MAKERERE UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE

LOSS TO FOLLOW- UP AND ASSOCIATED RISK FACTORS AMONGST ADULT HIV/AIDS PATIENTS IN WAKISO DISTRICT: A RETROSPECTIVE COHORT STUDY

BY

OPIO DENIS (BES, KYU; PGD M&E, UMI)

SUPERVISORS:

ASSOC. PROF. JOAN NAKAYAGA KALYANGO

(B. Pharm, MSc. Community Pharm, MSc. CEB, PhD)

DR. FRED C. SEMITALA

(MBChB, M.MED, MPH, Imp Science)

A DISSERTATION SUBMITTED TO THE DIRECTORATE OF RESEARCH AND GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS OF MAKERERE UNIVERSITY

November, 2018

DECLARATION

I, Denis Opio, declare that the work submitted in this dissertation is my own compilation and has not been submitted for another degree in this or any other University or Institution of higher learning.

Denis Opio (Principal Investigator)

Signature: 28/11/2018

Date: .....

This dissertation has been submitted for examination with approval of my supervisors:

1. Assoc. Prof. Joan Nakayaga Kalyango, B. Pharm, M.Sc. Community Pharm, M.Sc. CEB, ~~PhD~~

Signature: .....

Date: 30/11/2018

2. Dr. Fred C. Semitala, MBChB, M.MED, MPH, Imp. Science

Signature: .....

Date: 28/11/2018

DEDICATION

I dedicate this work to my lovely family for the unlimited support provided during the course of the programme and this research.

ACKNOWLEDGEMENTS

I, first and foremost, want to be grateful to God for the abundant blessings that enabled me to be admitted into the programme and eventually having to successfully conduct this research.

I want to thank my supervisors, Prof. Joan Kalyango and Dr. Fred Semitala for their relentless guidance throughout the study. In the same spirit, I also want to thank my lecturers, Prof. Charles Karamagi, Dr. Joaniter Nankabirwa and Dr. Achilles Katamba for their efforts towards molding me into an outstanding epidemiologist.

Finally, I want to appreciate the conducive environment at Clinical Epidemiology Unit, my classmates, Mrs. Christine Kusasira for making this a dream come true. May the Almighty God bless you all!

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LIST OF ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
AIDS	Acquired Immune deficiency Syndrome
ART	Anti-retroviral Therapy
AZT	Zidovudine
BMI	Body Mass Index
CD4	Cluster of Differentiation 4
CHBC	Community Home- Based Care
CI	Confidence Interval
EFV	Efavirenz
eMTCT	Elimination of Mother-to-Child Transmission
FBFCA	Facility- Based Family- Centred
HART	Highly Active Anti-retroviral Therapy
HC	Health Centre
HIV	Human Immunodeficiency Virus
HR	Hazard Ratio
HSD	Health Sub- District
IQR	Interquartile Range
KII	Key Informant Interview
LTFU	Loss to Follow- Up
MOH	Ministry of Health
NVP	Nevirapine
OI	Opportunistic Infections
PH	Proportional Hazards
PPS	Probability Proportional to Size sampling
TASO	The AIDS Support Organization
TDF	Tenofovir
UAC	Uganda Aids Commission
UNAIDS	United Nations AIDS Program
UPHIA	Uganda Population- based HIV Impact Assessment

WDLG Wakiso District Local Government

WHO World Health Organization

OPERATIONAL DEFINITIONS

Retention in care: Defined as a patient who visited the health facility at least once in three months to receive highly active Anti-retroviral therapy after their last scheduled appointment date in the duration between January 1st, 2015 and December 31st, 2017 (MOH, 2016).

Loss to follow- up: Defined as a patient who has not visited the health facility in three months to receive highly active Anti-retroviral therapy after their last scheduled appointment date between January 1st, 2015 and December 31st, 2017 (MOH, 2016).

Transfer out: A patient whose care and Anti-retroviral therapy treatment has been officially transferred to another clinic with documentation to that effect available.

Time to loss to follow- up: The duration between when the patient is initiated on Anti-retroviral therapy and loss to follow- up.

ABSTRACT

Background: The Human Immunodeficiency Virus/ Acquired Immune deficiency Syndrome (HIV/AIDS) epidemic is still a major global public health challenge, particularly to resource constrained countries like Uganda. The availability of Anti-retroviral Therapy (ART) for HIV treatment and prevention has helped to suppress the virus. However, there is still a problem of loss to follow- up (LTFU) since patients have to stay on treatment for a lifetime. With the current policy of 'test and treat' for HIV/AIDS, we anticipate the problem of LTFU to be more pronounced given that more people need to be immediately initiated on ART. Several studies have been conducted in 'Centres of excellence' where patients are provided with extra support to ensure that they are retained in care. However, we need more evidence from the public health care delivery system. This study sought to determine the incidence of and the factors that are associated with LTFU amongst adult HIV positive patients in Wakiso district.

Methods: The study employed a concurrent- nested mixed methods (quantitative and qualitative) design of data collection and analysis. For the quantitative study, a retrospective cohort design was used to review 646 records of HIV positive individuals who were registered for care in 13 health facilities of Wakiso district between January 2015 and December 2017. The study used systematic sampling technique to randomly select the patients to study from the list of patients receiving ART in the selected health facility. The data was extracted from the patient ART cards in the health facilities using a data extraction form. The study described the properties of patients lost to care. The cox proportional hazards regression model was used to determine the factors that are associated with LTFU. Sub-group analysis was done using the log rank test to compare the patients that were enrolled on a 'Test and Treat' strategy to those enrolled on the basis of CD4 count or World Health Organization (WHO) Clinical staging. For the qualitative study, we conducted in-depth interviews with patients and key informant interviews with health service providers to

explore perceptions about LTFU. The information was coded and synthesized to conduct a thematic analysis.

Results: Out of 646 patients, 216 were LTFU, 359 were still in care, 55 were transferred out, and 16 died. The overall incidence rate of LTFU was 21 per 1000 person-months (95%Confidence Interval (CI): 18- 25 per 1000 person- months). Normal weight patients were 36 percent less likely to be LTFU (Adjusted Hazard Ratio (aHR) =0.64, 95%CI: 0.453-0.903) compared to underweight patients; and hospital level patients were 78 percent less likely to be LTFU (aHR=0.22, 95%CI: 0.121- 0.408) compared to health centre III level patients. The patients with no telephone contact were twice as likely to be LTFU (aHR=2.16, 95%CI: 1.330- 3.511). The patients initiated on the basis of the traditional CD4 count had an incidence rate of LTFU of 30 per 1000 person-months (95%CI: 24- 39 per 1000 person-months) compared to 'Test and Treat' strategy with an incidence rate of LTFU of 33 per 1000 person months (95%CI: 23- 49 per 1000 person-months). The p-value of the difference was 0.231. Perceptions about stigmatization, competing life activities, and long waiting time were prominent among the lost patients compared to the active patients.

Conclusions: The incidence rate of LTFU is higher in the public health care setting, mainly due to high patient loads, compared to the 'Centers of excellence'. The factors such as normal weight, hospital level and not having telephone contact are important while addressing the problem of LTFU in the public health care setting.

CHAPTER ONE

1.0 INTRODUCTION

The Human Immunodeficiency Virus/ Acquired Immune deficiency Syndrome (HIV/AIDS) epidemic is still a major public health challenge in the world particularly to resource constrained countries like Uganda. In 2017, there were 1.8 million estimated new HIV infections worldwide, adding up to a total of 36.9 million people with HIV (UNAIDS, 2018). More crucially, an estimated 35.4 million people have died from AIDS- related illnesses since the start of the epidemic, including 940, 000 in 2017 (UNAIDS, 2018). In Uganda, the prevalence of HIV among adults aged 15 to 64 is 6.2 percent, corresponding to approximately 1.2 million people aged 15 to 64 living with HIV in Uganda (MOH, 2017). The available treatments such as ART and prophylaxis are the mainstay in HIV management (Mberi et al., 2015). ART prevents HIV multiplication and reduces the viral load in the blood, resulting into improved immune function of an HIV- infected person and decrease in the risk of transmitting the virus (Mberi et al., 2015; Organization, 2012). Nonetheless, when patients are provided with efficacious ART, they get better and most regain normal function (Organization, 2012); this sometimes makes patients reluctant to return to the clinic for follow-up visits and ART replenishment.

Retention in care is crucial to ensure ongoing receipt of ART; timely evaluation of ART toxicity and any new Opportunistic Infections (OIs); and thus helps to contain health care costs by improving HIV- specific health outcomes and reducing emergency department visits and hospitalizations (Cree, Bell, Johnson, & Carriere, 2006; Geng et al., 2010). Patient retention in care also helps to reduce HIV- related morbidity and mortality, reduce the incidence of new infections in children and adults, and reduce development of ART resistance (Organization, 2012).

The Loss to Follow-up (LTFU) of patients is one of the challenges to effectively implementing treatment and preventive strategies (Tsadik, Berhane, Worku, & Terefe, 2017). Previous studies on LTFU in Uganda have found levels ranging from 9 % among 3345 adult patients initiated on ART in Jinja, Ugandan site of The AIDS Support Organization (TASO) followed up for 5 ½ years (Okoboi et al., 2015) to 20 % among 6473 adult patients from Mulago ISS and Mbarara Municipal Council clinics in Uganda, followed- up over 2.5 years (Namusobya et al., 2013). However, findings from these studies cannot be generalized on all patients on ART care because they were conducted from clinics that provide extra support to patients to ensure that they are retained in care.

The recent Ministry of Health (MOH) study, reported that central 1 sub- region, where Wakiso district is located, has the highest HIV prevalence in Uganda at 8 percent (MOH, 2017). This may lead to high patient loads in the district, yet there is no sufficient capacity in the ART clinics (UAC, 2018b). The recommended 'Test and Treat' strategy for all HIV positive patients may lead to more pressure on the health care within Wakiso district. And yet, for the 'Test and Treat' guideline implementation to contribute to the achievement of the UNAIDS 90-90-90 targets: where by 90% of all people living with HIV will know their HIV status by 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy by 2020 and 90% of all people receiving antiretroviral therapy will have viral suppression, patients must be retained in HIV care (MOH, 2016).

Several factors have been reported to be associated with LTFU including: being older, higher CD4 counts at ART initiation, WHO clinical stage III and IV at initiation, not having a treatment supporter, being self- employed (Mberi et al., 2015; Opio, 2015). However, more evidence is required on LTFU in the setting of the public health care delivery system but also in the context of the 'Test and Treat' treatment strategy. The aim of the study was to

determine the incidence of and the factors that are associated with LTFU amongst HIV positive adults in Wakiso district in the duration between January 2015 and December 2017.

