

**HEALTH-RELATED QUALITY OF LIFE AMONG ANTIRETROVIRAL
THERAPY (ART) EXPERIENCED AND ART NAÏVE ADULTS
ATTENDING AN URBAN HIV CLINIC IN KAMPALA, UGANDA**

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DECLARATION

I, **SEKABIRA ROGERS**, hereby declare that the work submitted in this dissertation is original and a result of my own study except where otherwise acknowledged. This thesis has not been submitted for another degree award in this or any other University or institution

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DEDICATION

I dedicate this piece of work to my dear parents, Mr. Dan Nsubuga and Mrs. Grace Nsubuga, for educating me and making me a God fearing person and to my dear wife Grace Sekabira Nakanwagi, for keeping my dreams alive.

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ACRONYMS

ACTG	AIDS Clinical Trials Group
AIDS	Acquired Immunodeficiency Syndrome
ARVs	Antiretroviral drugs
BP	Bodily Pain
CF	Cognitive Functioning
CI	Confidence Intervals
Coef.	Coefficient
HAART	Highly Active Antiretroviral Therapy
HAQ	Health Assessment Questionnaire
HCSUS	Human Immunodeficiency Virus Cost and Service Utilization Study
HIV	Human Immunodeficiency Virus
HRQoL	Health Related Quality of Life
HUI3	Health Utility Index Mark 3
IDI	Infectious Disease Institute
IQR	Inter-quartile Range
IRBs	Institutional Review Boards
JCRC	Joint Clinical Research Centre
MH	Mental Health
MHS	Mental Health Summary
MOS-HIV	Medical Outcome Survey Human Immunodeficiency Virus
MQoL	Multidimensional Quality of Life

MUSPH	Makerere University School of Public Health
OR	Odds Ratios
PARSE	Patient Reported Status and Experience Survey
PCA	Principle Component Analysis
PF	Physical Functioning
PHS	Physical Health Summary
RF	Role Functioning
SD	Standard deviation
S.F	Short form
SF	Social Functioning
SG	Standard Gamble
TTO	Time Trade-Off
UNCST	Uganda National Council for Science and Technology
UDHS	Uganda Demographic Health Survey
VAS	Visual Analogue Scale
VT	Vitality

OPERATIONAL DEFINITIONS

ART Experienced: For purposes of this study, these are adults who have been on ART medication for at least six months.

ART Naive: These are adults who are infected with the HIV but are not on Anti retroviral viral medications

Antiretroviral Therapy: A treatment combination with two or more antiretroviral drugs to effectively suppress the Human immune deficient virus resulting into a marked drop in the viral load.

Cognitive Functioning: an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It involves all aspects of perception, thinking, reasoning, and remembering.

Convergent validity: tests that constructs that are expected to be related are, in fact, related.

Discriminant validity: (or divergent validity) tests that constructs that should have no relationship.

General Health: The current health status of the participant. The rating is based on the individual's judgement and items in this dimension report the patient's general health, ability to resist illnesses and health outlook.

Health Related Quality of Life (HRQoL): Considered as part of the individual's quality of life that is primarily determined by his or her health status, it's the functional effects of an illness and its consequent therapy upon a patient/client and as perceived by the patient/client. HRQoL is not observable and it's distinct from the broader construct of QOL in that, it's limited to those life influences that fall

within current health, health care and health promotion.

HIV/AIDS Targeted Quality of Life (HAT-QoL): A tool used to measure areas such as overall function, life satisfaction, health worries, financial worries, medication worries, sexual function, and disclosure worries of an HIV infected client in the past four weeks.

Health transition (HT): this dimension measures the amount of change in the patient's physical and emotion health over a four week period.

Mental Health (MH): the general effect of mood and psychological wellbeing including his/her past experience.

Pain: defined as the intensity of bodily tenderness in the specified past weeks.

Physical functioning (PF): the extent to which health interferes with a variety of physical activities like running, climbing up a hill.

Role functioning (RF): the extent to which health interferes with the usual daily activities like house work, bathing.

Social functioning (SF): the extent to which health interferes with the normal social activities like attending parties, visiting friends.

