. The funds are needed to: support CHVs and defaulter tracers during physical tracing; maintain and support air time, used for calling patients as a reminder. On the other hand, most patients (337) did not provide their correct contact phone number/did not have any; hence they became hard to reach. This finding was supported by Saumu, (2017) by providing the fact that, inadequate staffing and funding to facilitate physical tracing would contribute to LTFU.

5.5 Summary

The goal of this study was to explore the predictors of LTFU among adult patients initiated on ART in Nakuru West Sub-County facilities. From the quantitative data, it was observed that most patient with high viral load, higher BMI non-IPT users, both from rural facilities were LTFU. In addition, the qualitative data obtained from the key informants reveal that wrong documentations, long waiting time, the HIV and AIDS management policies (test-treat and defaulter tracing) brought challenges in patients retention incorporating inadequate clinic resources, all these contributed immensely to LTFU in this study findings.

CHAPTER SIX

RECOMMENDATION AND CONCLUSION

6.1 Conclusion

This study revealed a higher overall incidence rate of LTFU of 161.1 per 1000 person years of follow up time.

Four clinical predictors were identified to be statistically significant to LTFU, they included: lower BMI of less than 18.4; attending rural facility; higher VL and not using IPT.

Finally, the following health systems factors were also identified to be associated with LTFU, namely: wrong/poor documentation; long waiting time; implementation of the HIV and AIDS management policies- both: *"Test and Treat"* and *"defaulter tracing"* and inadequate funds to support staffing and to manage support groups.

6.2 Recommendation

The following recommendations were made following the finding of this study. They include:

- Due to the higher incidence rate of LTFU among patients initiated on ART in the study areas, there is need for collaborative action and support to be taken from the policy makers and the implementers (MOH/NCG/APHIA-PLUS and the entire CCC staffs) to further re-examine the policy related to commencement of ART due to this up-surge in the incidence rate. This is evidenced by the high cumulative incidence rate compared to other studies with a leading first year of LTFU in ART initiation. More so, this study recommends that, the MOH, NCG and APHIAPLUS to build capacity of personnel working at the CCC/HIV clinic to improve provision of HIV

care services in the Sub-County hence reducing the incidence rate of LTFU.

- This study found some association between these clinical predictors and LTFU. They include: Low CD4 counts <200 cells/mm^3; BMI ≥18.4; high VL, attending rural facility and non-using IPT. Therefore, the study recommends that, the CCC/HIV staff should ensure that such patients experiencing the above findings need to be prioritized for close follow-up and tracing, so that they can be supported to be retained in care and on ART.
- This study identified poor documentation; long waiting time; implementation of the HIV and AIDS management policies and inadequate clinic resources contributed to LTFU.

➢ To address wrong/poor documentations, the researcher recommends that all CCC/HIV clinics staffs should ensure proper, evidenced based finding and update the health data collection systems to be integrative as much as possible so as to minimize duplication of efforts and wastage of scarce resource. They CCC staffs need to capture details on deaths as they occur, at the death and notification office, in order to update any mortality arising and help correct LTFU estimates.

➢ In addition, to reduce long waiting time due to long queues, CCC staffs should advise patients to follow their schedule appointments and address to them the importance to adhering to their appointment dates to minimize congestions, thus help to decongest the clinic in return reduce waiting time. The initiative is evident to help in patient retention.

➢ They MOH/ APHIA-PLUS, need to address the challenges that impede the implementation of HIV and AIDS management policies. These policies

need to be reviewed from planning to implementation. Thus, further research is needed to know the extent of this as an effect of LTFU in the country.

- In addition, the inadequacy of resources need to be addressed by the MOH/ APHIA-PLUS. They need to assist in updating all the staffs including the MOH to bring them to per, thus reducing gaps in managing HIV/CCC patient in absentees of the APHIA-PLUS staff. Also, they need to embrace the WHO recommendation of using PLHIV as CHVs, by recruiting more CHVs, to assist in physical and contact tracing (home visits) which should commence soon after the patient is enrolled/started on ART. Patients to be encouraged to provide their correct locations and mobile phone contacts, which should be updated with every visit to enhance defaulter tracing. More so, referral planning should commence on enrolment. They need to be informed about the need to transfer to the nearest facilities for ease follow up.
- Finally, further studies, is recommended to identify the linkage of LTFU/self-transfer patients between County Referral Hospital and all other health facilities in Nakuru County and nationally.

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APPENDIX: 1 (Information sheet)

Title of the study: Predictors of loss to follow up among adult patients initiated on antiretroviral therapy in Nakuru West Sub-County Health Facilities.