1.1 Problem Statement

The prevalence of HIV among adults aged 15 to 64 in Uganda is 6.2 percent, corresponding to approximately 1.2 million people aged 15 to 64 living with HIV in Uganda (MOH, 2017). The current treatment strategies to minimize HIV morbidity and mortality including ART and prophylaxis have led to improved outcomes. However, these require patients to remain in care for lifetime. Previous studies have shown incidence of LTFU from HIV care ranges between 9% and 20% (Namusobya et al., 2013; Okoboi et al., 2015). However, these studies have been conducted in program settings where there is more streamlined follow- up of patients. We anticipate that the problem of LTFU is more prevalent in the public health facilities in Uganda due to several inadequacies that include: the high patient numbers that visit the ART clinics coupled with low staffing levels. In addition, the current recommended strategy of 'Test and Treat' may further lead to LTFU as more patients will be more rapidly initiated onto ART. If the problem of LTFU is not urgently addressed, there is likely to be development of treatment failure with potential for drug resistance, mother- to- child transmission, increased healthcare costs, but also an increase in deaths from AIDS- related illnesses. However, there is limited information on LTFU in public health care setting in Uganda especially after the initiation on 'Test and Treat' policy.

It is on this basis that we estimated the incidence of and determined the factors that are associated with LTFU amongst adult HIV- infected patients in Wakiso district.

1.2 Justification

The MOH consolidated HIV prevention and treatment guidelines (2016) recommend a 'Test and Treat' policy where by all individuals confirmed HIV positive are immediately enrolled on ART, regardless of their CD4 count or WHO HIV clinical staging. As a result, this sudden increase in the number of patients in immediate need of ART exerts a lot of pressure on the health facilities. This study has provided evidence to the problem of LTFU and its associated factors in the era of 'Test and Treat' and in the setting of the public health care system.

The UNAIDS 90-90-90 HIV treatment targets are based on all the people living with HIV as the denominator. Thus, if patients are lost from care, then it will be impossible to achieve the 3rd "90" inspite of excellent performance in the first 2 "90s". Consequently, the findings from the study will support development of interventions to prevent LTFU.

The findings will also be used to consolidate on the body of knowledge and generate more hypotheses on the possible factors that may lead to LTFU in order to minimize LTFU among HIV positive adults.

1.2 Conceptual Framework

Figure 1. Conceptual framework for risk factors that may affect and the likely outcomes of LTFU in HIV positive adults.

1.3.1 Scope of the Study

The scope of the study included socio- demographic factors, clinical factors, health system factors and social factors. The outcomes of LTFU were not included in this study.

1.4 Research Questions

i) What is the incidence rate of loss to follow-up of adult HIV/ AIDS patients in the duration between January 2015 and December 2017 in Wakiso district?

ii) What are the risk factors associated with loss to follow- up amongst adult HIV/ AIDS patients in duration between January 2015 and December 2017 in Wakiso district?

iii) What are the perceptions of patients and health providers about loss to follow- up from HIV care in Wakiso district?

1.5 Research Objectives

1.5.1 Main Objective

To determine the incidence of and the risk factors that are associated with loss to follow- up amongst adult HIV/AIDS patients in Wakiso district.

1.5.2 Specific Objectives

i) To estimate the incidence rate of loss to follow- up of adult HIV/AIDS patients in the duration between January 2015 and December 2017 in Wakiso district.

ii) To determine the risk factors associated with loss to follow- up amongst adult HIV/AIDS patients in the duration between January 2015 and December 2017 in Wakiso district.

iii) To explore the perceptions of patients and health providers about loss to follow-up from HIV care in Wakiso district.

CHAPTER TWO

2.0 LITERATURE REVIEW

In 2016, there were 1.8 million new HIV infections worldwide, adding up to a total of 36.7 million people with HIV (UNAIDS, 2017). More crucially, an estimated 35 million people have died from AIDS- related illnesses since the start of the epidemic, including 1 million in 2016 (UNAIDS, 2017). In Uganda, the prevalence of HIV among adults aged 15 to 64 is 6.2 percent, corresponding to approximately 1.2 million people aged 15 to 64 living with HIV in Uganda (MOH, 2017). In 2015, Uganda registered an estimated 83, 000 AIDS- related deaths (UAC, 2016).

The national HIV treatment programme has evolved over the past one and half decades. In 2005, the public sector ART programmes were commenced and HIV positive individuals who were at the stage of infecting others were eligible, then in 2008 the national ART guidelines modified CD4 cut- off for ART initiation to 350 cells/mL, then in 2014 the cutoff for ART initiation was modified to 500cells/mL (including "test and treat" for specific populations) and also the MOH introduced routine viral load monitoring in the public- sector (Kambugu, 2016; MOH, 2003). Currently, the national guidelines have moved to a universal "test and treat" policy to consolidate the gains of the interventions done over the previous decade and consequently as an effort to achieve the UNAIDS 90-90-90 targets (MOH, 2016).

2.1 Definition of Loss to Follow- Up

The definition of LTFU has varied according to setting and institution. The industrialized settings base on the frequency of visits to the health unit whereas the resource limited settings define LTFU on the basis of failure to visit a health unit after a certain period of time (Geng et al., 2010). WHO (2012) defines loss to follow- up as "patients with unknown outcomes" and further stresses that loss to follow- up should point to gaps in knowledge and information

systems. However, sometimes, there is some confusion on the clear distinction between loss to follow- up and disengagement from care (Organization, 2012). Berheto et al. (2014) defined loss to follow- up as not taking an ART refill for a period of 3 months or longer from the last attendance for refill and not yet classified as 'dead' or 'transferred- out'. Other studies have defined loss to follow as "a patient who has not been seen in an ART clinic for 3 months since the last missed appointment" (Opio, 2015; Sessolo, 2009). Janssen et al. (2015) defined LTFU as "a patient not retained in care; on ART or ART naïve, not returning to care during the study period with a patient delay for scheduled visits of more than 6 months". Mberi et al. (2015) defined LTFU as "a patient who had been followed up at the sentinel site, who had not had contact with the health facility for 180 days or more since their last recorded expected date of return or if there were 180 days or more between the expected date of return and the next clinic visit". For this study we chose a definition by the Ministry of Health, Uganda – that defines LTFU as a patient who has not visited the health facility clinic in 3 months. This conventional definition will enable comparability with other studies on LTFU.

2.2 Incidence of Loss to Follow- Up

The incidence of LTFU from HIV care has been estimated in several studies conducted both in Uganda and on the African continent at large. In Africa, a study conducted in 2010 using 72 cohorts and 226,307 patients estimated a 24 month retention rate in Africa at 70% and 36 month estimate was 64.8 % (Fox & Rosen, 2010). A retrospective cohort study done in Ethiopia by Berheto et al. (2014) on 2133 HIV/AIDS infected patients at an ART clinic between 2005 and 2013 reported the cumulative incidence of LTFU at 8.8 per 1000 person months. A retrospective study by Janssen et al. (2015) conducted in an HIV clinic in Gabon that followed- up 223 patients reported that 34.1% were lost to follow- up and 8.1% died.

In Uganda, a study by Okoboi et al. (2016) on 1228 adolescents aged 10 to 19 years, that were followed- up from January 2006 and December 2011 in TASO centres, reported that 400 (32%) were loss to follow- up where as 792 (65%) were retained in care and 36 (3%) had either died or transferred out. A study by Namusobya et al. (2013) on 6473 HIV- infected adult patients in a program reported a loss to follow- up of 20% over a 2.5 year period.

Whereas in the public setting, a retrospective cohort study was conducted in Nsambya hospital, Uganda by Massavon (2014) that reviewed records (2003 to 2010) from 1623 children aged 0 to 18 years in engaged in Community Home- Based Care (CHBC) and Facility- Based Family- Centred (FBFCA) models of care reported that retention was higher in CHBC at 94.8% and 84.7% in the FBFCA.

2.3 Factors Associated with Loss to Follow- Up

2.3.1 Socio- Demographic Factors

Several studies have enlightened different socio- demographic characteristics that are linked with LTFU; and when more attention is provided to patients with these characteristics, the problem of LTFU may be minimized.

The factor- older age, has been cited in several studies to be linked with retention. Berheto et al. (2014) reported adults Aged>20 (Adjusted Hazard Ratio (aHR): 1.4, 95%C.I: 1.0- 2.0) to be associated with LTFU; whereas Opio (2015) reported that patients aged 35- 59 years (aHR= .74, 95%CI: .58- .95) were associated with a reduced hazard of LTFU. However, Okoboi et al. (2016) reported risk factor being older (aHR= 1.38, 95% CI: 1.02- 1.86) as associated with attrition.

Evidence also suggests that unemployment has a significant association with LTFU. Perhaps, unemployed patients may not be able to keep all the appointment due to transportations costs.

Namusobya et al. (2013) evaluated all HIV- infected adults who enrolled with a CD4 level>350 cells/µL between 1 October 2008 and 30 April 2011 at 2 prototypical HIV clinics in Uganda reported that lower income, unemployment, and rural residence were associated with failure to be retained. Also, an un-matched case control study by Sessolo (2009) on 428 HIV adult patients at Infectious Diseases Institute in the duration between 2005- 2007 on the factors associated with loss to follow-up reported that lack of employment (Adjusted Odds Ratio (aOR)= 5.19, 95%CI: 3.36- 8.01) were significantly associated with LTFU. However, Mberi et al. (2015) reported being self- employed (aHR: 13.9, 95%CI: 2.81- 69.06, p=.001) was not associated with LTFU.

Meanwhile, Mberi et al. (2015) reported that socio- demographic factors associated with becoming LTFU as not having a committed partner (aHR: 2.9, 95%CI: 1.19- 6.97, p=.019). Other socio-demographic factors reported not to be associated with LTFU include: the reported that age, marital status and religion (Sessolo, 2009).

2.3.2 Clinical Factors

There are clinical patient characteristics that are known to be associated with LTFU. These characteristics include the patient CD4 count, the viral load, WHO clinical HIV staging, Regimen substitutions, TB co-morbidity among others. A retrospective cohort study conducted in Ethiopia by Berheto et al. (2014) reported that risk factor: Baseline CD4 counts≥200cells/mm^3 (aHR 1.7; 95% C.I: 1.3- 2.2) was significantly associated with LTFU. Similarly, Mberi et al. (2015) reported that baseline CD4 count>200 cells/ml (aHR: 3.8, 95%CI: 1.85- 7.85, p=.001) was associated with becoming LTFU. Another study by Okoboi et al. (2016), that used different cutoff for CD4 cell count, reported having a higher CD4 cell count (250+ cells/mm^3) at initiation (aHR= .49, 95%CI: .34- .69) was associated with

attrition. On the contrary, Sessolo (2009) reported that CD4 count of less than or equal to 200 at initiation (aOR= 17.72; 95%CI: 10.87- 28.88) was significantly associated with LTFU.

Several studies have also linked higher viral loads and WHO HIV clinical staging to LTFU. Mberi et al. (2015) reported detectable last known viral load (aHR: 3.6, 95%CI: 1.98- 6.52, p<.001) and WHO clinical stage three or four (aHR: 2.0, 95%CI: 1.22- 3.27, p=.006) to risk factors for LTFU; whereas ART adverse event had a lower risk (aHR: .6, 95%CI: .38- .99, p=.044) of becoming LTFU than those that had not. Whereas, Massavon et al. (2014) reported Mild immunosuppression (aHR: 4.66, 95% CI: 1.21- 17.98, p=.026) to be significantly associated with the risk of attrition.

Other studies have reported TB co- infection to be associated with LTFU- Janssen et al. (2015) documented tuberculosis (aHR: 1.80, 95%CI: 1.05, 3.11, P= .03) to be associated with an increased risk of being LTFU. However, Berheto et al. (2014) reported that TB co-infection was not associated with LTFU.