Standard gamble: a preference based method of measuring HRQoL in which respondents are asked to choose between remaining in a state of ill health for a period of time or having a medical intervention which has a chance of either restoring them to perfect health, or kill them.

Time-trade-off: also a preference based method of measuring HRQoL in which, respondents are asked to choose between remaining in a state of ill health for a

period of time, or being restored to perfect health but having a shorter life expectancy

Quality of Life (QoL): This single item dimension measure the patient's quality of life during the past four weeks and the response categories range from very well, could hardly be better to very bad, could hardly be worse.

Vitality (VT): A measure of the patient's ability, energy or power

ABSTRACT

Introduction: Antiretroviral therapy has reduced HIV/AIDS related mortality. However, unlike in developed countries, little is documented about its impact on Health-related quality of life (HRQoL) in developing countries, where HRQoL is rarely assessed. This highlights a deficiency in assessment of health status of HIV infected people in clinical setting where ART scale-up continues to expand.

General objective: To measure HRQoL among HIV-infected adults attending an HIV clinic in Kampala using the medical outcome study HIV tool and to assess the reliability, convergent and discriminant validity of this tool in this setting

Specific Objectives:

- 1) To measure reliability, convergent and discriminant validity of the adopted MOS-HIV tool in assessing HRQoL in an urban HIV clinic
- 2) To compare scores of HRQoL scales between ART-experienced and ART-Naïve individuals attending an urban HIV clinic using the MOS-HIV tool
- 3) To determine factors associated with HRQoL among ART-experienced and ART-Naïve patients attending an urban HIV clinic

Study Design: Across sectional study with a random sample of 188 participants.

Results: Overall, ART-experienced patients had higher HRQoL scores than ART-Naïve patients. Reliability coefficients were >0.8 for all scales and the attenuated correlations were < 0.85 confirming discriminant and convergent validity. The expected average difference between an ART-Experienced patient who had attained post secondary education and one with pre secondary education was 4.78 for PHS score and 5.42 for MHS score. The expected average difference in the MHS score between an ART-Naïve patient who had employment and one who did not have employment was 4.47. The expected average difference in PHS and MHS for an HIV infected adult was between 6.5 and 8.4 holding other variables in the model constant.

Conclusion: Education level, presence of symptoms and employment status are associated with HRQoL. The MOS-HIV tool is a reliable and valid tool to measure HRQoL among HIV-infected adults in Uganda.

CHAPTER 1: INTRODUCTION AND BACKGROUND

An estimated 22 million adults and children were living with HIV in sub-Saharan Africa, according to the 2008 report on the global AIDS epidemic with over 1million infected adults living in Uganda. There were also 91,000 HIV/AIDS associated deaths by the end of 2007 (UNAIDS/WHO 2008).

However, a 70% decline in HIV prevalence has been observed in Uganda since the early 1990s and this has been linked to a reduction in casual sex, communication through social networks and substantial condom use (Stoneburner et al. 2004). Availability of Anti-Retroviral Therapy (ART) led to a reduction of approximately 80% in heterosexual transmission of HIV, irrespective of changes in other factors that affect transmission (Castilla et al. 2005).

A number of other benefits have been attributed to the introduction of antiretroviral drugs such as prolongation of life and the reduction of mortality (Murphy et al. 2001; Messeri et al. 2003; van Sighem et al. 2003; Van der Paal et al. 2007), despite the various limitations associated with HIV and its co-infections (Sahai et al. 1997; Thomas et al. 2005; Breen et al. 2006; Yew et al. 2006). Unlike in developed nations, little is known about the impact of ART on health-related quality of life (HRQoL) in the developing countries (White et al. 2009).

HRQoL refers to peoples' subjective evaluations of the influences of their current health status, health care, and health promoting activities on their ability to achieve and maintain a level of overall functioning that allows them to pursue valued life goals and that is reflected in their general wellbeing(Shumaker et al. 1997).

It focuses specifically on QoL as it relates to health with the major domains of functioning such as physical, social, emotion and cognitive function; mobility and self-care; patient perception; and symptoms (Shumaker et al. 1995; Vanhems P et al. 1996; Wu.Albert. 2000). HRQoL is broadly measured using disease specific health status instruments or preference-based instruments.

