# FACTORS ASSOCIATED WITH NON ADHERENCE TO ART AMONG HIV INFECTED PATIENTS ATTENDING ART CLINIC AT KITAGATA

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# DISSERTATION SUBMITTED TO FACULTY OF CLINICAL MEDICINE AND

# DENTISTRY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

# FOR THE AWARD OF BACHELOR OF MEDICINE, BACHELOR

# OF SURGERY OF KAMPALA INTERNATIONAL

UNIVERSITY

DECEMBER, 2014.

#### DECLARATION

I hereby declare that the work presented in this report is entirely the result of my own effort and has been submitted to you with my supervisor's approval and to the best of my knowledge has never (partially or in its entirety) been submitted in any form, for either publication or award of any qualification to any institution.

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# SUPERVISOR'S APPROVAL:

This report has been produced under my supervision and submitted with my approval.

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(SUPERVISOR) Signed ..... ..... Date. 10/12/0519

# DEDICATION

This report is dedicated to KIU administration and Kitagata Hospital administration with whose help I was able to carry it out.

#### ACKNOWLEDGEMENT

I sincerely thank the Almighty, God, for my life and the gift of perseverance he gave me throughout this research.

I wish to acknowledge and appreciate the valuable contribution of my lecturer and supervisor Mr. Emorut Simon Peter who tirelessly guided me throughout this project.

I would like to give a token of appreciation my family ; my sister Obbu Evalyn, my uncles; (Mr. Korsuk, Mr.Moi) and my auntie (Mrs Poni .J.) for their support.

Special thanks to my Uncle Mr. Kei Samuel Lokugi for the sacrifices he made for me and my mother Mrs. Kojjo Esther for the encouragement and financial support. May God, the most gracious, reward you abundantly.

I would also like to appreciate the help given to me by my friends Erinah, Francis, Rachael, Gladys, Benjamin and Amos by whose help I was able to complete the project in time.

I would like to thank the entire staff of KIU- western campus and more so to faculty of clinical medicine & dentistry who equipped me with relevant knowledge & skills.

I also acknowledge the Kitagata Hospital administration for allowing me to carry out research & all the staff for their support throughout the study.

Finally, I would like to thank the volunteers who participated in my research.

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# LIST OF ABREVIATIONS

- ART Anti-Retroviral Therapy
- HIV -Human Immunodeficiency Virus
- AIDS Acquired Immune Deficiency Syndrome
- HAART Highly Active Antiretroviral Therapy
- WHO World Health Organization
- PLHIV People living with HIV
- TASO The AIDS support organization
- AEs Adverse effects
- KIU- Kampala International University
- UNAID United Nations Agency for International Development.

# **OPERATIONAL DEFINITIONS**

- **ARV Drugs** –these are drugs developed to manage and slow the progression of HIV infection among infected individuals.
- **ART Clinic-**this is a special clinic concerned with giving HIV patients drugs/medication to manage the disease.
- **ADHERENCE-** this is defined as the extent to which a patient takes a medication in the way intended by a health care provider.

#### ABSTRACT

**Background:** Patient adherence to Antiretroviral Treatment (ART) is an issue that is growing in prominence and generating a burgeoning interest with ART roll-out. In the absence of a cure, ART is the only available option that offers the possibility of dramatically reducing HIV/AIDS-related morbidity and mortality. Therefore, successful administration of this treatment depends on sustained and strict adherence to the prescribed regimens. However, sustaining adherence to antiretroviral therapy (ART) over the long term is still a particular challenge for countries in sub-Saharan Africa. Therefore, this study was based on finding the proportion of participants who are non adhering to ART, the pill burden related factors, individual factors and the healthcare related factors associated with non adherence to ART among patients attending ART clinic at Kitagata Hospital.

**Methods:** The study employed a descriptive cross-sectional design where both quantitave and qualitative methods were used to collect data from the study population which consisted of patients (20-50 years) attending ART clinic at Kitagata Hospital. The sample size of 150 participants was calculated from the Kish Leslie, 1965 formula and a systematic sampling method was used to get the participants.

**Results**: Majority of the participants were females (60.7%) where, most of them were between 31-40 years, 75(50%). Among the 150 study participants, the magnitude of non adherence to ART in the past 7 days was 13.3% only 8(40%) men and 12(60%) females non adhering. The main reasons for non adherence were forgetting (63.2%), being busy (26.3%) and the long distances to the ART clinic since most, 59(39.3%) of them were staying over 10km away from the ART clinic.

**Conclusion**: Compared to other similar studies done in Kitagata, in this study a relatively low adherence rate was found. Forgetfulness was the most common reason for the non adherence followed by the long distance to the ART clinic. Therefore, the ART counseling needs to give emphasis to using memory aids and Government should provide clinic annex in strategic locations across the villages as a means of bringing treatment closer to patients. In addition, a further study on adherence rate and the factors associated with non adherence is recommended.

# **CHAPTER ONE**

#### **1.1 BACKGROUND**

Acquired immune deficiency syndrome (AIDS) is one of the most destructive epidemics the world has ever witnessed. Presently an estimated 33.4 million people are living with HIV worldwide, nearly two-thirds of these live in sub-Saharan Africa. (*WHO*, 2009). The emergence of HIV/AIDS in sub-Saharan Africa over two and half decades ago presented a devastating health crisis to millions of people in the continent. Over 24.5 million people were estimated to be living with the disease at the end of 2005 (*UNAIDS*, 2006), which represents about 65% of the global figure. Also an estimated 2.7 million people were newly infected and 2.5 million adults and child deaths occurred from AIDS in the region during 2005 (*UNAIDS 2006*). Currently, 7.2 percent of Uganda's population is living with HIV. This amounts to an estimated 1.4 million people, which includes 190,000 children. An estimated 62,000 people died from AIDS in 2011 and 1.1 million children have been orphaned by Uganda's devastating epidemic HIV prevalence has been raising since its lowest rate of 6.4 percent in 2006. (*Tekabe Abdosh, et al, 2012*)

Globally, rapid expansion and early access to antiretroviral treatment (ART) services have resulted in a dramatic decrease in HIV-related mortality and mobility. However, the current regimens are life-long requirement of strict compliance by patients to achieve treatment success and prevent drug resistance. In resource-scarce settings, where second and third line ART regimens and viral load monitoring are limited, routine assessment of and interventions for patients' adherence have become one of the biggest priorities in delivering ART services.(*Bach Xuan Tran,2013*)

Patient adherence to Antiretroviral Treatment (ART) is an issue that is growing in prominence and generating a burgeoning interest with ART roll-out. In the absence of a cure, ART is the only available option that offers the possibility of dramatically reducing HIV/AIDS-related morbidity and mortality, while improving the status of people living with AIDS. However, successful administration of this treatment depends on sustained and strict adherence to the prescribed regimens (*Lewis et al, 2006*) .Patients who reported an intake of  $\geq$  95% of the prescribed medication were considered adherent, those with a reported intake of < 95% were classified as non-adherent.(*Visanou Hansana, et al, 2013*) In sub-Saharan Africa, there has been a dramatic increase in the number of HIV/AIDS patients on antiretroviral treatment from just 100,000 persons in 2003 to 3.9 million in 2009 involving close to 40% of those in need of the treatment. Two sub-Saharan Africa countries, Botswana and Rwanda, have achieved universal access target (treatment coverage of 80% or more of patients in need) at the end of 2009, while countries such as Ethiopia, Zambia, Namibia, and Senegal are moving closer to the same target having covered 50–80% of patients in need of treatment. According to recent studies, ART regimens require 70–90% adherence in order to be effective. However, sustaining adherence to antiretroviral therapy (ART) over the long term requires accurate and consistent monitoring, and this is a particular challenge for countries in sub-Saharan Africa. (*Tekabe Abdosh, et al, 2012*)