There are several other risk factors for LTFU that have been reported in literature. Berheto et al. (2014) reported that risk factors: not taking INH prophylaxis (aHR 3.7; 95% CI: 2.3- 6.1), and Regimen substitutions (aHR 5.2; 95% C.I: 3.6- 7.3) were significantly associated with LTFU.

A study by Opio (2015) reported that appointment duration of two months for next visit (aHR= .31; 95% CI: .17- .57) and good adherence level>95% (aHR=.32; 95%CI: .17- .57) were associated with a reduced hazard of LTFU. Janssen et al. (2015) documented early starting ART was associated with a decreased risk of LTFU (aHR .43, 95%CI: .24- .76, P=.004).

2.3.3 Health System Factors

The health system factors involve the infrastructure (both technical and physical) in place to facilitate retention of patients, which are normally beyond the control of the patient. These often include: the transportation system or distance to health facility, mode of care, and the health service providers, among others.

A cohort study on 469 HIV-1-Discordant Couples in Nairobi, Kenya found that participants living between 5 km and above from the study clinic had a two- fold (aHR: 2.17; 95% CI:1.09- 4.34; p=.03) increase in likelihood of loss to follow- up compared to those living within 5 km from the clinic (Conley et al., 2012). A retrospective cohort study by Massavon et al. (2014) on children and adolescents reported that the risk of attrition was significantly associated with the model of care- Community home- based care (aHR: .29, 95%CI: .12- .7, P= .006). A qualitative study by Yehia et al. (2015) reported that expensive and unreliable transportation, insufficient health insurance, challenges with appointment scheduling, and difficult relationships with clinic staff as the barriers to retention in care whereas patient-friendly clinic services (transportation, co- location of services, scheduling/ reminders), and positive relationships with providers and clinic staff to be facilitators of retention in care.

2.3.4 Social Factors

The social factors involve the environment in which the patient is living in that is supportive to ensure that they are encouraged to stay on treatment. These factors normally include: having a committed partner, social support group, family and friends among others.

A prospective study by Evangeli et al. (2014) reported that higher LTFU rates were associated with increased openness with friends/ family and believing that community problems would be solved at higher levels; whereas lower LTFU rates were independently associated with increased year of age, greater reliance on family/ friends, and having

children. Meanwhile, Waldrop- Valverde et al. (2014) and Yehia et al. (2015) reported that patients with greater use of social support were less likely to miss medical visits. Yehia et al. (2015) also reported that stigma as barrier of retention in care where as social support to be a facilitator of retention.

CHAPTER THREE

3.0 RESEARCH METHODS

3.1 Study Design

The study employed a concurrent- nested mixed methods (quantitative and qualitative) design of data collection and analysis. The quantitative part of the study was a retrospective cohort design- where the data was obtained from the records of the health facilities.

3.2 Study Setting

The study was conducted in Wakiso district that is located in Central Uganda. The district consists of 12 Divisions, six Sub-counties and 720 villages. Wakiso district is projected to have a population of 2,111,061 people (UBOS, 2016). The HIV/ AIDS prevalence rate for Wakiso district is 10 percent (WDLG, 2016). The district has one general hospital, six public Health Centre IVs, 24 public Health Centre IIIs. The district is divided into six Health Sub-Districts (HSDs); with each government Health Centre IV acting as a referral for a particular HSD. The district has a total of 31 government health facilities that are providing HIV care (WDLG, 2016). The HIV care services offered in these ART clinics are free of charge, and provided by government. Each ART clinic is headed by the ART Clinic In-charge, who is supported by a Clinical Officer, Counsellors, a Data Management Team and Volunteers, who help to organize the patient files. Patient records are kept in the ART register that is updated whenever the patient visits the clinic. Additionally, the patient data is also stored on OpenMRS, an HIV data management computer program that helps to digitize the patient information. The ART clinics in these health centres are provided with technical support in form of workshops and also small grants from Mildmay, Uganda, a non-governmental organization that supports government efforts in response to HIV/ AIDS.

3.3 Population

3.3.1 Target Population

All HIV/ AIDS patients that were 18 years and above in Wakiso district.

3.3.2 Accessible Population

All HIV/ AIDS patients that were 18 years and above initiated on ART in Wakiso district between the period January 2015 and December 2017.

3.3.3 Study Population

All HIV/AIDS patients that were 18 years and above initiated on ART in Entebbe Hospital, Wakiso HCIV, Namayumba HCIV, Kasangati HCIV, Buwambo HCIV, Ndejje HCIV, Kajjansi HCIV, Kira HCIII, Nabweru HCIII, Nsangi HCIII, Kakiri HCIII, Nakawuka HCIII, and Kigungu HCIII between January 2015 and December 2017 and met the eligibility criteria for the study.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

The study included adult HIV/AIDS patients receiving care at public health facilities within Wakiso district and initiated ART between January 1st, 2015 and December 31st, 2017.

3.4.2 Exclusion Criteria

The subjects who missed data on important variables such as date for start of ART, 1st line initial regimen, sex, age and CD4 count at initiation were excluded from the study.

3.5 Sample Size Determination

3.5.1 Sample size estimation for incidence of loss to follow- up

The researcher used Cochran (1963) method for the sample size calculation for a single proportion.

$n_o = [Z^2PQ]/ e^2$

Where n_o was the sample size and Z was the abscissa of the normal curve with a confidence interval of 95 percent. Fox (2010) estimated retention (P) at 70 percent. The level of precision (e) was +- 5%.

$n_o = [1.96^2*.7*.3]/ .05^2$

n_o = 323 patients

To correct for the design effect in the sampling = 323*2 = 646 patients (McLean, Cogswell, Egli, Wojdyla, & de Benoist, 2009).

3.5.2 The sample size estimation for cox proportional hazards model

$\Delta = \lambda_1/ \lambda_2 = Ln\pi_1/ Ln\pi_2$

$= Ln .68/ Ln .32$

$= .3385$

Where $\lambda 1$= hazard in group 1; $\lambda 2$ = hazard in group 2; π_1= proportion of retention in group 1 at time t, π_2= proportion of retention in group 2. Okoboi et al. (2016) estimated retention among patients with CD4 count< 250cells/mm^3 (group1) at 68% and 32% among patients with CD4 count≥250cells/mm^3 (group2). Previous studies have indicated that variable CD4 count is a major predictor of LTFU and hence used to compute for sample size (Mberi et al., 2015; Namusobya et al., 2013; Opio, 2015).

$e_2 = [(Z_{\alpha/2} + Z_{1-\beta})^2 / \theta] * [(1 + \theta\Delta)/ (1 - \Delta)]^2$

$= [(1.96 + .84)^2 / 2] * [(1 + (2 * .3385))/ (1 - .3385)]^2$

$e_2 = 25.194$

$e_1 = \theta e_2 = (2 * 25.194) = 50.388$

$E = e_1 + e_2 = e_2 (1+\theta) = 25.194(1+2) = 75.582$

Where $Z_{\alpha/2}$= standard normal value corresponding to level of significance (α=.05), $Z_{1-\beta}$= standard normal value corresponding to power of study (1-β= 80%), θ= ratio of group 2 to group 1 (assuming the ratio is 2:1), e_1= expected events in group1, e2=events in group 2.

$N_{total} = [(1+\theta) E]/ [(1-\pi_2) + (\theta (1-\pi_1))]$

$= [(1+2) * 75.582]/ [(1-.32) + (2(1-.68))]$

$= 171.77 = 172$

$N_{adjusted} = N/ (1-w)$

$= 172/ (1-.02)$

$= 175.5 = 176$ patients

Using a parameter, w to adjust for anticipated drop out due to other factors such as death (w= .02), the sample size for cox was adjusted to 176 patients.

We also corrected for the clustering in the data due to the different health facility levels: 176*2= 352 patients (McLean et al., 2009).

Consequently, for purposes of power, the study adopted a sample size of 646 patients.

3.6 Sampling Procedures

The general hospital and all the 6 HC IVs were included in the study because they are referral centres for the lower health facilities. Simple random sampling technique was used to select 1 HC III from each HSD. These facilities included Entebbe Hospital, Wakiso HCIV, Namayumba HCIV, Kasangati HCIV, Buwambo HCIV, Ndejje HCIV, Kajjansi HCIV, Kira HCIII, Nabweru HCIII, Nsangi HCIII, Kakiri HCIII, Nakawuka HCIII, and Kigungu HCIII. The study used Probability Proportional to Size (PPS) sampling technique to determine the number of patients to select at each health facility level. Then systematic sampling technique was used to randomly select the patients to study from the list of patients receiving ART in the selected health facility. The sampling interval was determined by dividing the population of eligible patients in the clinic by the required sample. The first patient (random start) was determined using simple random sampling to select between 1st positioned and average positioned patient, then the subsequent patients were selected after the predetermined constant interval. This was done using Microsoft excel.

3.7 Study Variables

3.7.1 The Outcome Variable

The outcome variable in this study was time to LTFU. A patient LTFU was one who did not visit the health facility in three months to receive highly active ART after their last scheduled appointment date between the study duration of January 1st, 2015 and December 31st, 2017. The time observations were censored for patients that died or were transferred to other ART clinics. The confirmation on death or transfer status was gotten from the ART cards.

3.7.2 The Predictor Variables

- **Socio- demographic factors**: sex, age at initiation, marital status, baseline weight and height, and having telephone contact.
- **Clinical factors**: CD4 count at initiation, WHO clinical stage, toxicities of ART, hemoglobin level, BMI, ART initiation regimen and pregnant woman.
- **Health system factors**: level of health unit, distance from home to facility, waiting time, and adequacy of documentation.
- **Social factors**: social support group, stigma, and beliefs and misconceptions.

3.8 Data Collection Methods

The research assistants extracted data on time to LTFU, sex, age at initiation, marital status, baseline weight, CD4 count at initiation, WHO clinical stage initiation, toxicities of ART, hemoglobin level at initiation, pregnancy, ART initiation regimen, BMI, telephone contact and level of health unit from the patient- HIV care/ART cards in the health facilities using a data extraction form.

3.9 Data Management

The data entry screen was designed using Epi-data 3.1 version. The data entrants entered 1/3 of the forms (randomly selected) again to assess for accuracy of data entry. The data cleaning and validation was done using excel program. The data were then exported to STATA version 13 for analysis.

3.10 Data Analysis

3.10.1 Descriptive Statistics

We estimated the incidence of loss to follow- up of the adult HIV/ AIDS patients in the district.

Incidence rate per 1000 patients = {[Number of patients lost to follow- up in the duration January 1st 2015- December 31st 2017]/ [Total Person Months]} *1000

We also described baseline characteristics of the patients at initiation according to the outcome of the patients.

We conducted a univariate comparison of retention times between patients recruited on a 'Test and Treat' strategy and those recruited on the basis of their CD4 count using the Kaplan Meier curve and log- rank test. The study also adjusted the estimates for the clustering in the different health facilities.

3.10.2 Bivariate Analysis

The cox proportional hazards regression model was used to determine how the risk factors are associated with the time to LTFU. The times were censored in the data for patients who either died or transferred to other ART clinics.