Disease specific health status instruments may include Medical Outcome Study (MOS-HIV), Multidimensional Quality of life-HIV (MQoL-HIV), SF-36, SF-12, ACTG SF21, SF-56, Patient Reported Status and Experience Survey (HIV-PARSE), HIV Cost and Service Utilization Study (HCSUS) ,HIV-QL31, AIDS-Health Assessment Questionnaire (AIDS-HAQ) and modular approach(Lenderking et al. 1997; Leplege et al. 1997; Lubeck et al. 1997; Wu et al. 1997) while preference-based instruments include Health Utilities Index Mark 3 (HUI3), EQ-5D, EQ-5D visual analogue scale(EQ-5DVAS), standard gamble(SG), and time trade-off(TTO) (Joyce et al. 2009).

Among the above instruments, the MOS-HIV holds the highest promise of moving the field forward in resource limited settings and covers the critical persistent gaps in HIV HRQoL measurement arena unlike most preference based instruments which provide imprecise estimates (Wasson et al. 1992; Bayoumi et al. 1999).

MOS-HIV addresses a range of HRQoL dimensions and additional HRQoL components relevant to HIV through its direct interview with HIV patients versus investigator assumption (Revicki et al. 1998). The MOS-HIV has relatively good psychometric properties in the developed countries; reliability greater than, or

equal to 0.75 and evidence of construct validity (Burgess et al. 1993; Revicki et al. 1998; Holmes et al. 1999; Schifano et al. 2003). It has been used in the rural regions of Uganda (Mast et al. 2004). It is also more sensitive than MQoL-HIV (Badia et al. 2000)

HRQoL is vital to clinical practice because it is used to track changes in functional status over time for chronic illness, evaluate and monitor treatment effects, improve patient provider communication and adherence to medications(Howard A. G et al. 2004). Only a few studies have been conducted in rural Uganda about HRQoL among persons on ART and these are even fewer in urban Uganda. Hence there is currently a knowledge gap on HRQoL in Uganda to direct policy.

Designing and identifying strategies that improve the quality of life of HIV-infected adults is key as part of care. Given the chronic nature of HIV/AIDS, measurement and documentation of empirical differences between HRQoL scores among ART-Naïve and ART-Experienced using a validated and standardized questionnaire is necessary.

This study therefore aimed at measuring the Health-related quality of life for antiretroviral therapy (ART) experienced and ART Naïve adults in an urban HIV clinic in Kampala, Uganda.

CHAPTER 2: LITERATURE REVIEW

HIV/AIDS has had various detrimental effects which may impinge on HRQoL of different populations such as higher child mortality of those born to HIV infected mothers than HIV negative mothers (Newell et al. 2004). In Uganda, it is associated with over 73% of adult deaths leading to increased incidence of orphanhood (Sewankambo et al. 2000; Makumbi et al. 2005). Evidence also shows that child-headed households were significantly less likely to seek health care from health facilities (Amuge et al. 2004)

The use of information is becoming more vital not only to policy makers but also to clinical practice. For instance, studies show that patients whose physicians were given HRQoL data experienced an improvement in some HRQoL domains (Osoba et al. 2006). Such information would assist patients in determining their preferences for therapeutic clinical decision-making. However, their study used computer adopted testing which may not be feasible in resource limited settings unlike the approach used by this particular study.

Unfortunately, much as measurement of HRQoL data is important, patients perceive the effects of ART on their quality of life (QoL) as a trade-off between poorer QoL and being alive (Park-Wyllie et al. 2007). These effects further encroach on most families. For instance (Alkenbrack et al. 2004) reports that children living with HIV infected parents score significantly lower than those with HIV uninfected parents in a number of health-related to quality of life domains.

A study conducted in Tanzania, East Africa, reports that HIV infected people with co-morbidities have lower HRQoL scores than the general population especially the mental health summary scores (Magafu et al. 2009).

In rural Eastern Uganda, ART increased the HRQoL summary scores by 11.2 ($p<0.001$) and 7.4 ($p<0.001$) for both physical and mental health summary scores respectively (Stangl et al. 2007). In rural Rakai, more than four-fifth of HIV-infected women reported substantial limitation in their quality of life (Mast et al. 2004).