In Uganda however, the introduction of antiretroviral therapy (ART) and multidrug regimens, or highly active antiretroviral therapy (HAART) has substantially improved the survival of persons infected with HIV. These drug regimens however are complex. This, alongside issues of toxicity, side-effects, disruptions to patient's daily life and difficulties in returning for scheduled follow-up consultations, often makes maintaining adherence over the long term challenging. Yet the individual and public health benefits of ART are adherence dependent. Inadequate adherence results in antiretroviral agents not being maintained at sufficient concentrations to suppress HIV replication in infected cells to lower the plasma viral load. In addition, suboptimal adherence can accelerate development of drug-resistant HIV and mitigate ART's role in reducing HIV incidence and transmission. Promoting adherence is especially important as these treatments become increasingly available and affordable for people living with HIV (PLHIV) in developing countries where viral load monitoring is not usually possible. Consequently, more attention is being focused on issues related to ART adherence. (*WHO*, 2013)

#### **1.2 PROBLEM STATEMENT**

In the case of ART, adherence to treatment implies taking the drugs in their right quantities, at the right time, life-long. A meta-analysis of adherence studies done in Sub-Saharan Africa and North America established an estimated 77% in Africa (*Mills, et al., 2006*). However, a study on the determinants of Adherence to Antiretroviral Therapy among HIV-Infected Patients in Africa revealed that the challenges to ART adherence include factors related to patients and their families, socioeconomic factors, medication, and healthcare systems. (*Ayalu A. Reda, 2012*)

In addition, it has been established by several studies that adherence to ART is a problem in Uganda where a relatively lower adherence level of 66% was reported in a study conducted. This study found that 80% of study patients achieved the optimal adherence. (*Byakika et.at, 2005*). Hence, these studies reveal that non-adherence seems to be a major challenge and threatens the long-term success of available ART's in sub-Saharan Africa. Around 130,000 Ugandans are infected with the HIV virus every year, according to the Uganda Aids Commission. The government's new national HIV/Aids strategic plan greatly predicts that the number of HIV positive Ugandans will rise from 1.1 million in 2006 to 1.3 million in 2012. This could have been attributed to the low adherence to the medication since it is not yet clear how they are dealing with their treatment and which challenges they are facing with ART adherence. (*Gardner EM, et al, 2009*)

However, there is scanty information about factors affecting adherence to ART among HIV infected patients in Uganda and those attending ART clinic in Kitagata Hospital in particular. As such, the findings of the study were to serve as a contribution to fill the research and knowledge gap.

#### **1.3 BROAD OBJECTIVE**

To determine the factors associated with non adherence to ART among patients attending ART clinic at Kitagata Hospital.

# **1.4 SPECIFIC OBJECTIVES**

To determine the proportion of HIV positive patients who are non adhering to ART, attending ART clinic at Kitagata Hospital.

To assess the individual factors that affect patients' adherence to ART in patients attending ART clinic at Kitagata Hospital.

To determine the health care related factors that affect adherence to ART in patients attending ART clinic at Kitagata Hospital.

To assess the pill burden related factors affecting adherence to ART in patients attending ART clinic at Kitagata Hospital.

# **1.5 RESEARCH QUESTIONS**

What proportion of HIV positive patients attending ART clinic at Kitagata Hospital was nonadherent to ART?

What were the individual factors affecting patients' adherence to ART in patients attending ART clinic at Kitagata Hospital?

Which health care related factors had affected the adherence to ART in patients attending ART clinic at Kitagata Hospital?

Which pill burden related factors had affected the adherence to ART in patients attending ART clinic at Kitagata Hospital?

# **1.6 SIGNIFICANCE OF THE STUDY**

The fundamental significance of the study was seen in the fact that, there is scanty information about factors affecting adherence to ART among patients attending ART clinic at Kitagata Hospital. As such, the findings of the study were to serve as a contribution to fill the research and knowledge gap.

The study was also of immense significance to the Ministry of Health, since it would keep them aware of the factors affecting adherence to ART among HIV patients attending ART clinics in Uganda more so as it relates to the situation in the study area; Kitagata Hospital to be specific.

The results were to inform policy makers and the Ministry of Health to put the necessary measures in place to address the problem affecting adherence to ART among HIV-positive patients.

#### **1.7 STUDY SCOPE**

#### **1.7.1 Geographical scope**

My study was limited in Kitagata hospital, the ART clinic to be specific. Located on the Kitagata-Rukungiri Road, just west of the center of town, in Western Uganda.

#### 1.7.2 Content scope

My scope was limited to determining the proportion of patients who are non adherent to ART, the individual, health care related and to assess how pill burden related factors affect the adherence to ART in patients attending the ART clinic at Kitagata Hospital.

#### 1.7.3 Time scope

My study was expected to be conducted within a period of six weeks hence expected to have ended by 29<sup>th</sup> November 2014.

# **1.8 CONCEPTUAL FRAMEWORK**

HEALTH CARE RELATED FACTORS Shortage of care. Shortage of drugs. Poor Patient-health provider relationship. Long waiting times. Long distance from the health centre.

PILL BURDEN Dosing schedule polypharmacy due to other chronic conditions.

INDIVIDUAL FACTORS Substance use (alcohol). Beliefs about the outcome. Knowledge and information. Forgetfulness.

NON ADHERENCE TO ART (not taking the drugs in their right quantities, at the right time)

#### AUTHOR; primary source

According to the above framework, my study focused on the factors affecting adherence to ART, the rate of non adherence which was measured in terms of missing any dose in the regimen given to a patient.

The factors were divided into individual factors (substance use, beliefs about the outcome, knowledge and information and forgetfulness), healthcare related factors (shortage of care, shortage of drugs, poor patient-health care provider relationship, long waiting hours and the long distance to the health center), pill burden related factors (Dosing schedule, polypharmacy due to other chronic conditions).

## **CHAPTER TWO**

#### LITERATURE REVIEW

#### **2.0 INTRODUCTION**

The aim of this chapter was to have a better understanding on the factors which affect antiretroviral treatment. The first section reviewed literature on previous research work done on the importance of adherence and the second reviewed on factors affecting adherence to ART.

#### 2.1 Importance of adherence to art

The importance of ART adherence makes accurate compliance assessment essential for effective and efficient therapy and evaluation of treatment regimens. (*Visanou Hansana, et al, 2013*). In addition to that, treatment adherence is generally regarded as an important factor in achieving optimal outcomes across many disease states; in the treatment of HIV, poor adherence to treatment has the potential to impact outcomes on multiple levels. Poor adherence to antiretroviral therapy (ART) is associated with less effective viral suppression, which risks the immediate health of the patient, but also risks creating permanent treatment resistance to that particular agent or group of agents within a given combination therapy regimen. This may have downstream effects on treatment costs as well as therapeutic options. (*Am J Manag Care. 2013*)

The primary goal of treatment with ART is to prevent HIV-related morbidity and mortality. Many studies have shown a strong correlation between adherence and clinical outcomes and/or laboratory markers (notably CD4 count). Non adherence has been found to diminish the immunological benefit of ART and increase AIDS-related morbidity, mortality, and hospitalizations. The association between adherence and clinical progression, however, may not be entirely explained by the full suppression of viral load. On one hand, full and durable viral suppression requires nearly perfect adherence. On the other, despite the average rate of adherence being 70%, few patients on combination ART are actually progressing to AIDS and death. Several factors may contribute to this apparent "disconnect" between adherence and clinical outcomes. *(Edward L. Machtinger, 2006)*.