3.10.3 Multivariate Analysis

The multivariate analysis technique was used to determine how the combination of risk factors influenced time to LTFU. Risk factors whose p- values were less than .2 in bivariate analysis, were considered for multivariate analysis. The scaled schoenfeld residual versus time plots and Proportional Hazards (PH) statistical test were used to test for the time-varying covariates. The plots of the martingale residuals were also used to assess for functional form of the continuous covariates. The researcher also assessed for interaction and confounding of risk factors in the regression model. The hazard ratios were used as the measure of association and the p-values of less than .05 suggested statistical significance. The goodness of fit of the cox model was assessed by plotting the Nelson- Aalen cumulative hazard versus the cox-snell residuals.

3.11 Qualitative Research

Purpose: To explore the perceptions of patients and health providers about loss to follow- up from HIV care in Wakiso district. The findings from the qualitative research were also used to explain the findings (triangulate) from the quantitative research.

Qualitative study variables: Adequacy of documentation, waiting time of patients, distance from home to health facility, social support groups, stigma, beliefs and misconceptions regarding LTFU.

Qualitative data collection: The study adopted in-depth and key informant interview methods of data collection. Purposive sampling technique was used to select the key informants; who were the In-charge at the ART clinics and an expert client, due their knowledge and role in management of HIV patients. The study used convenient sampling to select patients that were accessible to the research assistants. The patients who were easily reachable were contacted, using telephone contacts extracted from ART cards, and traced for in- depth interviews. The Principal Investigator conducted the key informant interviews with three in- charges at the selected ART clinic and one with an expert client; but nine in-depth interviews (3 LTFU and 6 active patients) were done by research assistants, using English and Luganda language respectively. The data collection was conducted using an audio recorder and interview guide until saturation was reached, to explore their perceptions regarding LTFU.

Qualitative data management and analysis: The collected information was translated and transcribed into text form. The information was coded and synthesized using Open Code version 4.02 in order to conduct a thematic analysis. The analysis included a comparison of the prominent themes between the two groups: patients LTFU and those retained in care.

3.12 Quality Control

The researcher trained the research assistants on the data extraction tool but also supervised the field work to ensure minimal errors at the stage of data collection. The data extraction tool was pre-tested for errors before data collection. The data entrants were trained before commencement of data entry. The data entrants re-entered 1/3 of the forms to assess for data entry quality. The study team also met frequently to discuss challenges and adopt practical solutions during the course of the study.

3.13 Ethical Issues

The study attained permission from Clinical Epidemiology Unit, Makerere University College of Health Sciences. We obtained approval and a waiver of consent from the Makerere University School of Medicine Research Ethics Committee, College of Health Sciences. Permission was also obtained from the district health authorities before accessing the patient files in the ART clinics. We used patient unique numbers in the study so to ensure the collected information was de-identified. The Principal Investigator also obtained consent from the health personnel before conducting the key informant interviews. We obtained written informed consent from the patients before conducting the in- depth interviews.

CHAPTER FOUR

4.0 RESULTS

4.1 Study Subjects

The study reviewed records of patients that were initiated on ART between January, 2015 and December, 2017. The patients ever registered in the selected ART clinics (13) at the point of data collection (April 11th, 2018) were 44,262.

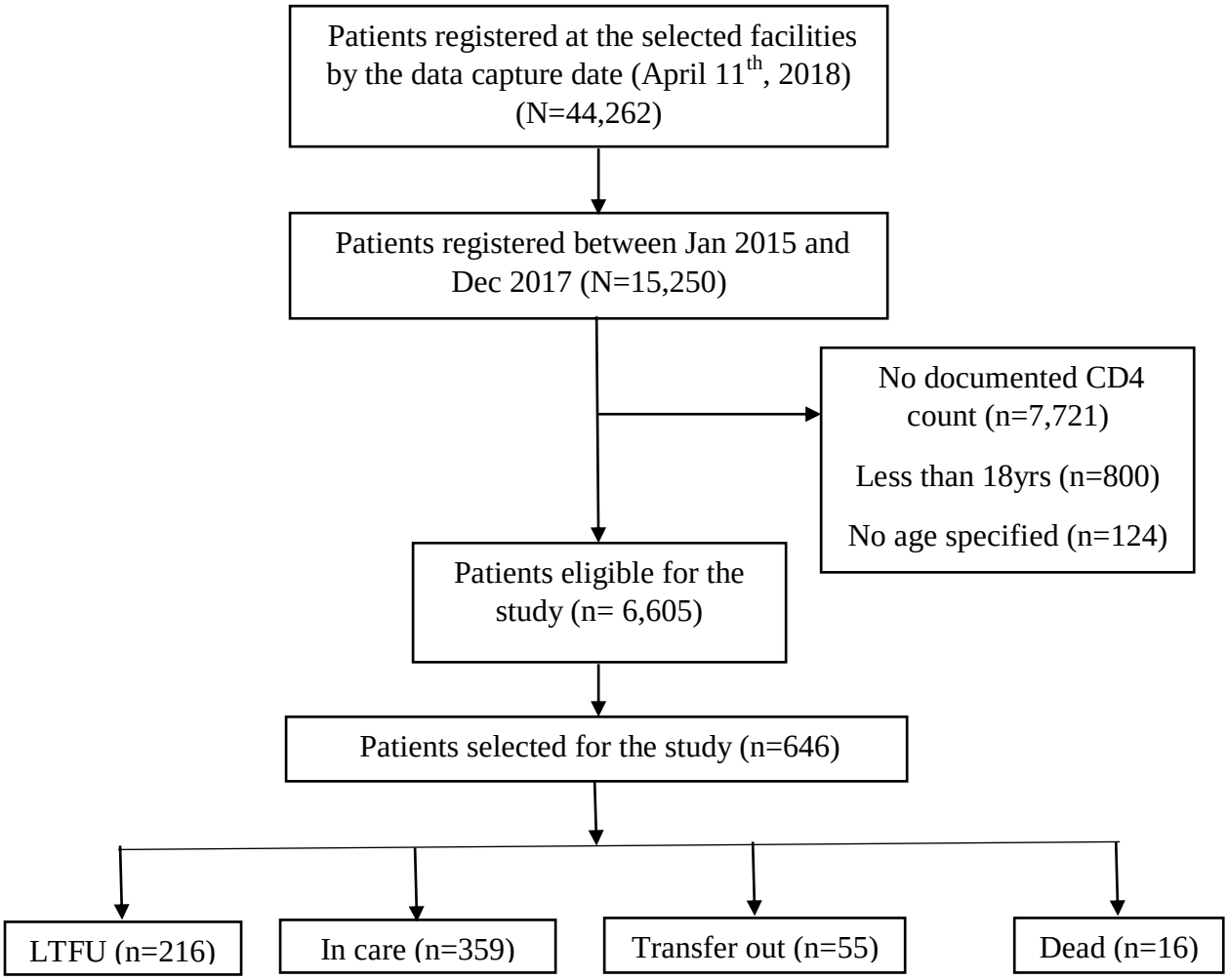

Figure 2. A flow diagram describing the patients included in the study and their various outcomes.

The patient registers indicated that a total of 15,250 patients (see figure 2) were initiated on ART between the period of January 2015 and December 2017 in the selected health facilities in Wakiso district. We excluded 8,645 patients of the 15,250 initiated patients because they did not meet the eligibility criteria (see Figure 2 for details). Then, a random sample of 646 patients were selected for the study. In the study period, 216 were lost to follow-up (33.4%), 55 patients were transferred out (8.5%), 359 patients were still in care (55.6%) while 16 patients died (2.5%) (Figure 2).

4.2 Baseline characteristics of study participants

Table 1. Baseline demographic characteristics of 646 patients included in study, Wakiso district cohort, January 2015- December 2017.

Variable	Total	
	N	(%)
Sex of subject		
Female	391	(60.5)
Age group		
Below 30yrs	282	(43.6)
30- 44yrs	268	(41.5)
45yrs and above	96	(14.9)
Marital status		
Never married	122	(18.9)
Married	207	(32.0)
Living together	18	(2.8)
Divorced/Separated	44	(6.8)
Widowed	22	(3.4)
Not documented	233	(36.1)
Telephone		
Yes	418	(64.7)
No	177	(27.4)
Not documented	51	(7.9)

The majority of patients in this study were female (60.5%); and many patients (43.6%) were below 30 years. The study included 122 patients who were never married (18.9%), 207 were married (32.0%). A total of 177 patients (27.4%) had no telephone contacts on their ART cards (Table 1).

Table 2. Clinical characteristics of 646 patients included in study, Wakiso district cohort, January 2015- December 2017.

Variable	Total	
	N	(%)
CD4 count		
Less than 500c/µl	535	(82.8)
500c/µl and above	111	(17.2)
WHO clinical stage		
I	359	(55.6)
II	214	(33.1)
III	54	(8.4)
IV	12	(1.8)
Not documented	7	(1.1)
Care entry		
In patient	4	(0.6)
Out patient	430	(66.6)
Outreach	12	(1.9)
STI	1	(0.1)
TB	1	(0.1)
Transfer in	32	(5.0)
eMTCT	74	(11.5)
Not documented	92	(14.2)
BMI (449)		
Under weight	68	(15.1)
Normal weight	312	(69.5)
Over weight	52	(11.6)
Obese	17	(3.8)
Pregnant woman (n=391)		
Yes	69	(17.6)
No	322	(82.4)
Regimen		
AZT/3TC/NVP	10	(1.6)
TDF/3TC/EFV	635	(98.3)
TDF/3TC/NVP	1	(0.1)
ART initiation strategy (n=389)		
CD4 count	260	(66.8)
Test & Treat	129	(33.2)

The study involved 535 patients (82.8%) with CD4 count less than 500c/µL. The majority of the patients (88.7 percent) were in WHO clinical stage I & II. The study also found that most of the patients entered care through the Outpatient department (66.6%), followed by the

eMTCT strategy, at 11.5% of the sample. Amongst the female population, nearly one fifth, 69 out of 391 patients (17.6%) were pregnant during the study period. Almost all the patients, 635 out 646 (98.3%) were initiated on TDF/3TC/EFV as the initial ART regimen. (See Table 2).

4.3 Incidence Rate of LTFU for Wakiso district

The study retrospectively followed-up 646 patients who were initiated between January 2015 and December 2017, yielding 69498.2 total person-months. The overall Incidence rate for LTFU of the patients was 21 per 1000 person-months, with a 95% Confidence Interval (CI): (18- 25 per 1000 person-months).

4.3.1 The Incidence Rate of LTFU by social demographic characteristics

The female patients had a higher incidence rate of LTFU of 23 per 1000 person-months (95%CI: 19- 29 per 1000 person-months). The patients below 30 years had a higher incidence rate of 32 per 1000 person-months (95%CI: 26- 40 per 1000 person-months) (see Table 3).

Table 3. The Incidence rate of LTFU by baseline social-demographic characteristics

Variable	Incidence Rate (per 1000 person-months)	95% CI
Overall	21	18- 25
Sex of subject		
Male	18	14- 24
Female	23	19- 29
Age group		
Below 30yrs	32	26- 40
30- 44yrs	16	12- 21
45yrs and above	13	8- 21
Marital status		
Never married	19	13- 29
Married	21	16- 28
Living together	11	1- 23
Divorced/Separated	15	6- 42
Widowed	28	17- 48
Not documented	24	18- 31
Telephone		
Yes	16	13- 21
No	33	26- 42
Not documented	24	12- 47

4.3.2 The Incidence Rate of LTFU by baseline clinical characteristics

The patients initiated with a CD4 count of 500c/µl and above had a greater incidence rate of LTFU of 27 per 1000 person-months (95%CI 18- 40 per 1000 person-months). The patients with WHO clinical stage III at initiation had a greater incidence rate of LTFU of 29 per 1000 person-months (95%CI 17- 49 per 1000 person-months). Furthermore, the patients who enter care through eMTCT also had greater incidence than other patients. (See table 4)

Table 4. The Incidence rate of LTFU by baseline clinical characteristics.