Introduction: My name is **Grace Jepchumba Kibet**, currently studying at Masinde Muriro University- Kakamega (Introduce other members taking part in the study; research assistants).

Purpose: I am working on the above study, to gain an understanding of adult - individuals who are the loss to follow up on ART. From the available data, many patients (30%) were getting lost of treatment, despite government and NGO (APHIA-PLUS) putting more effort to ensure patient retention in care. I will be focusing on issues/factors related to the facility, that contribute to LTFU in ART care; waiting for time/ documentation, availability of ART, follow-up policy, clinic resources- staffs and other support.

Outcome: My goal is to understand the characteristics of the population of people who are the loss to follow up on ART, what barriers exist, and explore potential solutions. This will help the governing authorities to plan for intervention to curb LTFU, subsequently retaining patients in care and later improving their quality of life.

What participation will involve

Participation in the research is dependent upon signing the informed consent form. You will be asked detailed questions by the investigator and where your information will be documented in a notebook as a form of data collection to attain data quality. You will be required to give honest information to their level best. Your findings will be used by the researcher to generate useful information and recommendation that will assist to reduce LTFU in ART care. There are no benefits attached to participating in this research (it is totally voluntary).

Data security

All information you provide will remain confidential. Only the study team will have access to this information and will be treated with confidentiality unless your express permission is obtained. You may withdraw from participating in this study at any time without giving reasons. This will not lead to any form of penalty or punishment.

APPENDIX: II Consent form

Please read the previous information sheet carefully before completing and signing this consent form. Should you have any questions about the study, please feel free to ask the investigator prior to signing your consent.

Consent form for the study

Title of the study: Predictors of loss to follow up among adult patients initiated on Antiretroviral Therapy in Nakuru West Sub-County health facilities.

Investigator: **Grace Jepchumba Kibet, HNR/G/01-54400/2017**, Masinde Muriro University- Kakamega Tel. **0721750166.**

Supervisor: Mr. John Arudo, Masinde Muriro University- Kakamega. Tel **0725430572.**

For completion by the study participant

I have read/ been read to, the previous sheet concerning this study and I have understood what will be required of me if I take part in the study. I understand that at any time I may withdraw from the study without giving a reason and this will not affect my service delivery/treatment provision.

I agree to take part in the study:

Initials of Participant: / No. provided……

Sign……

Date……

APPENDIX III: The key informants' interview guide

STUDY TITLE

"Predictors of loss to follow up among adult patients initiated on ART in Nakuru West Sub-County health facilities".

FOCUS: Health facility-related factors, associated with loss to follow up (LTFU) in ART care.

1. Tell me a little bit about yourself, your position, and your role as a CCC/HIV official.
2. How do you make your follow up of patients including the hard to reach (LTFU) in the ART clinic?

3. In reference to LTFU, what do you think are some of the reasons, contributing to LTFU among adult patients initiated on ART?

A). In relation to documentation/waiting time.

- Does the department have a standardized monitoring and evaluation system that helps in monitoring the patients' attendance to the clinic? If the answer is yes, how does it work?
- How many patients do you serve per day?
- How long do you take to finish one patient?
- Are there some instances where unscheduled patients come for the services? If the answer is Yes, How does this affect your service provision?
- How does your department reduce the frequency of visits for stable patients?
- Do you sometimes think wrong documentation can lead to LTFU? 1. Yes, 2. No. If the answer is yes, explain how.

B). Availability of ART

Probe:

- Has your department experienced lack of ART supplies in the last one year (January 2018 – December 2018)? If the answer is yes, what was the cause of the shortage and how did this affect client services and clinic attendance?
- Does your department dispense ART regimens that are reported to have side effects?
- If so, which ones are they?
- How have clients responded to such ART regimens?
- List some of the signs and symptoms most frequently reported.

C). Policy on HIV/AID management etc.

- What is the institutional/departmental follow-up policy on patients initiated on ART?
- Do you have a policy for tracking patients who were lost to follow up?
- What are the biggest challenges in each of these policies?

Others include

D). Clinic resources (staffs, support groups). *Probe*……

6. Do you have any recommendations/ probable solution to curb LTFU?

7. Do you think there is an area that we have left out in this session on how to improve on LTFU?

Wrap-Up: Thank you.