In addition to the primary objective of reducing the risk of morbidity and mortality, the secondary goal of treatment for HIV is viral suppression. Numerous effective therapeutic agents for viral suppression in HIV have been developed. Their efficacy, however, requires that patients with HIV be adherent to their prescribed regimens. Effective use of antiretroviral agents requires not only good adherence to therapy on the part of patients but sustained adherence over time (persistence) if viral suppression is to be successful. For HIV therapeutic regimens in which an un boosted protease inhibitor is a component, there exists a substantial risk of failed viral suppression with treatment adherence less than 95%. High levels of treatment adherence in HIV have been shown to predict better viral suppression outcomes, whereas poor treatment adherence in HIV is associated not only with less effective viral suppression but also with drug resistance and reduced survival. (*Kenneth L. Schaecher,2013*)

Furthermore, another study showed that strict adherence to antiretroviral therapy (ART) is key to sustained HIV suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission. Conversely, poor adherence is the major cause of therapeutic failure. Achieving adherence to ART is a critical determinant of long-term outcome in HIV infected patients. For many chronic diseases, such as diabetes or hypertension, drug regimens remain effective even after treatment is resumed following a period of interruption. In the case of HIV infection, however, loss of virologic control as a consequence of non-adherence to ART may lead to emergence of drug resistance and loss of future treatment options.(*MoH*, 2014).

#### 2.2 Proportion of HIV positive patients non adhering to ART.

A study in Asia based on patient recall of their compliance of the prescribed drug, adherence was calculated based on the number of pills reported to have been actually taken divided by the number of prescribed pills over in the past three days. Patients who reported an intake of  $\geq 95\%$  of the prescribed medication were considered adherent, those with a reported intake of < 95% were classified as non-adherent. Basing on that, the study found that non adherence to the prescribed medication and dosage was reported by 39.1% in PLHIV. (*Visanou Hansana, 2013*)

Furthermore, another study showed that out of two hundred eight, 87% of the participants had taken greater than 95% of their prescribed ARV drugs for the past 7 days. Almost similar adherence rate was observed among males (85.7%) and females (87.5%). Higher adherence rate was observed in the age group of 20–30 years (92.8%). However, adherence rate was not statistically associated with sex and age group. Furthermore, higher adherence rate (90.2%) was also observed among singles compared to married study participants (84.3%). The respondents who had high school and the above education were more adhered (90.7%) than those who were illiterate (80%). However, there was no statistically significant association between the adherence rate and the marital status and the educational level of the study participants.(*Habtamu Mitiku, et al, 2013*).

In Uganda, the first study on ART adherence levels was done in 2002 by Byakika et al. They found non-adherence levels to be 28.8%, 30.5%, 31.8%, 32.1% and 37.8% (n=302) one, two, three, four and seven days before the interviews, respectively, at the 5% benchmark. At the 20% benchmark, it was 28.8%, 29.8%, 30.2%, 28.3% and 25.7% (n=304), respectively. The prevalence of non-adherence in this population per day was 28.8%. The study was conducted in three centers in Kampala (JCRC, Nsambya Hospital, and Mildmay Centre) and included only adults. **Further studies have shown that out** of 35 patients with poor ART outcomes, 17 (49%) also had poor ART adherence with a median CD4 cell count of 95 (63–156) cells/mm Five patients with poor ART outcomes and adherence were described where, three were females, 2 (male and female) were teenagers and all had primary education level or lower.(*BN Mayanja, et al, 2013)* In addition, it has been established by several studies that adherence to ART is a problem in Uganda where a relatively lower adherence level of 66% was reported in a study conducted. (*Byakika et al, 2005*).

A study among HIV infected adults receiving ART in Kitagata Hospital revealed that there was 15% non adherence level. (*Bajunirwe Francis, et al, 2009*)

#### 2.3 Factors associated with adherence to ART.

#### 2.3.1 Individual factors

Patients' beliefs, knowledge and expectations regarding treatment strongly influence their medical decision making basing on a study which showed that a few patients believed that ART cured HIV or were unclear about how long they should take ART. (*sharada, et al,2012*)

Meaning, patients' beliefs and behaviors play an important role in adherence. Furthermore, other Studies have also shown that patient beliefs about illness and the efficacy of the treatment regime affect adherence (Mills, et al, 2006). A furthermore study also revealed that some side-effects were feared due to the belief that ART was designed to kill people. As a result, some people were afraid to take the ARVs in case they died and others delayed starting ART even when they had the opportunity. (WHO, 2006) therefore, Patient knowledge and information contribute to adherence since available studies suggest that a good understanding of HIV/AIDS and awareness of the consequences of non-adherence are associated with good adherence. (Fisher, et al, 2006). Education may also impact on adherence in several ways including facilitating communication with health care providers, increasing retention of information provided by health workers and thereby enhancing adherence to ART medication. It is possible that patients with limited literacy might be reluctant to ask others for the kind of help they need to take their medicines. Bettereducated people convinced of ART efficacy, perhaps as a result of educational programmes, show a propensity towards better adherence. (Sharada, et al, 2012). Therefore, every patient needs to understand the importance of adherence because inaccurate information and misconceptions towards the disease and treatment regimens are associated with poor therapeutic outcomes.

Patient forgetfulness to take their oral dose contributes significantly to non-adherence and makes it an issue of considerable debates. The patient-centered perspective on adherence points an accusing finger to the patient habit of forgetfulness.(*Hardon et al*, (2006). on one hand, cases of patients with HIV/AIDS failing to take their medication as required on account of forgetfulness has been documented by some studies (*Mukhtar-Yola, et al., 2006; Olowookere, Fatiregun, Akinyemi, Bamgboye, & Osagbemi, 2008; Skhosana, Struthers, Gray, & McIntyre, 2006; Uzochukwu et al., 2009*). This was also attributed to alcohol intake basing an a study where some individuals stated that several times they were expected to drink alcohol and that this caused difficulty with remembering their medication routine.(*sharada, et al,2012*), in emphasis to this, there are also other findings which suggest that Alcohol and substance use affects adherence in sub-Saharan Africa. Some of the patients who take alcohol end up forgetting to take their tablet or omitting treatment (*Hardon, et al., 2006*). A study in Uganda also found an association between alcohol use and missed doses. Alcohol use is known to be a proxy for loss of control, thus, affecting adherence. (*C. Shumba, et al, 2012*). In a study done in Botswana,

around 40% of the patients surveyed admitted missing a dose because of alcohol consumption. (*E. Kip, et al,2009*) Furthermore, a study in Harari national regional state found out that forgetfulness, traveling, and being too busy were the most common reasons for poor adherence to medications. Similar reasons were reported in studies conducted in Adama and Jimma hospitals (*M. Awel, 2008*) and Yirgalem Hospital (*E.Markos, et al,2008*), Ethiopia, and in Kenya (*N. C. Talam, et al*) Therefore, mere forgetting to take the drugs affects adherence.

Finally, a study conducted in Kitagata revealed that 15% of the patients non adhered to ART due to missing a scheduled clinic visit. (*Bajunirwe Francis, 2009*)

#### 2.3.2 Pill burden related factors

For people on ART, a typical combination of medicines consists of three ARVs, plus other medication to prevent opportunistic infections. This can result in a high pill burden, taking medicine three times a day, dietary and dosing idiosyncrasies, large capsules or tablets, and specific storage instructions. The complexity of this regimen may have a significant impact on a patient's ability to adhere. Additional medications taken for symptomatic relief (such as analgesics, cough remedies and other common treatments) in patients with advanced disease further add to the pill burden and toxicity.