In Kampala, a study conducted among HIV infected pregnant women using Dartmouth COOP charts revealed statistically significant reductions in HRQoL scores in feelings ($p<0.001$), daily activities ($p<0.001$), social activities ($p<0.001$), pain ($p<0.002$) and overall health ($p<0.003$) (Nuwagaba-Biribonwoha et al. 2006). This particular study focussed on HIV infected adults of both sexes.

Lower HRQoL scores have been consistently reported among women in several domains compared to men (Lenderking et al. 1997; Mrus et al. 2005), among individuals who progress to AIDS as compared to the symptomatic and asymptomatic (Lubeck et al. 1997) and among those diagnosed with HIV infection in the first two months (Honiden et al. 2006).

Further evidence from a number of studies shows that HRQoL scores are improved by bereavement groups aimed at enhancing coping with grief through affectionate and information social support (Sikkema et al. 2005; Bajunirwe et al. 2009) and self efficacy or willingness to take medicines (White et al. 2009).

CHAPTER 3: STATEMENT OF THE PROBLEM, JUSTIFICATION, CONCEPTUAL FRAMEWORK, AND RESEARCH QUESTIONS

3.1 Statement of the problem

The major challenge in Kampala and other resource-limited settings in Africa is lack of information on HRQoL of populations affected by HIV/AIDS, despite the abundance of information on the introduction and benefits of ART, treatment regimens and economic effects of HIV/AIDS. Secondly, there is limited information on the validity of the MOS-HIV tool in developing countries as compared to the developed countries.

To our knowledge, the MOS-HIV tool has only been validated in a rural setting (Rakai South-western Uganda) and amongst women. Thus there is limited evidence of its performance in the urban population in developing countries.

This study intended to specifically provided HRQoL information among ART experienced and ART Naïve patients attending an urban ART clinic. This information may be vital to healthcare practitioners in identification of unsuspected symptoms and understanding the association between HRQoL with socio-demographic characteristics for these two groups of people. This information may also be used by policy makers to monitor HIV disease progression alongside other indicators and this may serve as an economic productivity indicator among persons infected with the HIV.

3.2 Justification

The justification answers questions why the study was conducted, the gaps to be filled by the study in the existing body of knowledge and how this information will influence public health and practice.

This study was conducted to provide HRQoL information for both men and women HIV-infected adults living in the urban resource limited setting. Secondly, it was conducted to provide more information regarding to reliability and validity of the MOS-HIV tool in the urban resource limited setting.