APPENDIX IV: Abstraction form

Serial No.	Name of sub-county	Name of facility	MFL code	Unique patient Number	Date of Birth	Age (Current)	Gender (M/F)	Date started ART	WHO stage (At ART start)	Height	Weight	BMI (Calculated)	Initiated on IPT (indicate respective number ONLY) 1. Yes, or 2. No	TB status at ART start (indicate respective number ONLY) 1. Yes, or 2. No	CD4 (Baseline)	VL value (indicate respective number ONLY) 1. Detectable or 2. Undetectable (LDL	Date late seen (dd/mm/yyyy)	Date of the next appointment (dd/mm/yyyy)	Patient Status (indicate respective number ONLY) 1. Active 2.Defaulter 3. LTFU 4. Self-transfer 5. Not known	confirm status of LTFU 1.No conduct/Hard to reach 2.Self-transfer 3.Active 4.Transfer-out 5.Stopped 6.Died	Original regimen (At ART initiation) indicate ART Codes AF1A AF1B AF2A AF2B AF3A AF3B	Current or last ART regimen dispensed (indicate ART Codes)	Reasons for substitution (1st line) - indicate respective number ONLY - 1. Toxicity, 2.Pregnancy, 3. Risk of pregnancy, 4. Due to new TB; 5. A new drug available; 6. Drug out of stock 7. Other reason (specify).	Reasons for the switch (2nd or 3rd line) indicate respective number ONLY 1.Clinical treatment failure; 2. Immunological failure; 3.Virologic failure. 4. A new drug available; 5. Drug out of stock; 6. Other reason (specify).
1																								
2																								
3																								
4																								
5																								
6																								

APPENDIX V: APPROVAL LETTER FROM DIRECTORATE OF POSTGRADUATE STUDIES

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

Tel: 056-30870
Fax: 056-30153
E-mail: directordps@mmust.ac.ke
Website: www.mmust.ac.ke

P.O Box 190
Kakamega – 50100
Kenya

Directorate of Postgraduate Studies

Ref: MMU/COR: 509099

12th February, 2019

Grace Jepchumba Kibet,
HNR/G/01-54400/2017,
P.O. Box 190-50100,
KAKAMEGA.

Dear Ms. Kibet,

RE: APPROVAL OF PROPOSAL

I am pleased to inform you that the Directorate of Postgraduate Studies has considered and approved your Masters Proposal entitled: "***Predictors of Loss to Follow up among Adult Patients Initiated on ART in Nakuru West Sub- County Health Facilities "*** and appointed the following as supervisors:

1. Mr. John Arudo - SONMAPS, MMUST
2. Gregogory Sakwa - SONMAPS, MMUST

You are required to submit through your supervisor(s) progress reports every three months to the Director of Postgraduate Studies. Such reports should be copied to the following: Chairman, School of Nursing & Midwifery Graduate Studies Committee and Chairman, Department of Clinical Nursing and Health Informatics and Graduate Studies Committee. Kindly adhere to research ethics consideration in conducting research.

It is the policy and regulations of the University that you observe a deadline of two years from the date of registration to complete your master's thesis. Do not hesitate to consult this office in case of any problem encountered in the course of your work.