The generic fixed-dose combination Triomune, which is provided by the Global Fund/MoH, consists of three ARVs (lamivudine, stavudine and nevirapine) in a single pill. However, PEPFAR provides these same ARVs as three separate pills. As a result, patients taking the separate pills have to take three times as many pills as those on Triomune, with significant implications for adherence. A study in Senegal reveals that a high pill burden is associated with poor adherence among patients who have to take a large number of ARV pills (*Dansburg et al., 2006*). Furthermore, the studies conducted between 2004 and 2011 revealed that Higher pill burden was associated with lower rates of adherence (p = 0.004). But when the results were stratified by treatment strategy, the association between adherence and pill burden was only significant for twice-daily combinations (p = 0.001). Turning to dosing schedule, adherence was higher with once-daily regimens compared to twice-daily therapy (weighted mean difference [WMD] = 2.51%; 95% CI, 1.20%-3.83%, p = 0.0002). The adherence advantage of once-daily treatment was apparent in treatment-naive individuals. In addition, other studies have found that

lower pill burden is associated with higher rates of adherence to HIV treatment while higher pill burden was associated with lower adherence." (*Nachega JB et al,2014*)

In addition, the need for antiretroviral therapy coupled with treatment of chronic co-morbidities places HIV-infected patients at risk for polypharmacy. It was found that participants who had more than 3 co-morbidities had a problem with adherence which was significantly associated with high pill burden (over 10 pills per day). Therefore, they concluded that strategies to reduce pill burden and number of medications would become increasingly critical to maintaining adherence. (*Zhou S et al 2014*)

#### 2.3.3 Health care related factors

In relation to the health services related factors affecting non-adherence, there is a growing concern with health services and facilities in sub-Sahara Africa because it poses serious hindrance to adherence. To start with, there is lack of adequate health facilities or services in sub-Sahara Africa and when they are available they are not well equipped and lack good infrastructures. Some of these health facilities are located far away from the patients and sometimes, some of the patients do not have the fare to travel long distances to the clinic to receive their antiretroviral treatment, hence end up missing their doses which affects their adherence, (Uzochukwu, et al., 2009). This was also seen in a study conducted in Teso, northern Uganda, identified distance to health centers and access to health providers as the main concerns of clients in relation to HAART adherence.( Wilhelm-Solomon M, 2009), further studies in Nepel also found that Distance was a big concern particularly outside Kathmandu. Whereby, distance to treatment centre is of great concern to and one of the key factors preventing adherence. Patients who travelled more than one hour to hospital were more likely to be nonadherent and this was also discussed in the in-depth interviews. Participants stated that although patients were willing to take ART they became non-adherent because of difficulties in reaching the treatment centers due to unexpected transport and other strikes; long travel distance; geographical difficulty including lack of transportation services in many remote areas; and the seasonal deterioration of poorer roads during the rainy season. Therefore, long travelling distance to and from ART sites remains one of the most challenging adherence issues. (Sharada P et al, 2012)

In addition, there is inadequate room in health facilities that would allow for confidentiality. An example of this was a situation in which three doctors were sharing one consultation room and consulting with three different patients at the same time. This practice can stop some patients from attending consultations or from communicating openly, and so affects their adherence (*Hardon, et al., 2006*). Furthermore, a good patient–health-care provider relationship may be an important motivating factor for taking and adhering to complex combination drug therapies. On the other hand, factors that have been identified as strengthening patient–health-care provider relationships include perceptions of health-care provider competence, communication quality and clarity, compassion, willingness to include patients in treatment decisions, adequacy of referrals, and convenience of visiting the doctor (*Margaret A. Chesney, 2014*).Health-system factors also included inaccessibility of services and the relationship with service providers. Some healthcare delivery systems made it difficult to seek regular treatment. (*Sharmaet al, 2007*.).

Finally, the long hours spent by patients at the clinic waiting for health care personnel and during consultations, hours constitute time constraint to the patients and has also been mentioned as one of the factors affecting adherence.(*Torpey et al, 2008*)

# **CHAPTER THREE**

# METHODOLOGY

## **3.0 INTRODUCTION**

This chapter explained the methodology of the study, which included the study design, study setting study population, sample size determination, sampling procedure, inclusion criteria, definition of variables, research instruments, data collection procedures, data management, data analysis, ethical considerations, limitation of the study and the dissemination of the results.

#### **3.1 STUDY DESIGN**

The study employed a descriptive cross-sectional design where quantitave was used. This study design was selected because it assisted in easy access of the required data for the study which enabled a quicker assessment of the factors affecting adherence in HIV positive patients in relation to the time factor.

#### **3.2 STUDY AREA**

The study was carried out at Kitagata hospital located in Sheema district, which lies on the Kitagata-Rukungiri Road, just west of the center of town. The town lies on the Kasese-Ntungamo highway, approximately 18 km, south of Ishaka, Bushenyi district, the nearest large town Kitagata Hospital is a public 120- bed hospital administered by the Uganda Ministry of Health.

## **3.3 STUDY POPULATION**

The study population consisted of HIV positive patients between 20- 50 years attending ART clinic at Kitagata Hospital.

# **3.4 SAMPLE SIZE DETERMINATION**

The study sample size was determined using the formula given by:(Kish Leslie,1965)

$$n = \frac{Z^2 p q}{d^2}$$

Where n = sample size.

Z = value corresponding to 95% level of significance = 1.96.

P = expected proportion of population 50% = 0.5

q = (1-p) = (1-0.5) = 0.5

d = absolute precision 5% = 0.05

Therefore, from the above formula; n = 0.9604/0.0025=384.2

Hence, n=384

Since my sample population will be less than 10000;

$$nf = \frac{n}{1 + \frac{n}{N}}$$

where;

n= 384

N=4012

Then,

nf = 384/1.0957

nf = 350.4 ; Hence, nf=350

Therefore, my sample size was be 350 participants but due to limited time, I sampled 150 participants.

#### **3.5 SAMPLING PROCEDURE**

This study adopted a systematic sampling method to select the sample population from the eligible patients. This was done by selecting the first person randomly and adding an interval of 2 participants to get the next from the clinic register.

# **3.6 DATA COLLECTION METHODS AND TOOLS**

In this study, quantitative method was employed where questionnaires were used for data collection.

# **3.7 PRETEST**

Test questionnaires were given out to a few participants to assess the acceptability of data collection tool and necessary adjustments were made to ensure adequate data quality.

## **3.8 DATA ANALYSIS AND PRESENTATION**

The data analysis was done by using SPSS version 16 and the findings were presented in form of tables, bar graphs, charts and texts.

## **3.9 INCLUSION CRITERIA**

My study included HIV patients between 20-50 years of age who had been on ART for a period of six months and above and had been receiving their treatment at Kitagata Hospital.

# **3.10 EXCLUSION CRITERIA**

The study excluded pregnant mothers, persons with mental illness, those who had just transferred from another health center but had been on ART for the recommended period.

# **3.11 ETHICAL CONSIDERATIONS**

In the study, I adhered to the following ethical measures in the process of data collection, analysis and dissemination.

An introductory letter was acquired from the dean of clinical medicine and dentistry and permission was sought from the administration of Kitagata Hospital.

## Informed consent

I was open and honest with the participants about the aim and purpose of the study which enabled them to make their own decisions. Given the necessary information, Participants then signed on the consent form willingly.

# Justice

In this study, all participants were treated in the same way regardless of their circumstances such as gender, race.