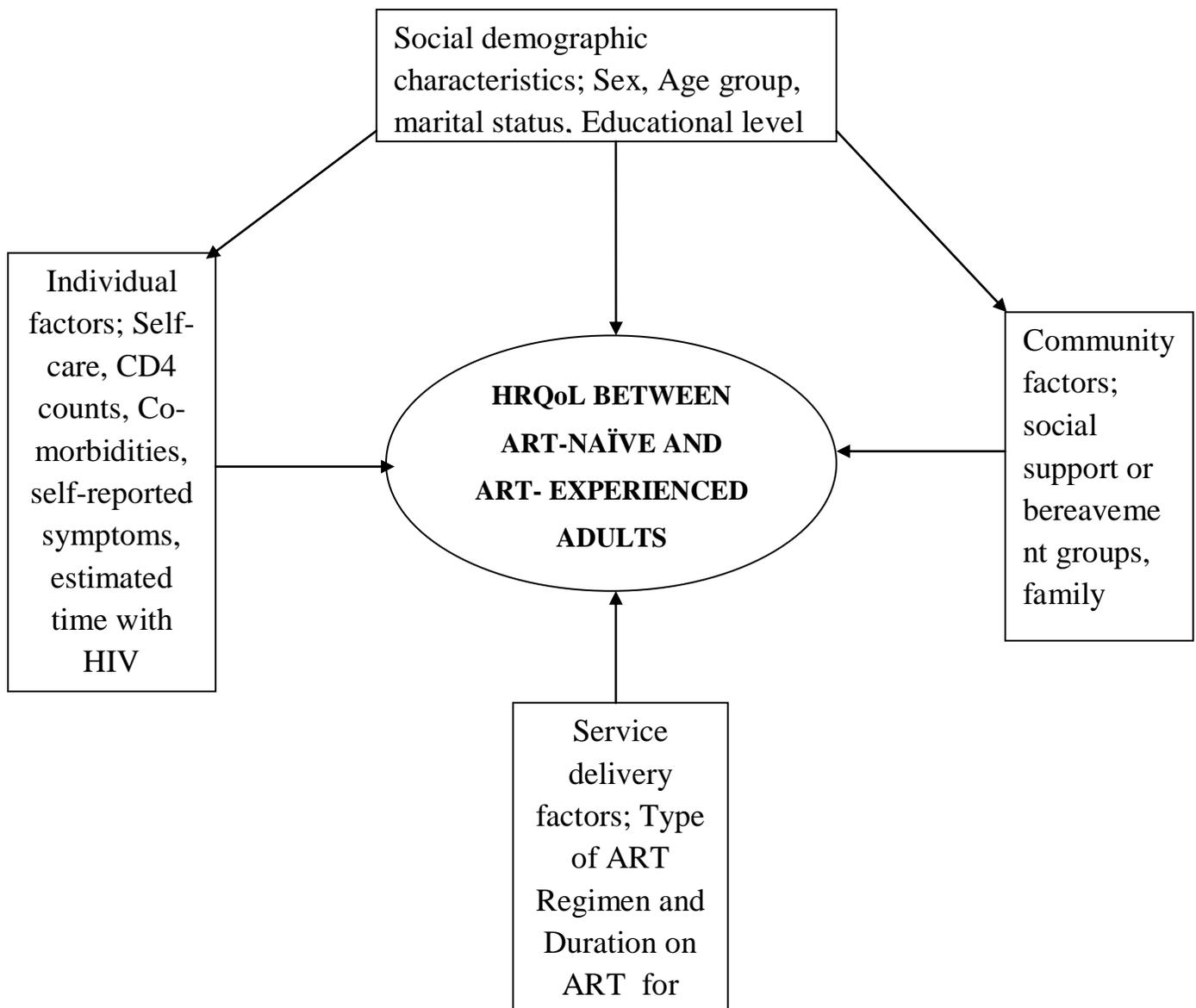
Majority of the HIV treatment centers are located in urban and peri-urban areas. Measuring HRQoL among HIV-infected patients residing in these localities is imperative for health care service delivery particularly in this era of antiretroviral scale-up at least in the case of Uganda. Secondly, there are cultural and socio-demographic differences between people living in the urban and rural areas as cited by (Weeks et al. 2004; Oguzturk 2008). Evidence also shows that there are gender differences based on a continuum of psychological, social and interactive characteristics(Pearson et al. 1994).This does not refute the earlier study conducted among women and in the rural setting but seek more evidence.

HRQoL Information from this study will inform healthcare practitioners not only about the physical but also the mental wellbeing of their patients and overall functionality. This will increase their suspicion index of detecting illness, thus enhancing the quality of service provided to their patients.

Last but not least, conducting this study will provide more evidence regarding the performance of the MOS-HIV tool in the urban setting.

3.3 Conceptual framework and narrative

3.3.1 Figure 1. Conceptual framework



3.3.2 Narrative

HRQoL among HIV/AIDS can be affected by several factors which for purposes of this study are categorized into individual, service delivery, community and social-demographic factors.

Some of the factors are intertwined, for instance educational attainment may be linked to self care. Through education an individual can be equipped with self-care skills. Marital status is linked to social support because in most cases, married persons have families that can be a source of social support.

Service delivery factors like type and duration of ART regimen and concomitant mediations for other illnesses since the study was conducted in a clinic setting and individual factors like CD4 counts, co-morbidities, self-reported symptoms and immunological state were considered.

3.4 Research questions

1. What is the reliability, convergent and discriminant validity of the adopted MOS-HIV tool in assessing HRQoL in an urban HIV clinic?
2. Does health-related quality of life differ between ART-Experienced and ART-Naïve patients attending an HIV clinic in Kampala, Uganda?
3. What factors are associated with HRQoL among ART-experienced and ART-Naïve patients attending an urban HIV clinic?

CHAPTER 4: STUDY OBJECTIVES

4.1 General objective

To measure health related quality of life among HIV infected adults attending an HIV clinic in Kampala using the medical outcome study HIV tool and promote it in routine HIV care.