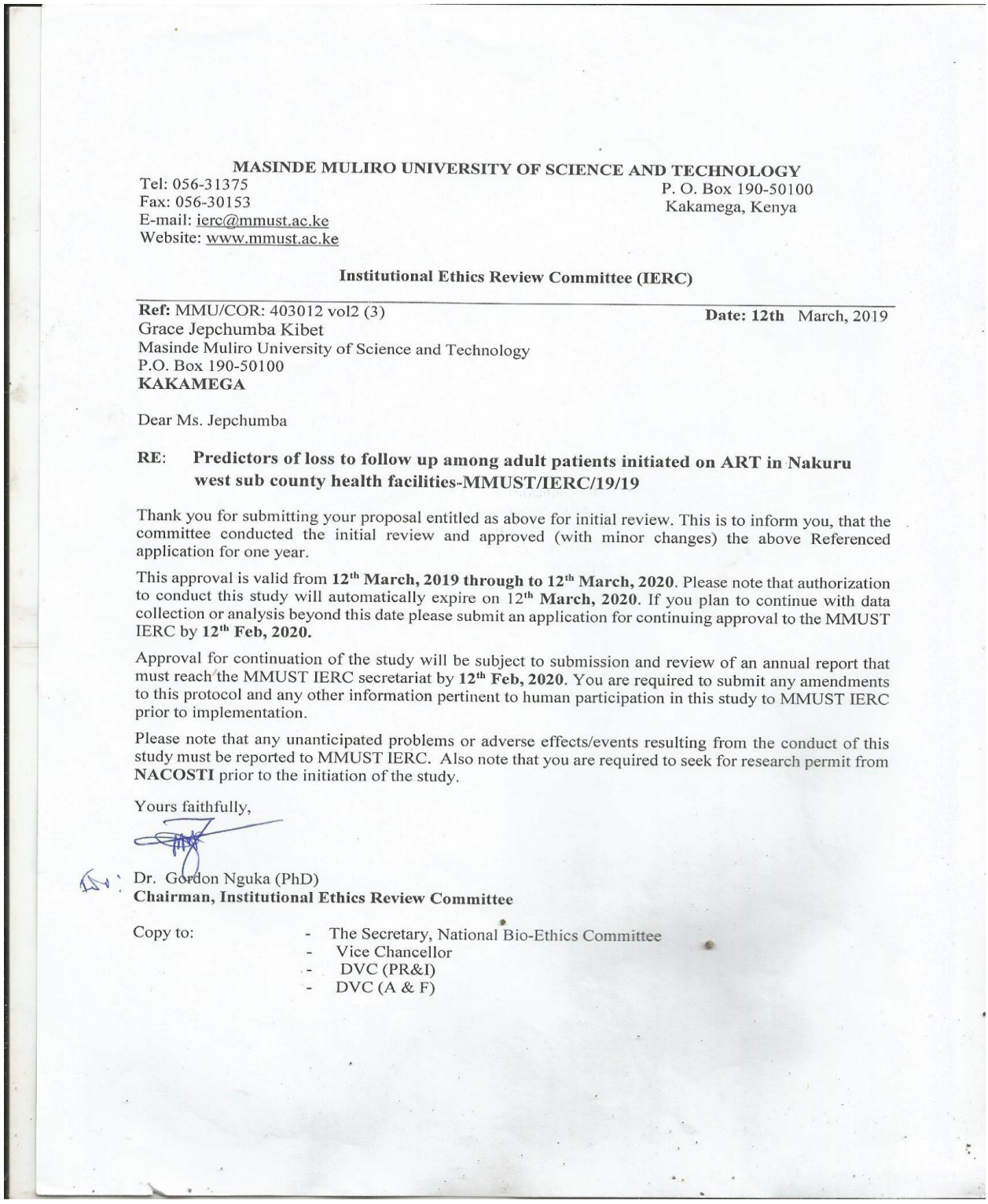
We wish you the best in your research and hope the study will make original contribution to knowledge.

Yours Sincerely,

DEAN
SCHOOL OF GRADUATE STUDIES
MASINDE MULIRO UNIVERSITY
OF SCIENCE & TECHNOLOGY
Date: Sign:

Prof. John Obiri
DIRECTOR, DIRECTORATE OF POSTGRADUATE STUDIES

APPENDIX VI: APPROVAL LETTER FROM INSTITUTIONAL ETHICS COMMITTEE



MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY
Tel: 056-31375
Fax: 056-30153
E-mail: ierc@mmust.ac.ke
Website: www.mmust.ac.ke
P. O. Box 190-50100
Kakamega, Kenya

Institutional Ethics Review Committee (IERC)

Ref: MMU/COR: 403012 vol2 (3) **Date: 12th** March, 2019

Grace Jepchumba Kibet
Masinde Muliro University of Science and Technology
P.O. Box 190-50100
KAKAMEGA

Dear Ms. Jepchumba

RE: Predictors of loss to follow up among adult patients initiated on ART in Nakuru west sub county health facilities-MMUST/IERC/19/19

Thank you for submitting your proposal entitled as above for initial review. This is to inform you, that the committee conducted the initial review and approved (with minor changes) the above Referenced application for one year.

This approval is valid from **12th March, 2019 through to 12th March, 2020**. Please note that authorization to conduct this study will automatically expire on 12th **March, 2020**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the MMUST IERC by **12th Feb, 2020.**

Approval for continuation of the study will be subject to submission and review of an annual report that must reach the MMUST IERC secretariat by **12th Feb, 2020**. You are required to submit any amendments to this protocol and any other information pertinent to human participation in this study to MMUST IERC prior to implementation.

Please note that any unanticipated problems or adverse effects/events resulting from the conduct of this study must be reported to MMUST IERC. Also note that you are required to seek for research permit from **NACOSTI** prior to the initiation of the study.