Variable	Incidence Rate (per 1000 person-months)	95% CI
Overall	21	18- 25
CD4 count		
Less than 500c/µL	21	17- 25
500c/µL and above	27	18- 40
WHO clinical stage		
I	21	17- 27
II	21	16- 27
III	29	17- 49
IV	11	2- 87
Not documented	31	5- 237
Care entry		
Out patient	22	18- 27
eMTCT	27	17- 42
Others*	23	13- 41
Not documented	14	9- 24
BMI		
Under weight	20	12- 36
Normal weight	15	12- 20
Over weight	27	16- 46
Obese	24	10- 61
Pregnant woman		
Yes	28	18- 45
No	22	18- 28
Regimen		
TDF/3TC/EFV	21	18- 24
Others**	95	36- 252
ART initiation strategy		
CD4 count	30	24- 39
Test & Treat	33	23- 49

Others* includes Inpatient, Outreach, STI, TB & Transfer In; Others** involves AZT/3TC/NVP & TDF/3TC/NVP.

4.3.3 Comparison of patients initiated on basis of CD4 count and 'Test and Treat' strategy

The incidence rate for patients enrolled on the basis of CD4 count was 30 per 1000 person-months with a median retention time of 24.1 months whereas that of patients initiated on the basis of 'Test & Treat' was 33 per 1000 person-months with median retention time of 16.6

months, with an Incidence Rate Ratio (IRR) of 1.05. However, there was no significant difference in the retention times of patients initiated on the basis of CD4 count and 'Test & Treat' strategy, with a p-value of 0.231. The figure 3 indicates line trends of patients who were initiated on the basis of 'test and treat' and CD4 count. It shows that in the first 10 months, the risk for LTFU was not different in the 2 groups. However, beyond 10 months, the patients initiated on 'test and treat' basis got LTFU earlier than those initiated on the basis of CD4 count.

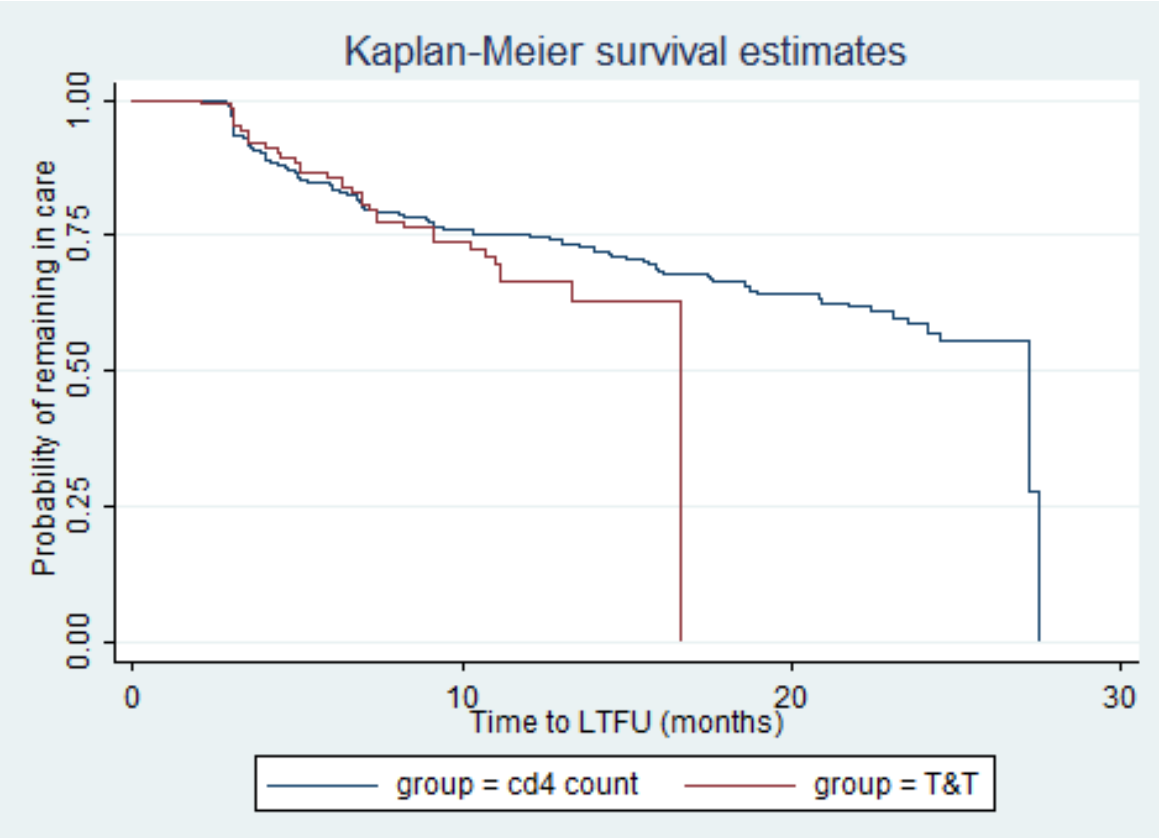

Figure 3. Kaplan-Meier graph showing the time to LTFU of 'CD4 count' and 'Test and Treat' groups.

4.4 Bivariate Analysis

The cox proportional hazards regression model was used to determine the factors that are associated with time to LTFU.

Table 5. Bivariate Cox Proportional hazards regression model to determine factors associated with LTFU, Wakiso district cohort, January 2015- December 2017.

	Univariate		
Characteristic	**HR**	**95%CI**	**P-value**
Sex			
Male	Ref*		
Female	1.28	1.027- 1.587	**0.028**
Age	0.96	0.947- 0.983	**<0.001**
Marital status			
Never married	Ref*		
Married	0.97	0.694- 1.355	0.857
Living together	0.91	0.396- 2.104	0.830
Divorced/Separated	0.70	0.297- 1.632	0.405
Widowed	1.37	0.657- 2.867	0.399
BMI			
Under weight	Ref*		
Normal weight	0.68	0.479- 0.958	**0.027**
Over weight	1.01	0.550- 1.869	0.965
Obese	1.18	0.592- 2.331	0.644
Telephone			
Yes	Ref*		
No	2.15	1.590- 2.895	**<0.001**
Cd4 count			
Less than 500c/ml	Ref*		
500c/ml and above	1.29	0.854- 1.939	0.228
WHO clinical stage			
I	Ref*		
II	0.94	0.647- 1.359	0.733
III	1.07	0.717- 1.597	0.741
IV	0.62	0.313- 1.245	0.181
Health facility Level			
HC III	Ref*		
HC IV	0.77	0.529- 1.116	0.166
Hospital	0.51	0.391- 0.678	**<0.001**
Care entry			
Others*	Ref*		
Out patient	1.03	0.669- 1.599	0.879
eMTCT	1.24	0.627- 2.456	0.535

Ref*- Reference category; Others* includes Inpatient, Outreach, STI, TB & Transfer In.

4.5 Multivariate analysis

In the bivariate analysis, factors- female-sex, age, BMI-normal weight, no telephone contact, clinical stage IV, health facility level IV, and hospital level had p-values less than 0.2 and were considered for multivariate analysis.

Table 6. Multivariate Cox Proportional hazards regression model to determine factors associated with LTFU, Wakiso district cohort, January 2015- December 2017.

Characteristic	aHR	95%CI	P-value
Age	0.98	0.949- 1.005	0.116
BMI			
Under weight	Ref*		
Normal weight	0.64	0.453- 0.903	**0.011**
Over weight	0.90	0.426- 1.911	0.789
Obese	0.99	0.523- 1.882	0.981
Telephone			
Yes	Ref*		
No	2.16	1.330- 3.511	**0.002**
Health facility Level			
HC III	Ref*		
HC IV	0.58	0.276- 1.229	0.156
Hospital	0.22	0.121- 0.408	**<0.001**

The adjusted cox regression model suggested that factors BMI- normal weight, no telephone contact, health facility level- hospital were significantly associated with LTFU; whereas age was not statistically significant. The factors age and health facility level- hospital were significantly associated with LTFU over time.

4.6 Qualitative Research

4.6.1 Results from Key Informant Interviews on LTFU

The Key Informant interviews (KIIs) were conducted with 3 ART clinic in-charges and 1 expert client, to explore the possible reasons for LTFU at their respective facilities. The KIIs were done in ART Clinics where LTFU was more prevalent.

4.6.1.1 Capacity of the ART Clinics

The capacity to retain patients in care in most clinics was very limited, mainly due to the overwhelming numbers of patients that visited these clinics. One KII asserted *"But then also we have only one counsellor and yet we have so many clients. So, the time they take counselling these clients is very minimal. Sometimes we do it in group and yet it should be done on an individual basis, because many people have different backgrounds and issues to deal with…sometimes there are certain issues you can talk about and somebody remembers something but then in a group setting, many times it's hard."* Another informant stated that *"Sometimes, with our clients, also they have a negative attitude towards public facilities. Even though, government facilities are now better, some patents prefer private. ……..that government doctors don't treat us well, they are arrogant. That kind of attitude. Then they get disinterested and drop from care."* Another key informant mentioned that *"Sometimes our attitude as health Workers make clients to get lost to follow-up. Caring is very- very important. When you care for clients positively, those people (clients) will come, but you care for them negatively, they will not come. So, attitude is very crucial."*

4.6.1.2 Perceptions about Stigma

The problem of stigma was still persistent, and contributing to a significant proportion of patient drop out. The stigmatized patients would resist from being transferred to nearer clinics to be managed better. This was affirmed by one informant *"And sometimes, we have clients*

who do not want to be transferred to the nearest facility…. where they are living, yet they can't foot the bill (transport) when we need them. I think it is stigma issues." Another informant reported *"Others, we have…..under KP, these sex workers, MSMs, the challenge with them, they have self-stigma. They find themselves difficult to come to the facility like this one. They can start the treatment like this one. Others they get customers somewhere else and they move away, they go to another area. In fact even their viral loads are high……today she is here, tomorrow she's at the landing site, the other he is at the border, that mobile thing it makes them get lost to follow-up."* The problem was also echoed by a different informant*"……..stigma is still high. People don't want to be seen coming from the ART clinic. Instead of coming to collect medicine in time, they find themselves staying because they don't want to be seen*." Stigma has also affected some patients' intimate lives of some patients. *"Then others, get new partners, and when they get a new partner, they do not want to associate with HIV anymore, because they are looking good and there able to attract someone; they just continue with their lives."* (A key informant disclosed)