## Confidentiality

Since, this study involved provision of sensitive information about the participant, confidentiality was censured by not including the participants' name on the questionnaire. The interviews were also conducted in a private room. The information provided by the participants was treated with much confidentiality.

# Benefits

Participation in this study did not cost anything. There was no direct benefits such as receiving payments for participation but exploring the factors affecting ART adherence helped to improve the adherence of patients receiving ART in Kitagata Hospital.

## Risks

There were no physical risks for participating in this study but time taken in answering some of the questions being asked.

# **3.12 LIMITATIONS OF THE STUDY**

Time frame was absolutely limited because I had to work on the research project as well as other studies for the course. However, this problem was be solved by proper budgeting of time and reducing my sample size to 150 participants.

Insufficient funds may have limited the work. However, the little funds allocated for research were budgeted and used carefully to meet the basic requirements of the research.

There was a problem of provision of inadequate information by respondents due to the sensitive nature of the study. However, the problem was resolved by explaining the purpose of the study to the participants so that they felt free to open up and gave the required information.

# **3.13 DISSEMINATION OF RESULTS**

The results of the study were disseminated as follows :

A copy to the faculty of Clinical Medicine and Dentistry, KIU.

A copy to the administration of Kitagata hospital.

A copy retained by the researcher for reference

# **CHAPTER FOUR**

# RESULTS

This chapter gives information about the findings of the study on factors associated with non adherence to ART among patients attending ART clinic in Kitagata Hospital. The findings were from a sample of 150 participants; data was analyzed in terms of percentages and frequencies and presented in frequency distribution tables, short statements, pie charts and bar graphs.

## 4.1 Demographic information of the Respondent:

	Frequency	Percent
MALE	59	39.3
FEMALE	91	60.7
Total	150	100.0

# Table 1: Gender of the target group

The table shows that among the 150 participants, 59 (39.3%) were male and 91 (60.7%) were female.

Table 2:	Age	distribution	of the	participants
	1 <b>1</b> 50	and in a citient		purticipulity

	Frequency	Percent
20-30	36	24.0
31-40	75	50.0
41-50	39	26.0
Total	150	100.0

Most of the participants were within 31-40 year (50%). Minorities were within 20-36 years (24%).

Table 3: Marital status of the target group

	Frequency	Percent
SINGLE	24	16.0
MARRIED	86	57.3
DIVORCED	18	12.0
WIDOW(ER)	22	14.7
Total	150	100.0

Majority of the participants were married (57.3%) while the minority had divorced (12.0%).

# **Table 4: Level of education**

-	Frequency	Percent
ILLITERATE	39	26.0
PRIMARY	74	49.3
SECONDARY	30	20.0
TERTIARY	7	4.7
Total	150	100.0

Out of the 150 participants, most of them had gone up to primary level (49.3%) while the least had reached the tertiary level (4.7%).

**Table 5: Occupation of participants** 

	Frequency	Percent
PEASANT	101	67.3
BUSINESS	35	23.3
STUDENT	4	2.7
EMPLOYED	10	6.7
Total	150	100.0

The table above shows that majority of participants were peasants 101 (67.3%) while the minority 4 (2.7%) were students.

# 4.2 Proportion of participants non adhering to ART.

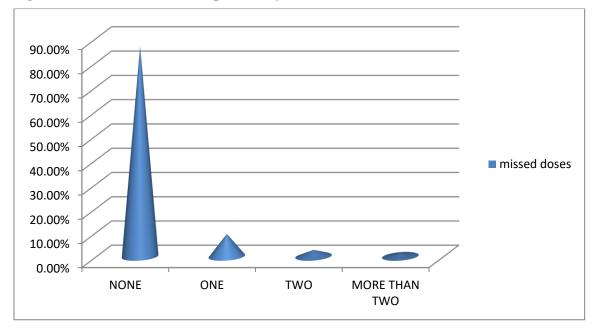


Figure 1: Missed doses in the past 7 days

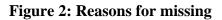
The figure above shows that 130 (86.7%) participants had not missed any dose in the past 7 days, 14 (9.3%) participants missed only one dose, 4 (2.7%) missed only two and only 2 (1.3%) participants missed more than two doses.

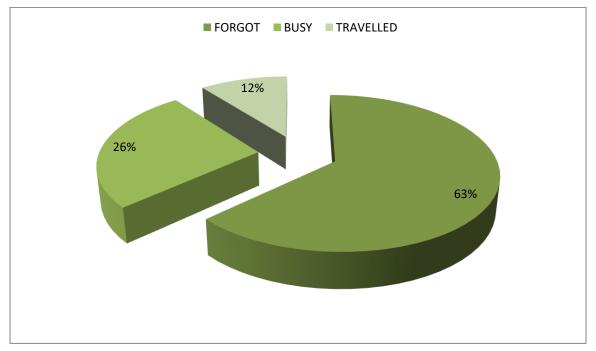
# 4.3 Factors associated with non adherence

## 4.3.1 Individual factors

## **Table 6: Reasons for missing**

	Frequency	Percent
FORGOT	12	63.2
BUSY	5	26.3
TRAVELLED	2	10.5
Total	19	100.0





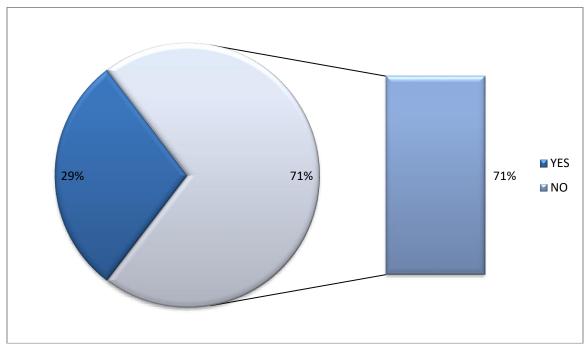
The figure shows that among the 20 participants who had missed taking their drug in the last 7 days, 12 (63.2%) of them had forgotten, 5 (26.3%) of them were busy and 2 (10.5%) had travelled.

 Table 7: Alcohol intake

-	Frequency	Percent
YES	44	29.3
NO	106	70.7
Total	150	100.0

From the table, 44 (29.3%) of the participants do take alcohol while 106 (70.7%) don't.





The figure shows that majority of the participants do not take alcohol while the minority do.

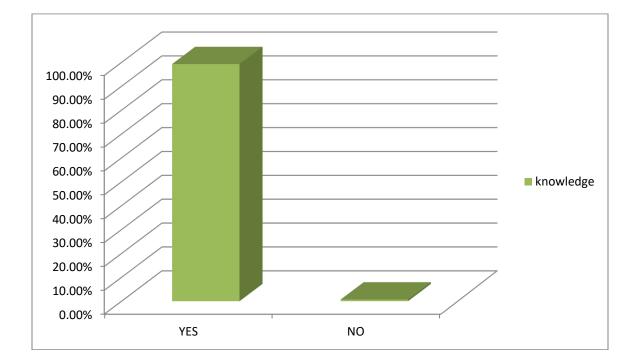


Figure 4: Knowledge on adherence

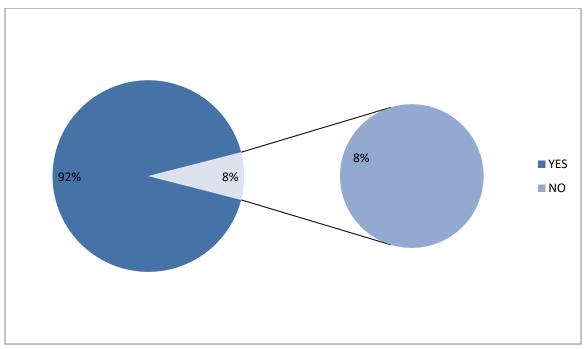
The figure above shows that among the 150 participants, the majority 149 (99.3%) of them had knowledge on adherence to ART while the minority 1(0.7%) had no knowledge.