Yours faithfully,

Dr. Gordon Nguka (PhD)
Chairman, Institutional Ethics Review Committee

Copy to:
- The Secretary, National Bio-Ethics Committee
- Vice Chancellor
- DVC (PR&I)
- DVC (A & F)

APPENDIX VII: AUTHORISED LETTER FROM NACOSTI

NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

Telephone:+254-20-2213471,
2241349,3310571,2219420
Fax:+254-20-318245,318249
Email: dg@nacosti.go.ke
Website : www.nacosti.go.ke
When replying please quote

NACOSTI, Upper Kabete
Off Waiyaki Way
P.O. Box 30623-00100
NAIROBI-KENYA

Ref: No. **NACOSTI/P/19/51808/29143**

Date: **2nd May 2019**

Grace Jepchumba Kibet
Masinde Muliro University of Science
And Technology
P.O. Box 190-50100
KAKAMEGA.

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ***"Predictors of loss to follow up among adult patients initiated on Antiretroviral therapy in Nakuru West Sub-County health facilities."*** I am pleased to inform you that you have been authorized to undertake research in **Nakuru County** for the period ending **2nd May, 2020.**

You are advised to report to **the County Commissioner and the County Director of Education, Nakuru County** before embarking on the research project.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit **a copy** of the final research report to the Commission within **one year** of completion. The soft copy of the same should be submitted through the Online Research Information System.

GODFREY P. KALERWA MSc., MBA, MKIM
FOR: DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioner
Nakuru County.

The County Director of Education
Nakuru County.

APPENDIX VIII: NACOSTI RESEARCH PERMIT

THIS IS TO CERTIFY THAT:
MS. GRACE JEPCHUMBA KIBET
of MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY, 0-20100 NAKURU,has been permitted to conduct research in *Nakuru County*

on the topic: *PREDICTORS OF LOSS TO FOLLOW UP AMONG ADULT PATIENTS INITIATED ON ANTIRETROVIRAL THERAPY IN NAKURU WEST SUB-COUNTY HEALTH FACILITIES*

for the period ending:
2nd May,2020

Permit No : NACOSTI/P/19/51808/29143
Date Of Issue : 2nd May,2019
Fee Recieved :Ksh 1000

.....
Applicant's Signature

.....
Director General
National Commission for Science, Technology & Innovation

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014.

CONDITIONS

1. The License is valid for the proposed research, location and specified period.
2. The License and any rights thereunder are non-transferable.
3. The Licensee shall inform the County Governor before commencement of the research.
4. Excavation, filming and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
5. The License does not give authority to transfer research materials.
6. NACOSTI may monitor and evaluate the licensed research project.
7. The Licensee shall submit one hard copy and upload a soft copy of their final report within one year of completion of the research.
8. NACOSTI reserves the right to modify the conditions of the License including cancellation without prior notice.

National Commission for Science, Technology and innovation
P.O. Box 30623 - 00100, Nairobi, Kenya
TEL: 020 400 7000, 0713 788787, 0735 404245
Email: dg@nacosti.go.ke, registry@nacosti.go.ke
Website: www.nacosti.go.ke

REPUBLIC OF KENYA

NACOSTI

National Commission for Science, Technology and Innovation

RESEARCH LICENSE

Serial No.A 24434

CONDITIONS: see back page

APPENDIX IX: NAKURU COUNTY IREC APPROVAL LETTER

DEPARTMENT OF HEALTH SERVICES

NAKURU COUNTY

CHIEF OFFICER, MEDICAL SERVICES
NAKURU COUNTY
P.O BOX 2600-20100
NAKURU

Ref No. NCG/CDMS/GEN.VOL.1/282

8th May, 2019

THE SCMOH
NAKURU WEST

RE: RESEARCH AUTHORIZATION

This letter serves as an authorization from the Department of Health Services Nakuru for **Grace Jepchumba Kibet** to conduct research on **"Predictors of loss to follow up among adult patients initiated on Antiretroviral therapy in Nakuru West Sub County health facilities".**

The County acknowledges receipt of clearance letter from NACOSTI and therefore authorizes the study to proceed. The study is in line with the County Research priorities in the county research agenda and therefore the researcher is expected to present and submit the final report to the County Research and Development Unit.

COUNTY DIRECTOR OF PLANNING & ADMINISTRATION HEALTH SERVICES
08 MAY 2019
P.O. BOX 2060-20100
NAKURU-KENYA

E. Kiptoo
For/County Director Administration and Planning
NAKURU

CC:

- **Grace Jepchumba Kibet**

APPENDIX X: MAP OF NAKURU COUNTY- SHOWING NAKURU WEST SUB-COUNTY STUDY AREA: KENYA