4.6.1.3 Distance and economic reasons

The findings also indicated that some patients had to move long distances from home to the health facilities to get drug replenishment. On days that they don't have money, they definitely get to miss clinic appointments. *"As for the older people, the men and the women, they almost have similar problems some them it is distance, some of them it is money…"* (One informant asserted). Another key informant reported that *"Others, the economic factors, loss of a job, or loss of bread winner in the family (especially women)."* The informant further stressed that *"…….you find that most of the loss to follow-up is high among women. You find that when, may be, they separate or the bread winner dies, they are left there and the woman cannot maintain the bills, so they decide to go back to the village."* "*Then the other issue is that some of the come from far places. Sometimes, transport becomes a*

challenge, and they stay back…..there is no money for transport so I can't make it (patients always lament)." (An informant disclosed). *"There is a problem of lack of transport. Others move for even up to 15 miles to get to the facility sometimes, the men refuse to give their wives transport to come to the facility."* (Disclosed by an expert client)

4.6.1.4 Documentation, filing system and space at the clinic

The filing system and documentation are important in the management of patients. When the files are not well organized and kept, critical patient information can get lost. This eventually makes it difficult to evaluate the patient and not to mention them being regarded as lost to follow-up. One informant revealed *"……because of the fact that we do not have a proper filing system, our files get lost. You have seen some of them (patient data) have no records, yet the records team told us everything is right there (in the database system); we are not so certain about it, but then am wondering how the file is not here and yet the number was given out."* The informant also added that *"Many times the records people do not get the files and then they drop out those people…and instead of bringing the lists to us ….some of these people come but then the files….i don't know what really happens; they files are misplaced somehow…"*. In many cases, the filing and documentation system was compromised by the limited space at the clinics. This was mentioned by one informant *"Definitely! Because now many times we have a problem where files are taken out and they are put in places where they are not supposed to be. Yah...they are taken by the records person or any other person. And then, you will find the male files in the maternity side. That is not proper."*

4.6.1.5 The long waiting time at the Clinic

The problem of long waiting time at the clinic was experienced by majority, if not all, of the patients. This was majorly because of the many patients that are being managed at these clinics yet the staff are limited. One informant said *"……That one is real challenge...because*

since am mostly the clinician there at the ART clinic, the rest are volunteers…you know how volunteers are, you do not push them….they come when they want." Another informant narrated that *"Then, the other issue is that in government we have huge turn-ups. And yet some do not have time to wait. One may want to come early get a service and then proceed. So, even when they come early, they will find a line, and then they just go. So, they decide to leave just because the line is long."*

4.6.1.6 Alcohol and drug abuse

The abuse of drugs and alcohol was also cited as one of the reasons for LTFU. *"Others, its alcohol and substance abuse. They drink and forget to come back for their treatment; they do not care because they have drunk and forgotten their problem."* (An informant mentioned).

4.6.1.7 Spiritual and cultural beliefs

The findings also suggested that some patients relied on spiritual and cultural beliefs for cure. Some patients get to be misled, and they get to abandon treatment. *"Others seek spiritual healing, after they have been prayed for; they say they have healed, they don't come back again."* (One informant disclosed).

4.6.1.8 Fear of disclosure

The fear of disclosure has also greatly led to LTFU. Some patient get to disassociate themselves from the clinic just because they have not yet disclosed to their friends or relatives. *"Just, that there is also fear of disclosure (lack of disclosure)…… they find it very difficult. Like am a pregnant woman, who has not disclosed to the husband……it is easy when you are going for antenatal… I have gone to take medicine (they say). But after giving birth, it is very hard to go back for antenatal. That's why you will see most of the eMTCT patients there is high loss to follow-up……."* (An informant said).

4.6.1.9 Stock outs

The drug stock outs are common in the setting of public health care system due to the high patient loads. These stock outs discourage the patients from returning to ART clinic. One key informant reported that *"And then, like in government setup, which is actually inevitable, sometimes we don't have stocks of some HIV medicine, we tell you to go and buy but it is very expensive, and most of our clients are poor. So, it becomes a challenge."*

4.6.2 In-depth Interviews

A thematic analysis was done to explore the perceptions of patients that were active and those lost to follow-up. The study reached saturation point after interacting with 9 patients; whereby 6 were actively in care and 3 were lost to follow-up. The interviews were conducted on 5 females and 4 males, ranging between the age of 30 and 52 years.

4.6.2.1 Stigma

The findings from the in-depth interviews revealed that stigma was still a huge problem in society. This social vice contributed to a large number of patients missing their appointments in the clinics. One patient disclosed that "……*There is a lot of stigma coming from our family members. This one am really sincere. My own mother stigmatizes me. When she uses a cup, she doesn't want me to touch that very cup."* Another patient said that "*…….she really looks at me like I killed a human being. It makes me feel terribly bad. I am over stigmatized in my family."*

4.6.2.2 Social support

The care and support that patients get from their friends and relatives is equally important in HIV treatment. This kind of support was not common especially among lost patients. One patient said *"……..I do not receive any kind of social support from friends or family members."* Another patient disclosed that "……*So, one time I asked her (sister) to send me*

some transport money, she started to through insults at me. she said you should tell your men who infected you to give you transport. So that is the kind of situation am in.

4.6.2.3 Transportation

The transportation means to the clinics was also critical, since patients require to keep returning to the clinics for drugs. One patient said "….*Lack of transportation sometimes to be able to come to the clinic because I stay very far from the health facility".*

4.6.2.4 Conduct of the clinic staff

The manner in which the clinic staff handle the patients was is also very important. Some patients found the patients unprofessional in the clinics. A patient said *"……you will find that some of the staff are young student girls, who do not know how to handle people like us."* Another patient said *".....they back-bite us and on many occasions they are gossiping….and some of them are very arrogant"*

4.6.2.6. Long waiting time and competing life activities

The patients were also concerned about the long waiting time that they spend at the clinic, yet they have a lot of work to do in order to make ends meet. As a result, the patients got to miss appointments at the clinic. In an interview, one patient asserted that *"……you can go there early morning at around 8am, but then you end up getting served after 2 pm."* "……*there is a waiting time at the clinic is sometimes too much since we have long queues at the ART clinic."(*A patient mentioned)**.***

The prominent themes among the LTFU were stigma, competing life activities and long waiting time; whereas among the active patients social support, transportation and misconduct by clinic staff were also prevalent.

CHAPTER FIVE

5.0 DISCUSSION

This study sought to provide evidence to the problem of LTFU and factors associated with LTFU in the setting of the public health care system. We found an overall incidence rate of LTFU of 21 per1000 person-months. The factors that were significantly associated with LTFU were normal weight, hospital level, no telephone contact; but also age and hospital level were associated with LTFU over time. The study also revealed that stigma, long waiting time and competing life interests were common among the patients LTFU. The findings of this study are key in understanding the problem of LTFU in the public health care system.

5.1 Incidence rate of LTFU

Our study shows an overall incidence of LTFU of 21 per 1000 person-months. Meaning, every month, 21 out of 1000 persons were LTFU in the ART clinics. This rate was much higher than for studies conducted in 'Centres of excellence' in Uganda, as they offer extra support to patients compared to the public health facilities. However, some of the studies had a different definition of LTFU, and with different follow-up durations. For instance, a study by Okoboi et al. (2015) reported an incidence rate of LTFU at 1.59 per 100 person-years, meaning about 1 out of 1000 persons every month were LTFU, yet they defined LTFU differently, as failure to visit centre at least once in 6 months.

In December 2016, the government released "consolidated guidelines for prevention and treatment for HIV in Uganda" that expanded the 'Test and Treat' policy to all adolescents and adults diagnosed with HIV (MOH, 2016). The outcomes of this policy were not clear-whether it would lead to more LTFU of patients since people would be initiated immediately, even when they are not really prepared to start taking Antiretroviral drugs (ARVs) or it would lead to improved medical outcomes. This study analyzed the subjects who were initiated on

the basis of their CD4 counts and compared them to those initiated on the basis of 'Test and Treat'; and it found out that those initiated on the basis of CD4 count had a better retention time (median =24.1 months) than those initiated on the 'Test & Treat' strategy (median= 16.6 months). However, the difference in the retention times was not statistically significant, given a p-value of 0.231. This finding was in line with what one key informant disclosed, that some patients would get lost on the very day they are initiated. In contrast, other studies have reported that early starting of ART was associated with a decreased risk of LTFU (Janssen et al., 2015).

5.2 Factors associated with LTFU

5.2.1 Social Demographic Factors

The factor- not having telephone contact was statistically significant in the study. The patients who had no telephone contacts were more than twice as likely to get LTFU as those with telephone contacts. The telephone contacts are normally used by the staff at the ART clinics to follow- up patients. Consequently, patients without telephone contacts become difficult to monitor by the clinic. However, Mberi et al. (2015) reported that having telephone contact does not significantly influence LTFU.

The variable age was not significantly associated with LTFU. However, the factor age significantly varied with LTFU over time. Mberi et al. (2015) also reported a non-significant association between age and LTFU, with a sample of 595 patients. Findings from Janssen et al. (2015) also concurred with our study, that age is not significantly associated with LTFU, even though it reviewed a sample (280) of fewer patients. Namusobya et al. (2013) reported the contrary, that age was significantly associated with LTFU.

5.2.2 Clinical factors

The factor- normal weight was significantly associated with a reduced likelihood for LTFU compared to the underweight patients. The normal weight patients were 36 percent less likely to get LTFU compared to the underweight patients. Perhaps the underweight patients were very sick, and could not keep some of their appointments at the clinics. However, this finding was not in tandem with that of Namusobya et al. (2013) who reported that weight was not significantly associated with LTFU.

5.2. 3 Health System Factors

The hospital level was significantly associated with a lower likelihood for LTFU compared to health centre III. The patients who received care from the hospital were 78 percent less likely to get LTFU, compared to those who went to health centre IIIs. This finding meant that lower health centres could have limited capacity to retain patients, compared to the patient loads they have to serve. A patient disclosed in an interview that "*...you can go there early morning at around 8am, but then you end up getting served after 2 pm."* This deters patients from returning to the facility for treatment.

Our qualitative study also revealed that transportation to the health facilities was a major challenge to the patients. Lack of transportation and long distance from the health facility were common amongst the LTFU patients. An expert client at one health centre four reported that *"some patients get to travel 15 to 20 km to the clinic"*. This finding was also supported by Waldrop- Valverde et al. (2014) that patients who reside closer to the clinic were associated with better appointment attendance.

The conduct of the clinic staff was also critical in ensuring that patients were retained in care. This involved professionalism and confidentiality of patients' information. In the in- depth interviews, some patients were not impressed with the conduct of the clinic staff. An

informant disclosed that "…*you will find that some of the staff are young student girls, who do not know how to handle people like us."* A study by Yehia et al. (2015) that conducted semi-structured interviews on 25 retained and 26 non retained patients reported that having a positive relationship with the clinic staff was critical in ensuring patients' stay at the clinic.

5.2.4 Social Factors

Stigma is still a big challenge in the treatment of HIV patients. The findings from some key informants suggested that some patients refuse to be transferred to facilities nearer to them because of stigma; consequently, they get to miss appointments on some days because of lack of transportation means. An informant reported "…*People don't want to be seen coming from the ART clinic. Instead of coming to collect medicine in time, they find themselves staying because they don't want to be seen*." Yehia et al. (2015) also reported that stigma was high amongst the non-retained patients.