	Frequency	Percent
YES	148	98.7
NO	0.0	0.00%
Total	150	100.0

 Table 8: Belief that adherence to ART can improve one's condition

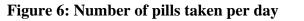
From the table, all 150 (100%) participants believed that adherence to ART could improve their lives.

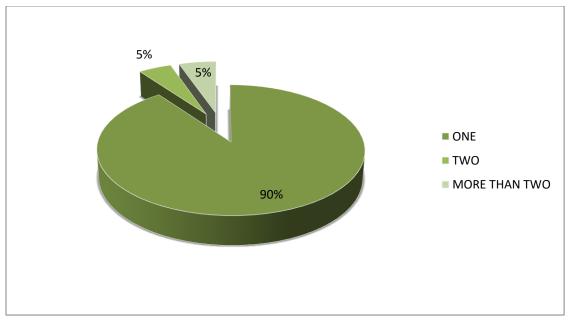
Figure 5: missed scheduled clinic visit



From the figure, 138 (92%) participants never missed any scheduled clinic visit while 12 (8%) participants did miss.

# 4.3.2 Pill burden related factors





Out of 150 participants, the majority 135(90.0%) took two pills per day while the minority 7(4.7%) took only one.

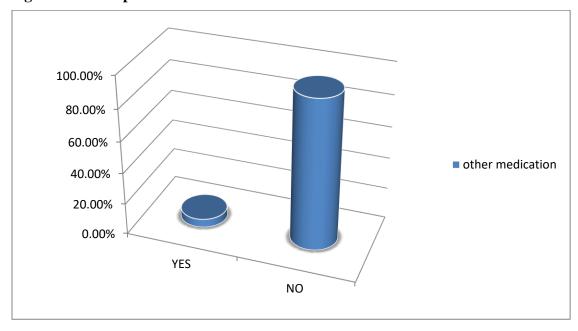
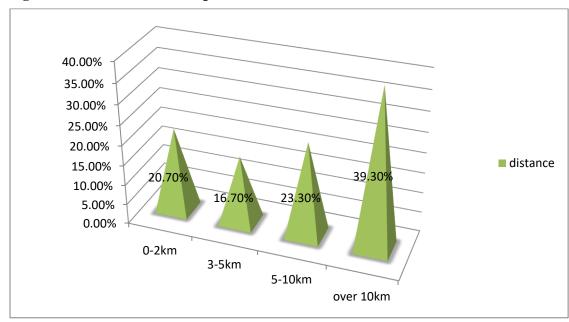


Figure 7: Participants on other medications

From the figure above, 142 (95%) participants were not on any other medications while 8(5%) participants were on other medications.

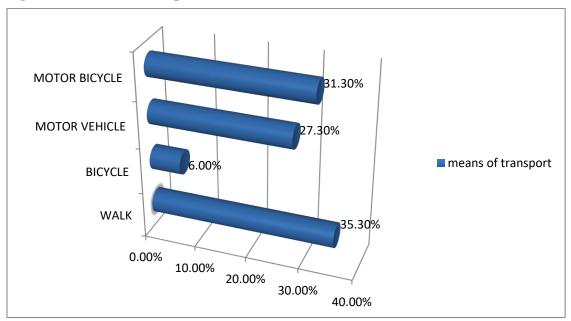


## 4.3.3 Health care related factors

**Figure 8: Distance to the hospital** 

The figure above shows how far the ART clinic is from the participants' home. Majority of the participants residential homes were over 10 kilometers from the clinic 59 (39.3%). Still, a significant number of people were relatively nearer to the clinic.

**Figure 9: Means of transport** 



The figure above shows that most of respondents walk to the ART clinic 53 (35.3%). Others use bicycles 9 (6.0%), motor vehicles 41 (27.3%), and motor bicycles 47 (31.3%)

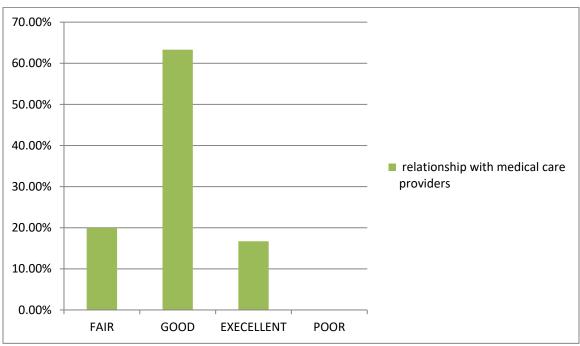


Figure 10: Relationship with medical care providers.

Figure 19 shows that when the participants were asked about their relationship with the medical workers, majority 95(63.3%) of them rated it as good, 30(20.0%) participants rated it as fair,25(16.7\%) participants rated it as excellent and none of them rated poor.

	Frequency	Percent
YES	150	100.0
NO	0	0.0
Total	150	100.0

## Table 9: DRUG AVAILABILITY

All the participants reported that drugs were always available at the clinic whenever they visited.

## **CHAPTER FIVE**

#### **5.1 INTRODUCTION**

This chapter involves discussion of the findings presented in the previous chapter, the conclusion and recommendations made.

#### **5.2 DISCUSSIONS**

#### **Demographic findings**

The study targeted respondents who were HIV positive between the age ranges of 20-50 years. From table 1, majority of the respondents were females (60.7%). Meaning that most of the patients attending ART clinic at Kitagata Hospital are females. Table 2 shows that majority (50%) of them were in the age range of 31-40 years, with table 3 also showing that most (57.3%) of the participants were married. However, as it was already stated in a study done at Harari (*Habtamu Mitiku,et al, 2013*) age, sex and marital status do not significantly affect adherence.

Furthermore, on the demographic findings, table 4 shows that most participants had reached only reached primary level (49.3%) while only 4.7% of them had reached the tertiary level. In this study, the researcher found that adherence rate of the respondents increased with an increase in their educational level. This could be due to the fact that the better educated participants generally have access to information and are more likely feel free while making inquiries from the health care providers which keeps them more informed. As seen in a study where better educated participants seemed to make better informed decisions though verbal instructions to patients who were illiterate seemed equally as effective as written instructions which are given to all patients (*P. O. Erah, et al, 2008*). Furthermore, table 5 shows that majority of the participants were peasants (67.3%) while only 6.7% of them were employed. This meant that most of the population had a low economic status. However, this was not a predictor of non adherence as seen from several studies (*E. Markos, et al, 2008, M. B. Cauldbeck, et al, 2009, A. Amberbir, et al, 2008*).

#### **Rate of non adherence**

Figure 1 shows that majority130 (86.7%) participants had never missed any dose in the past 7 days therefore, they had taken 100% of their prescribed dose while 20 (13.3%) participants had missed whereby, 9.3% had only missed one dose that is, they took 85.7% of their prescribed dose, 2.7% had missed two doses that is, they had taken 71.4% of their dose and only 1.3% had missed more than two doses that is, they had taken less than 71.4% of the prescribed dose. From those, 12 of them were female and 8 of them were male. Therefore, all the participants who had missed taking their pills were considered non adhering since they had not taken < 95% of their prescribed doses during the past 7 days. Hence, the rate of non adherence was found to be at 13.3% with men adhering more than females. This was also comparable with other studies in Harari National Regional state (13%), Yirgalem Hospital (11.7%), South Africa, (12%). However, in comparison with the previous study in same area, the level had relatively reduced since the study found that non adherence was at 15% basically due to missing scheduled clinic visits. (*Bajunirwe Francis, et al, 2009*). This difference might have been due to the improvement in patients' attendance during the scheduled clinic visits.