4.2 Specific objectives

The specific objectives of the study were

1. To measure reliability, convergent and discriminant validity of the adopted MOS-HIV tool in assessing HRQoL in an urban HIV clinic.
2. To compare scores of HRQoL scales between ART-experienced and ART-Naïve individuals attending an urban HIV clinic using the MOS-HIV tool.
3. To determine factors associated with HRQoL among ART-experienced and ART-Naïve patients attending an urban HIV clinic.

CHAPTER 5: METHODOLOGY

5.1 Study site

The research was conducted at JCRC HIV/AIDS treatment centre of excellence located in Rubaga, one of the divisions in Kampala district. JCRC pioneered the use of antiretroviral drugs in Uganda in 1992 and provides care to over 7,000 adults of mixed heritage, some on first line therapy and others on second line therapy.

Drugs are free of charge but adults are expected to meet their transportation costs to the centre. It also has a fully functional laboratory network and provides adherence counselling and peer support group though not all patients fully utilize these services, some decide to ignore them claiming to have limited time. This centre also provides a few drugs to treat opportunistic infection to its patients.

5.2 Study Population

This comprised people receiving HIV care from JCRC; majority reside in and around Kampala. They include adults and children but this study focused on adults due to differences in HRQoL dimensions in the two groups. The study was conducted in the month of December 2009. This data focused on HRQoL dimensions, baseline characteristics like age, sex, educational status and marital status. It also included service delivery factors like the type of regimen the patient was taking if he/she was ART experienced and an estimate of the time lived with HIV.

5.3 Study design

A cross sectional study was conducted to measure health related quality of life between the two comparative groups; ART experienced and ART naïve adults. Both groups of individuals were at least 18 years of age.

5.4 Sample size determination and considerations

Given that this was a cross sectional study using two independent samples with a continuous primary outcome of interest (HRQoL), we determined the difference between means and standard deviation of the primary outcome of the sample. Hence the most suitable formula for sample size determination was:

$$2N = \left[\frac{4(Z_{\alpha/2} + Z_{1-\beta})^2 \sigma^2}{\delta^2} \right] \text{ (Friedman et al. 1998)}$$

Where:

$Z_{\alpha/2}$ = the standard normal deviate at 95% Confidence (1.96)

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

σ = Variance of the outcome of interest HRQOL, 22.5 (Mast et al. 2004)

δ = Maximum error, difference between the two means we are willing to allow. This is also known as the precision, 7 (Mast et al. 2004)

$$\begin{aligned} \text{Effect size} &= (\delta/\sigma) \\ &= (7/22.5) \end{aligned}$$

Effect size = 0.31

Table 1: Table of Sample size determination

Effect size, E.S (δ/σ)	Power of 80%, Z $\alpha/2=0.84$		Power of 90%, Z _{1-β} $\beta=1.282$	
	N _{1a} = N _{1b}	2N ₁	N _{2a} = N _{2b}	2N ₂
0.20	392	784	525	1050
0.31	162	324	217	434
0.50	63	126	84	168
0.80	25	50	33	66

In this study, the power of 90% was preferred to that of 80% because the probability of a type II error, false negative rate (β) decreases as the power of the study ($1 - \beta$) is increased. This implies that the probability of correctly noticing a difference which actually exists was increased. An effect size of 0.5 was used because it was a relative feasible sample size in terms of cost, time and availability of participants.

To cater for non response effect anticipated during the study, the calculated sample size (168) above was divided by the difference between 1 and assumed non response rate of 10%. Hence the adjusted sample size was 188 participants.

5.5 Sampling procedure & eligibility criteria

5.5.1 Sampling procedure

Patients' information is routinely entered and stored in Navision database at every clinic visit. This provided the sampling frame; numbers were assigned to the clients in the system and the internet was used to generate a set of random values. This was done for both ART-experienced and ART-naïve patients. The first 188

internet based random values comprised the sample size. This sampling procedure was suitable for identifying the sample size since an estimate of the sampling framework could easily be established from the database hence minimizing on selection bias.