The in-depth interview results also revealed that patients who had competing life interests like work or employment had a challenge being retained in care. Participants disclosed that sometimes they could get taken-up by their daily routines and occasionally missed appointments. This was consistent with a study by Yehia et al. (2015), who also reported that competing life activities were prominent among the non-retained patients. Additionally, a study by Mberi et al. (2015) reported that the self-employed patients had a higher risk of LTFU.

5.4 Strengths of the study

The study used a relatively large sample size (646 patients) that had sufficient power to attain significant results. The study also adopted mixed methods in order to explore factors that would not be studied only with the quantitative research. The data entrants conducted re-

entry of 1/3 of the forms in order to ensure data quality at the entry phase. Finally, the study adjusted the sample size for the clustering at the different health facility levels.

5.5 Limitations of the study

The study did not include, in the sampling frame, two thirds (2/3) of the patients initiated in the era of "Test and Treat" due to no CD4 count at baseline. As a result, there was uneven number of subjects (260 for CD4 count & 129 for 'test and treat') for the comparative analysis between patients initiated on the basis of their CD4 count and "Test and Treat" strategy. This may raise a challenge of generalizability of this sub-group analysis.

The study did not track the patients who were documented as LTFU, hence we were not able to ascertain their vital status at the time of the study. Some may have self- transferred to other facilities.

The patients that were recruited for the in-depth interviews were mostly from one place. This may also have generalization issues.

5.6 Trustworthiness

The qualitative study had relatively high credibility and neutrality. However, the applicability of the findings may be limited given that it was conducted in a public health care setting.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The overall incidence rate of LTFU of the study was 21 per 1000 person months. This rate was higher than for studies conducted in 'Centres of excellence'. The study also suggested that the variables- normal weight, no telephone contact, and hospital level improve the retention times of the patients. But, age and hospital facility level significantly varied with LTFU over time. The perceptions about stigmatization, competing life interests such as employment, and long waiting time were highly prominent amongst patients that were lost to follow-up.

6.2 Recommendations

The study suggested the following policy recommendations from the study conclusions.

- The health care providers should encourage patients to provide telephone contacts to the ART clinic staff so as to assist in follow-up activities in case the patient misses an appointment. But also, in the event that the patient has no telephone, they can provide contacts of their closest relative, their immediate neighbor, or even the LC1 of their village.
- The study recommends that the clinic staff conduct a detailed evaluation and manage patients with low BMI more appropriately.
- Additionally, the study also recommends that Wakiso district health office should build more capacity at the lower level health centres so as they are well equipped with sufficient staff, logistics, and other necessities to strengthen their efforts in preventing LTFU of patients.

- The government should consider opening the ART clinics also on Saturdays so as the working patients can have an opportunity to attain care when they miss appointments on the weekdays.
- Furthermore, a qualitative study should be conducted to explore reasons why patients who enter care through eMTCT (pregnant women) have a higher incidence of LTFU compared to patients from other care entry points.

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APPENDICES

Appendices 1. Data extraction tool

LOSS TO FOLLOW- UP FROM HIV CARE STUDY

DATA EXTRACTION TOOL

#	Variable	Code	Skip/ Instruction
Qn.1	Unique Number:		
Qn.2	District		
Qn.3	Health Unit		
Qn.4	Date confirmed HIV +ve		
Qn.5	Pt. Clinic #		
Qn.6	Sex	1 Male 2 Female	
Qn.7	Date of Birth		
Qn.8	Age at initiation		
Qn.9	Marital status	0 Child 1 Never married 2 Married 3 Living Together 4 Divorced/ Separated 5 Widowed	
Qn.10	Baseline weight		
Qn.11	Height		
Address			
Qn.12	District		
Qn.13	Division/ Sub- County		
Qn.14	Parish/ Ward		
Qn.15	Village/Zone/Cell		
Qn.16	Telephone (whose)	1 Yes 2 No	**If Yes, record contact**
Clinical factors			
Qn.17	CD4 count at initiation		
Qn.18	WHO clinical stage		
Qn.19	Date of ART initiation		
Qn.20	ART treatment interruptions	1 Yes 2 No	**If No → Qn.22**
Qn.21	If yes in Qn.20, Why?	1 Toxicity/Side effects 2 Treatment failure 3 Poor adherence 4 Illness, hospitalization 5 Drugs out of stock 6 Patient lacks finances 7 Other patient decision 8 Planned Rx interruption 9 Excluded HIV infection in 10 Other (specify)	
Qn.22	Hemoglobin level at initiation		

Qn.23	Pregnant woman	1 Yes 2 No	**Only for female Patients**
Qn.24	ART initiation regimen		
Qn.25	Status	1 Transfer out 2 Lost to follow- up (drop) 3 Dead 4 Still in care	**Please record DATE for categories 1- 3**
		Health systems factors	
Qn.26	Level of health facility	1 Health Centre II 2 Health Centre III 3 Health Centre IV 4 Hospital	
Qn.27	Care entry point	1 eMTCT 2 TB 3 YCC 4 SMC 5 Outreach 6 Outpatient 7 STI 8 Inpatient 9 Other(specify)	

Appendices 2. Waiver of Consent

March 23rd, 2018

The Chair,

School of Medicine Research and Ethics Committee,

Makerere University College of Health Sciences,

P.O. Box 7072 Kampala Uganda.

CC: The Director Clinical Epidemiology Unit,

College of Health Sciences, Makerere University.

Dear Sir,

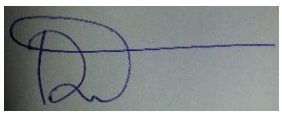
REF: Request for a waiver of consent for a study entitled **"Loss to follow- up and associated risk factors amongst adult HIV/AIDS patients in Wakiso district: A retrospective cohort study."**

I am writing to request for a waiver of consent for the above mentioned observational study. This study will review patient information from the already existing registers in the ART clinics. Consequently, there will be less than minimal risk on the study subjects, as the study is an observational retrospective study where there is no intervention that is being evaluated.

Furthermore, the confidentiality of the subjects will be upheld as the study will not capture the patient names but rather their patient identification numbers. Additionally, the analysis will be done collectively and will not on individual basis. The data extraction forms will be kept in a safe locker where they will only be accessible to the study team. The entered data into the computer will be password protected and out of reach from the public.

The benefits of this study to the society out- weigh its economic, social and legal risks to the study subjects as more knowledge will be generated on the factors associated with loss to follow- up of HIV- infected patients in the public health care system but also in the context of 'Test and Treat'. We are grateful for your consideration of our request for waiver of consent.

Yours Sincerely,



Mr. Denis Opio

Principal Investigator

Tel: 0783016061/ Email: denisopio55@gmail.com

Appendices 3. In- depth Interview Guide

IN-DEPTH PATIENT INTERVIEW GUIDE

Thematic area	Key questions	Methodology
Waiting time	• What do you think about the waiting time that patients have to spend on the queue while waiting for care at the clinic? (probe for the long waiting time, what is the adequate waiting time …) • Can the length of waiting time influence the lead to drop- out of a patient from care? (probe further for how …)	• Probing
Social support	• Do you have family/ friends/ relatives? • How are these friends/ relatives/ family supportive in your healthcare? (probe further on how they are supported…) • Is it the support that you are given that motivated you to keep in care?	• Probing • Priority ranking • Listing
Stigma	• Do you think stigmatization leads to drop out of patients from the health care? (probe for further on how….) • Have you been ever stigmatized against due to your HIV status? • If yes, in what different ways have you been stigmatized against? (probe for the various forms of stigmatization…) • How did you cope with the stigmatization? (probe for the various ways..)	• Probing • Priority ranking • Listing
Transportation	• How does transportation lead to drop out of patients from care? (probe for reliability of the transport means, the costs involved in transport and how long it takes for the patient to reach the ART clinic …)	• Probing • Priority ranking • Listing

Patient- friendly services	• Does the ART clinic provide schedules/ reminders? (probe on how often, and when the reminders are done…) • Do you think these reminders are helpful? (probe on how…) • What do you think about the conduct of health workers at the ART clinic? (probe for privacy & confidentiality, ethical issues, professionalism…) • Do you think the health worker conduct may motivate patients to be retained in care? (probe on how…)	• Probing • Priority ranking • Listing
Competing life activities	• Do you have any activities you are engaged in? (probe for activities like employment, education…) • Do you think these activities hinder retention in care? (probe on how…)	• Probing • Priority ranking • Listing
Beliefs and misconceptions	• Are there common beliefs/ or misconceptions regarding receiving HIV care in this community? (probe for the different kinds.) • Do you think these beliefs can lead to drop out of a patient from care? (probe for reasons…) • How have you perceived the different beliefs about receiving HIV care (probe for perceptions…)	• Probing • Priority ranking • Listing

Instructions: 1) Probe for how and why, where applicable and keep all questions open ended; 2) Specific probes are in Agency FB, in brackets.

Appendices 4. In-depth Interview Informed Consent Form

INFORMED CONSENT FORM FOR IN- DEPTH INTERVIEW

Title of the proposed study:

Loss to Follow- Up and Associated Risk Factors amongst Adult HIV/AIDS Patients in Wakiso District: A Retrospective Cohort Study.

Investigators:
Mr. Denis Opio, Student- Clinical Epidemiology Unit, Makerere University

Background and rationale for the study:
There is still a high prevalence of HIV/AIDS in Wakiso district. This has resulted into high patient loads at the ART clinics, yet there is limited capacity at the clinics. Consequently, this has led to a challenge of retention in care of these patients. With the current policy of test and treat, it is anticipated that the problem of loss to follow- up will be more pronounced given that more people will need to be immediately enrolled in care. It is on this basis that the researcher wants to determine the factors that are associated with loss to follow- up amongst adult HIV- infected patients.

Purpose:
You have been invited to participate in this study about Loss to follow- up of HIV- infected patients on ART care because we believe that your perceptions regarding loss to follow- up of patients will help to enrich the study. The results from the study will help to generate more knowledge on the factors that are associated with patient loss to follow- up.

Procedures:
If you agree to participate in this study, a trained research assistant will discuss with you to seek your opinions on loss to follow- up of patients. This interview will not take longer than 30 minutes. We shall conduct these in- depth interviews with other patients to seek for more views on the topic. We shall use an audio recorder to collect the information so as to ease our data management.

Who will participate in the study:
This qualitative research is expected to interview a few participants (both male and female) and each interview is expected to take about 30 minutes.

Risks/Discomforts:
There are very minimal risks that are expected to yield from the participation in the study since it is qualitative in nature. Participation in this study is voluntary and feel free to discontinue the discussion if at any one point you feel uncomfortable.

Benefits:
The participants should not expect any direct benefits due to their participation, however we believe that the information from the study will help in policy formulation in regards to loss to follow- up of patients.

Confidentiality:
The information that you will provide will be treated with utmost confidentiality. The information will be kept in a secure place and will ONLY be accessible to members of the study team. When the findings are published your identity will remain anonymous.

Alternatives:
Participation in this study is not mandatory and the participant may choose to participate or not.

Cost:
The investigator does not expect the participant to incur any cost as the research assistant will conduct the interviews from the participant's household. Consequently, the participant will not be paid for taking part in the study.

Compensation for participation in the study:
The participants should not expect any compensation due to their participation, however a soft drink will be offered to facilitate the discussion. These in- depth interviews are qualitative methods to enrich the entire study and it is not expected that they cause any kind of harm or injury to the participant.