#### Factors associated with non adherence

Few participants 20 (13.3%) did not adhere to ART. This could have been due to various factors that is, individual, pill burden related factors or health care related factors.

#### **Individual factors**

From my study, figure 2 shows that most of the participants who had missed their treatment reported that they missed due to forgetting (63.2%), some due to being busy (26.3%), and few due to travelling (10.5%). Forgetfulness was a common reason which could have been due to alcohol intake since most participants who had forgotten to take drugs reported that after taking alcohol, they could not remember their medication schedule hence missing a given dose. On the other hand, cases of patients with HIV/AIDS failing to take their medication as required on account of forgetfulness has been documented by some studies (*Mukhtar-Yola, et al., 2006; Olowookere, Fatiregun, Akinyemi, Bamgboye, &Osagbemi, 2008; Skhosana, Struthers, Gray, & McIntyre, 2006; Uzochukwu et al., 2009, sharada, et al, 2012*). From the interviews, one of the participant said she was too busy since her job (Business person) was demanding which

caused her to miss the dose. From this, the researcher found that one's occupation could on the other hand affect his/her adherence to ART though it was mentioned earlier from the previous studies that this was not a predictor of non adherence (*E. Markos,et al,2008, M. B. Cauldbeck,et al,2009, A. Amberbir,et al,2008)*. For travelling, the researcher found that this could have been due to the anticipated changes such as weather changes that come when they travel. This may cause them to skip a dose or fail to take at the right time.

Figure 3 shows that majority (70.7%) of the participants did not take alcohol while the minority (29.3%) did. As stated before, the participants who took alcohol missed some of the doses and this could have been due to forgetfulness.

Figure 4 shows that majority (99.3%) of the participants had acquired some knowledge on adherence to ART. This was due to the continuous counseling sessions organized by the hospital for every scheduled clinic day. This has equipped the participants with knowledge hence improving on their level of adherence. As it was stated in a study that patients' beliefs, knowledge and expectations regarding treatment strongly influence their medical decision making (*sharada, et al, 2012*). This was almost in line with table 8 which shows that all the participants believed that the drugs would improve on their health status. This was further exploited from the interviews where one of the participants believed basing on the improvement the drugs had brought in their lives.

Finally, figure 5 shows that only 12 (8%) of the participants had missed their scheduled clinic visits which could have contributed to the relatively reduced level of non adherence as compared to the previous level observed a study conducted by Bajunirwe Francis, et al, 2009.

#### Pill burden related factors.

Figure 6 shows that majority (90.0%) of the participants reported that they took only two pills a day, 4.7% took only one and 5.3% took more than two pills a day. This shows that majority of the participants had a low pill burden. This therefore could have contributed to the reason for a relatively reduced non adherence level in Kitagata hospital. This was similar to other studies which have found that lower pill burden is associated with higher rates of adherence to HIV

treatment while higher pill burden was associated with lower adherence."(Nachega JB et al, 2014, Dansburg et al., 2006).

In addition, figure 7 also reveals that out of 150 participants, 142 (95%) of them were not on any other medication while only 8 (5%) reported that they were on other medications such as anti hypertensive drugs which also increased on the number of pills taken a day. Therefore, this could have contributed to non adherence among the participants as seen in a study which revealed that, the need for antiretroviral therapy coupled with treatment of chronic co-morbidities places HIV-infected patients at risk for polypharmacy hence affecting their adherence. (*Zhou S et al 2014*)

#### Health care related factors

Figure 8 shows that majority of the participants 59(39.3%) were staying very far from the hospital that is, a distance of over 10km, 35 respondents were within 5-10km, 25(16.7%) respondents were within 3-5km while others 31(20.7%) were within 0-2km. Participants stated that although they were willing to take ART they became non-adherent because of difficulties in reaching the hospital due to unexpected weather changes and the long distances. This therefore led to missing of their scheduled clinic visits. This was also seen in a study conducted in Teso, northern Uganda (*Wilhelm-Solomon M, 2009*), further studies in Nepel also found that Distance was a big concern (*Sharada P et al, 2012*). Therefore, long travelling distance to and from ART sites remains one of the most challenging adherence issues.

Furthermore, figure 9 shows that the study found that 53(35.3%) of the participants walked to the hospital in foot, 47(31.3%) used motor bicycle, 34(27.3) used motor vehicles and only 9(6.0%) used bicycles. This reflected that, most participants using motor bicycles and motor vehicles were staying far from the hospital whereby some participants mentioned that their roads were basically not good especially during the rainy season. In addition to that, some of the participants stated that sometimes they do not have the fare to travel to the hospital to receive their antiretroviral treatment, hence end up missing their doses which affects their adherence. The same findings were seen in Nepel and in Nigeria (*Sharada P et al, 2012, Uzochukwu, et al., 2009*). Generally, distance was closely related to the means of transport.

A study conducted by Margaret A. Chesney, 2014 found that a good patient-health-care provider relationship may be an important motivating factor for taking and adhering to complex combination drug therapies. However, according to this research, figure 10 shows that majority

95(63.3%) of respondents reported that they had a good relationship with their medical care providers, 30(20.0%) of them reported a fair relationship, 25(16.7%) reported an excellent relationship and none of them reported a poor relationship. This relationship might have contributed to a better adherence since the participants felt free to interact with the medical care providers.

Finally, from the study, drug availability was not a problem since all (100%) of the participants as seen in table 9 reported that drugs were always available whenever they visited the ART clinic. This was due to the Government's initiative to supply free ARVs to the different ART clinics in Uganda meaning that, if the drugs were always out of stock, the participants would have missed taking their drugs due to the scarcity. However, this was different from studies done in Arumeru Hospital and in Nigeria. (*Hardon, et al, 2006, Monjok, et al., 2010; Uzochukwu, et al., 2009*)

#### **5.3 CONCLUSION**

This study found a relatively lower adherence rate (13.3%) compared to the previous studies done in Uganda, Kitagata in particular.

The most common individual factor associated with the non adherence was forgetfulness (63%) which was mostly associated with alcohol intake (29%).

The study also found the most common healthcare related factor was the distance to the hospital since most (39.3%) of them were staying over 10km away from the ART clinic since all of them (100%) reported that drugs were always available and (63.3%) also reported a good healthcare provider relationship.

Finally, the researcher found that most (90%) participants were taking two pills per day which meant that the low pill burden favored adherence for most of them.

In general, this study reported a relatively lower adherence rate (13.3%) compared to the other previous studies in Uganda and Kitagata in particular. This might have been due to the improved attendance at the ART clinic, good healthcare provider relationship and the availability of drugs. However, Forgetfulness and the long distance to the ART clinic were the most common reasons for poor adherence to the medication.

## **5.4 RECOMMENDATIONS**

For the case of forgetting, adherence counseling and health information dissemination needs to include strategies to minimize forgetfulness using memory aids such as written schedule, and watch bell.

Patients travel long distances and are exhausted by the time they get to the clinic. Government should provide clinic annex in strategic locations across the villages as a means of bringing treatment closer to patients. In this case they will not need to travel far distance before accessing treatment.

In addition, a further study on adherence rate and its determinants with multiple adherence measurements to resolve the barriers to adherence is also recommended.

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# **APPENDICES**

## **APPENDIX I: CONSENT FORM**

I am Ms. Juan Caroline, a medical student from Kampala International University carrying out a research on factors affecting adherence in HIV positive patients attending ART Clinic at Kitagata Hospital.

You have been identified as a potential respondent, and therefore I am requesting you to spare some little time out of your busy schedule and feel in this questionnaire. I would like to inform you that you have all the rights to fill this questionnaire or to refuse and nothing will be implicated against you. I will be very grateful.

The participation of respondents by answering the questionnaire will help the researcher to assess the factors affecting adherence to ART among HIV-positive patients attending ART clinic at Kitagata Hospital which will also help the MOH to identify the strategies that can help to reduce non adherence to ART. The information provided will be purely for academic purposes and will be kept confidential.

## Consent

I the participant, consent to the participate in the research as explained to me by the researcher.

Participants signature .....

Researchers signature.....

Date .....

# **APPENDIX I1: QUESTIONAIRE**

# Factors affecting adherence to ART among HIV-positive patients attending ART clinic at Kitagata Hospital.

## Instructions:

Answer all the questions

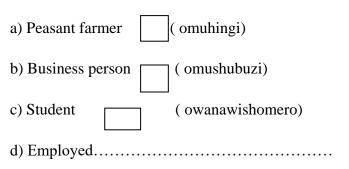
Tick or circle the most appropriate answer and write where necessary.

## A. Biographic data

1. Sex

a) Male	(omushaija)	b) Female	(omukazi)
2. Age (emyaka	yawe)		
a) 20-30	( makumiabiri- makumiashatu)		
b) 31-40	(ashatunagumwe- makumiana)		
c) 41-50 (ananagumwe- makumiatano)			
3. Marital status			
a) Single	( Tinkashwire OR tinkashwirwe)	c) Divorced	(okutaana)
b) Married	(washire)	d) widow(er)	
4. Education level ( okushomakwawe)			
a) Illiterate	( toshomire)		
b) Primary	( osomiirepurayimare)		
c) secondary	( osomiiresinia)		
d) Tertiary	( osomireomumwitendekyero)		

5.	Occupation (	omulimo)
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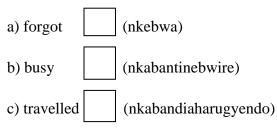
# **B.** Proportion of non adhering participants

6. Number of missed doses during the past 7 days?(Emirundiyotamizireemibaziomubiromushanjuebihingwireho?)

a) None	(Tebiriho)
b) one	(gumwe)
c) Two	(ebiri)
d) more (	than two (nerengaebiri)

## **C. Individual factors**

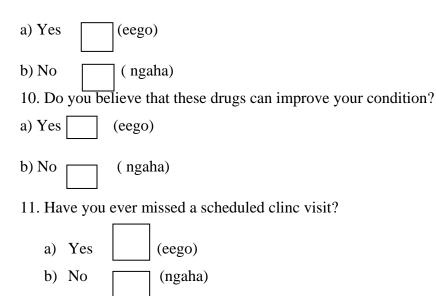
7. If you have ever missed, then why? (kwobeorayoshize, kandiahabwenki?)



8. Do you take alcohol? ( Nonwaamarwa?)

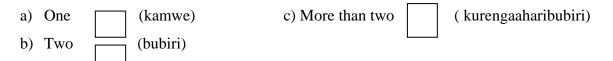
a) Yes	(eego)
b) No	(ngaha)

9. Do you have any knowledge regarding the importance of adherence to ARVs? (oyineamagezigoonaagalikukwataahamigashoyokumiragyeemibaziyasirimuomubwire)



## **D.** Pill burden related factors

12. How many pills do you take a day? (Nomiraobujumabungahi)



13. Are you on any other long term( more than 1 month) medication apart from this?( Harihoemibaziandijooyorikumiraetariegyi?)

a) Yes (eego)

b) No (ngaha)

## E. Health center related factors

14. How far is the health unit from your home? ( nibulingwakikuligaowawekuhika aha eirwariro?)

A. 0-2km ( ) B. 3-5km ( ) C. 5-10km ( ) D. Over 10km ( ) 15. What means of transport are available for you to use?(entamburanokozesaziha?)

- A. On foot () (notambura)
- B. Bicycle () (egari)
- C. Motor vehicle ()(emotoka)
- D. Motor bicycle ()( epikyi)

16. How is your relationship with the medical care providers? ( enkwatanisayawenabashahoeryeta)

a) Poor	(nimbi)
b) Fair	(Tikubimunonga)
c) Good	( ninungi)
d) excellent	( ninungimunonga)

17. Are the drugs always available at the hospital?(Emibazinekyirakubaerihoahirwariiro?)

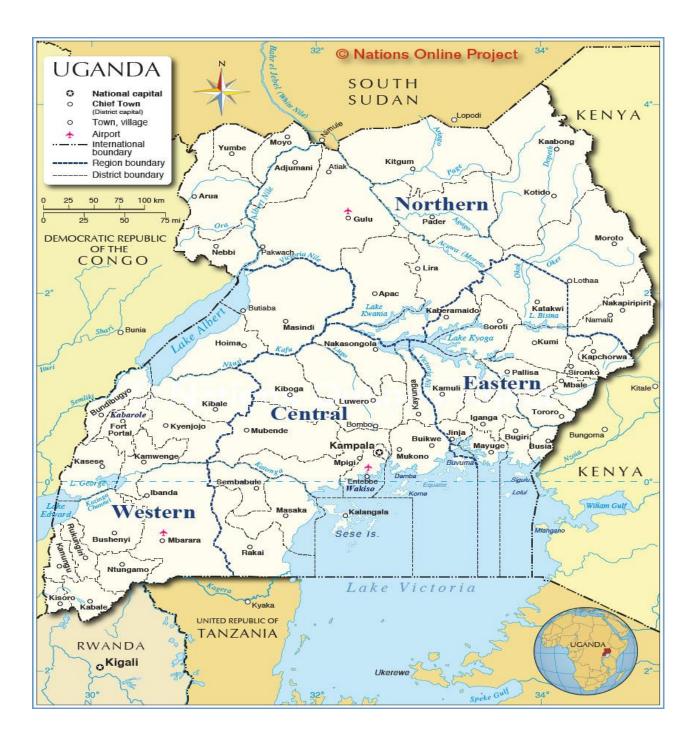
a) Yes	(eego)
b) No	(ngaha)

## "THANK YOU VERY MUCH FOR YOUR CO-OPERATION"

## **APPENDIX III: INTRODUCTORY LETTER**

KAMPALA Ishaka Sushenyi \* PO BOX 71 ishaka, Uganda Tel: +256 (0)771695711/0703817216 Fax: +256 (0) 41 - 501 974 INTERNATIONAL E-mail: admin@kiu.ac.ug \* Website. http://www.kiu.ac.ug UNIVERSITY OFFICE OF THE DEAN, FACULTY OF CLINICAL MEDICINE & DENTISTRY 1/12/2014 Accepted and allowed to use. Appletal poemises ol TO WHOM IT MAY CONCERN 0 2 DEC 2014 RE: JUAN CAROLINE WINGAIN NUSPI (BMS/0088/113/DU) 60, KABWOHE S The above named is a student of fourth year at Kampala International University pursuing a Bachelor of Medicine, Bachelor of Surgery (MBChB) programme. She wishes to conduct her research project in your hospital. Topic: Factors associated with non adherence to art among HW infected patients attending art clinic at Kitagara Hospital, Shorms District. Any assistance given will be appreciated. ELICINA Thank you NEC Dr. Benjamin Oonge Dean, FCM &D Exploring the Heights

## **APPENDIX IV: A MAP OF UGANDA**



# APPENDIX V: A MAP SHOWING KITAGATA