Reimbursement:
There will be no reimbursement to the participant as they will not incur any travel costs since the research assistant will be expected to meet the participants from their homes.

Questions:
If a participant has any questions or needs more clarification on the study, you can contact the Principal Investigator, Mr. Denis Opio at 0783016061.

Questions about participants rights:
The participant will not waive his/ her legal rights by signing the form and accepting to participate in the study. In a scenario that the participant has any concerns regarding the study or encroachment on their rights, they are advised to contact Prof. Ponsiano Ocama, Chairman of the Makerere University School of Medicine and Ethics Committee (SOMREC) on +256 772 421 190

Statement of voluntariness:
Participation in this study is voluntary and participants may join on their own free will. Participants also have a right to withdraw from the study at any time without penalty.

Statement of consent:

.....has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name ……Signature/ Thumb print of participant……..…Date ……...……
Name ……Signature of witness (If applicable)…….…..... …….Date ……..
Name ……Signature of interviewer…… Date ……

Appendices 5.Key Informant Interview Guide

KEY INFORMANT INVERVIEW GUIDE

Thematic area	Key questions	Methodology
Documentation	• What do you think about the documentation of patient information in the ART clinic? (probe for the knowledge of documentation, adequacy, importance…) • What needs to be done to improve the quality/ adequacy of documentation of patient information to improve retention in the ART clinics? (probe for the different strategies,)	• Probing
Waiting time	• What do you think about the waiting time the patients have to spend on the queue while waiting for care at the clinic? (probe for the long waiting time, how waiting time is affecting retention…) • Do you think the length of waiting time influences the drop- out rate of patients from care? (probe further for how …) • What are you doing to motivate the patients to keep coming for their medication? (probe for the different strategies.)	• Probing • Priority ranking • Listing
Patient- friendly services	• Does the ART clinic provide schedules/ reminders to ensure patients are retained in care? (probe on how often, and when the reminders are done, influence on retention…) • What do you think about the conduct of health workers at the ART clinic? (probe for privacy & confidentiality, ethical issues, professionalism…) • Do you think the conduct of health workers may influence the patient to be retained in care? (probe on how it motivates, or demotivates retention…)	• Probing • Priority ranking • Listing
Model of care	• What do you think about the model of HIV care/ refill venue of	• Probing • Priority ranking

	the health facilities? (probe for accessibility, different models of care …) • Do you think the model of care may lead to patient drop- out? (probe for how, and why …) • What are you doing about the model of care in order for the services to be more accessible to the patients? (probe further for how …)	• Listing

Instructions: 1) Probe for how and why, where applicable and keep all questions open ended; 2) Specific probes are in Agency FB, in brackets.

Appendices 6. Key Informant Consent Form

INFORMED CONSENT FORM FOR KEY INFORMANT INTERVIEW

Title of the proposed study:

Loss to Follow- Up and Associated Risk Factors amongst Adult HIV/AIDS Patients in Wakiso District: A Retrospective Cohort Study.

Investigators:
Mr. Denis Opio, Student- Clinical Epidemiology Unit, Makerere University.

Background and rationale for the study:
There is still a high prevalence of HIV/AIDS in Wakiso district. This has resulted into high patient loads at the ART clinics, yet there is limited capacity at the clinics. Consequently, this has led to a challenge of retention in care of these patients. With the current policy of test and treat, it is anticipated that the problem of loss to follow- up will be more pronounced given that more people will need to be immediately enrolled in care. It is on this basis that the researcher wants to determine the factors that are associated with loss to follow- up amongst adult HIV- infected patients.

Purpose:
You have been invited to participate in this study about Loss to follow- up of HIV- infected patients on ART care because of the key position you hold in the district in respect to HIV treatment and care and we believe that your perceptions regarding loss to follow- up of patients will help to enrich the study. The results from the study will help to generate more knowledge on the factors that are associated with patient loss to follow- up.

Procedures:
If you agree to participate in this study, a trained research assistant will interview you on questions related to loss to follow- up of patients. This interview will not take longer than 30 minutes. We shall conduct these key informant interviews with Wakiso district health officials and the in- charge at each selected ART clinic.

Who will participate in the study:
This qualitative research is expected to hold about 6 key informant interviews with Wakiso district health officials and the in- charge at each selected ART clinic and each interview is expected to take about 30 minutes.

Risks/Discomforts:
There are very minimal risks that are expected to yield from the participation in the study since it is qualitative in nature. Participation in this study is voluntary and feel free to discontinue the discussion if at any one point you feel uncomfortable.

Benefits:
The key informants should not expect any direct benefits due to their participation, however we believe that the information from the study will help in policy formulation in regards to loss to follow- up of patients.

Confidentiality:
The information that you will provide will be treated with utmost confidentiality. The information will be kept in a secure place and will ONLY be accessible to members of the study team.

Alternatives:
Participation in this study is not mandatory and hence the key informant may choose to participate or not.

Cost:
The investigator does not expect the key informant to incur any costs as the research assistant will conduct the interviews from the either the district health office or the ART clinic. Consequently, the key informant will not be paid for taking part in the study.

Compensation for participation in the study:
The key informant should not expect any compensation due to their participation. These key informant interviews are qualitative methods to enrich the entire study.

Reimbursement:
There will be no reimbursement to the key informant as they will not incur any travel costs since the research assistant will be expected to meet the informants from their places of work.

Questions:
If an informant has any questions or needs more clarification on the study, you can contact the Principal Investigator, Mr. Denis Opio at 0783016061.

Questions about participants rights:
The key informant will not waive his/ her legal rights by signing the form and accepting to participate in the study. In a scenario that the informant has any concerns regarding the study or encroachment on their rights, they are advised to contact Mr. Ponsiano Ocama , Chairman of the Makerere University School of Medicine and Ethics Committee (SOMREC) on +256 772 421 190

Statement of voluntariness:
State that participation in the proposed study is voluntary and participants may join on their own free will. Participants also have a right to withdraw from the study at any time without penalty.

Consent:
Participation in this study is voluntary and the key informant may join on their own free will. Informants also have a right to withdraw from the study at any time without penalty.

Statement of consent:

.....has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name……Signature of key informant ……Date ……...
Name…….Signature of interviewer ……Date …….

Appendices 7. Luganda Version In-depth Interview Informed Consent Form

INFORMED CONSENT FORM FOR IN- DEPTH INTERVIEW_LUGANDA VERSION

Omulamwa gwokunonyereza:

Lwaki abalwadde bakawuka kamukenya bamala ebbanga eriwela nga tebamanyidwa bibakwatako ngate bali kudagala mu Wakiso.

Omunonyereza:
Mr. Denis Opio, Omuyizi- Clinical Epidemiology Unit, Makerere University

Ebikwata kununyereza kuno:
Obulwadde bwamukenya bukyali bungi mu wakiso era abantu bangi bali kudagala eliweweza kubulwadde buno lwakuba abalwadde abasinga obungi tebalinywelelako. Enkola eyo kutandikizawo omuntu kudagala nga azulidwa nakawuka esubirwa okwogenza kumuwendo gwabo abava kudagala. Okunonyereza kuno kugenderedwa okumanya esonga ezenjawulo lwaki abantu abangi ababa kudagala bamala ebbanga eliwela nga tebamanyidwa bibakwatako.

Omugaso gwo kunonyereza kuno:
Tukwaniriza okweetaba mu kunonyereza kuno okumanya esonga ezenjawulo lwaki abantu abasinga abali kudagala eriweweza ku bulwadde bwamukenya bamala ebbanga eliwela nga tebamanyidwa bibakwatako. Kisubilwa nti ebilowoozo byo bigenda kuba bya'mugaso nnyo mukunonyereza kuno. Ebinaava mukunonyereza kuno bigenda kwongera kumanyisa kunsonga ezanjawulo lwaki abalwadde abamu abali kudagala babulwako amayitire**.**

Emitendera:
Bwokiriza okwetaba mu kunonyereza kuno, ogenda kubuzibwa ebibuuzo ebyenjawulo owe endowooza yo kunsonga eno. Kisubilwa nti kino kiyinza okutwala eddakika nga asatu. Byona ebyogerwa tugenda kuba tubikwata katambi okubijukira obulungi.

Abasubirwa okwetaba mukunonyereza kuno:
Abalwadde abenjawulo abasajja nabakazi be basubilwa okwetaba mu kubuzibwa kuno era nga kusubilwa okumala ebanga lyadakiika nga asatu.

Obuvune:
Tetusubilwa muntu yena kosebwa nga yetabye mukunonyereza kuno. Okwetaba mukunonyereza kuno si kwabuwaze era omuntu yena waddembe okuvaamu wona waaba ayagalidde.

Okuganyulwa:
Abagenda okubela mukunonyereza kuno sibakusasulwa, naye ebinaava mukunonyereza kuno bya kuyaamba okulongoosa oba okutekawo enkola empya okuziyiza abantu okumala ebbanga eddene nga tebamanyidwa bibakwatako.

Okuuma ebyaama:
Amanya go tegeetagibwa nga oddamu ebibuzo bino. Byona ebinaaba bididwaamu bigenda kuumibwa nga bya kyama era nga abali mukunonyereza boka bebalina olukusa okuba nabyo.

Ebyenjawulo:
Okwetaba mukunonyereza kuno sikwabuwaze.

Omutemwa:
Bona abanaaba mukunonyereza kuno tebasubilwa kufulumya nsimbi oba okusasulwa kuba ababuuza ebibuuzo bagenda kubasanga mu maka gaabwe.

Okuyililwa:
Abanaaba betabye mukunonyereza kuno siba kusasulwa okujjako akokunywa akanakuweebwa nga oddamu ebibuuzo. Ebiva mubibuzo bino bya kwongereza kwebyo ebinava mukunonyereza okulala.

Okudizibwa sente:
Olwensonga nti abali mu kunonyereza kunno bakubasanga mu maka gaamwe, yenna anabela mu kunonyereza kuno tekisubilwa nti kijja kwetagisa okudizbwa sente zona.

Ebibuuzo:
Bwoba olina okwebuuza kwona. Ntukilila ku number yesimu eno wamanga.
Omwami. Denis Opio ku 0783016061.

Okumanya ebisingawo:
Okutekako omukono tekikujjako dembe lyo elyo buntu. Oliwaddembe okwebuuzako ebikwata ku kunonyereza kuno oba ku dembe lyo kundagilo eno wamanga.
Prof. Ponsiano Ocama, Ssentebe wa Makerere University School of Medicine and Ethics Committee (SOMREC) ku +256 772 421 190

Okukiriza okwetaba mu kunonyereza kuno:

…….. Ayinyonyede era ntegedde byona ebikwata ku kunonyereza kuno. Ntegedde nti okwetaba mukunonyereza kuno tekulina nkyukakyuka eyenjawulo kubujanjabi bwendi mukufuna kati. Amanya gange tegalina kulabikila mukunonyereza kuno era ndi wadembe okuvamu wona wenaba njagalide.
Nzikiriza okwetaba mukunonyereza kuno.

NZE……. OMUKONO/ EKINKUMU……...
NGA……
OMUJULIZI…… OMUKONO…….
NGA…….
ANONYEREZA……..... OMUKONO…….
NGA…….