5.5.2 Inclusion criteria

The study used the following inclusion criteria

- All HIV infected adults aged ≥ 18 years seeking care at JCRC
- Both inpatients and outpatients
- At all stages of HIV disease stage

5.5.3 Exclusion criteria

- Those unable to consent to the study
- Too ill to participate in the study
- Patients who could not communicate in the study languages

5.6 Study Variables

5.6.1 Dependent Variables

The dependent variable was HRQoL represented by physical and mental health summary measures. These two summary measures were derived from the aggregation of scales scores using factor analysis.

5.6.2 Independent Variables

- Social demographic characteristics; sex, age group, marital status, educational level attained, income levels
- Individual factors; self-care, CD4 counts, co-morbidities, self-reported symptoms HIV disease stage, pregnancy, estimated time with HIV
- Service delivery factors; type and duration of ART, regimen, concomitant medications
- Community factors; social support or bereavement groups, family

5.7 Data Collection

5.7.1 Data collection tools

In this study the principle investigator and research assistants used both the English and Luganda versions of the culturally adopted, translated and validated MOS- HIV tool, adopted from the Rakai Health Sciences Program. The version of the tool was determined by the language for which the participant felt comfortable to be interviewed in. This tool was administered via face to face interview. The dimensions were measured on likert scale and mainly quantitative data was collected. A number of additional items were included in the tool to meet the objectives of the study other than the HRQoL items.

5.7.2 Data collection procedure

Data collection was done in a quiet secluded or secure part of the compound. The interviewer introduced him/herself to the participant. The participant was told the purpose of the study, duration of the interview and his/her consent was sought before he/she was engaged in a face to face interview. Effort was made to ensure

that the interviewer was confident, comfortable and knowledgeable throughout the training and practiced reading the questionnaire in advance. This was done to ensure more natural responses and hasten the establishment of rapport with the participants. The interviewer thanked the participant for his/her time at the end of the interview.

5.7.3 Quality Assurance/Quality Control Procedure

5.7.3.1 Training of research assistants

Research assistants were recruited and trained prior to data collection. The training was divided into two practical sessions. The pre and post tests were administered to determine their competence and applicability of the acquired interviewing skills. There was also continuous rehearsal of how to administer a face to face interview to instill confidence.

5.7.3.2 Pre-testing

The tool was pre-tested for one week among 10% of the clients calculated sample size (10 respondents per group). The pre-testing established the ability of the tool to elicit relevant responses and ease of administration.

5.7.3.3 Field editing

A meeting was held with the research assistants at the end of the day's work to edit the items and modify item responses identified as double barreled and ambiguous.

5.8 Data Management and Analysis framework

5.8.1 Data Management

This data was entered in Epi Info 2008 version 3.5.1, CDC statistical software and analyzed in Stata (StataCorp. 2007. *Stata Statistical Software: Release 10*. College Station, TX: StataCorp LP). Data was collected using a coded measurement tool. It was checked for consistency, cleaned to eliminate errors and checks were made on the values of the variables during data entry and analysis.

5.8.2 Variable categorization

The categorization of age was adopted from Uganda Demographic and Health Survey (UDHS) 2006 in assessing the distribution of social demographic factors with ART status. Despite the inclusion criteria of greater or equal to 18 years, age group 20-24 was the reference. This was because the sample did not have participants less than 20 years. Religion was categorized into none for those who did not believe in anything, then Catholics, Protestants, Pentecostals, Muslim and others for other beliefs. Attained levels of education were categorized into pre-secondary, secondary and post-secondary, given that most of the individual in the urban and peri-urban setting were educated. All those participants from “without education to primary level” were considered to be in the pre-secondary category, then those that attained secondary, and post-secondary as the third category for those that “attained tertiary and university education”. Occupation was categorized as ‘currently employed’ and ‘currently not employed’. The currently not employed category included peasants, full time students, house wife and any person without a steady source of income. This was also adopted from the UDHS, with an aim of reducing noise in the model. Marital status was categorized into

three groups; 'Never married' for all the singles, 'currently married' for those living together and 'Ever married' for all those that were widowed, separated or divorced. Presence of symptoms was dichotomized into Yes or No for presence or absence of symptoms respectively and the CD4 counts per ml were also dichotomized into below and above 250 because it was the basis for commencing ART at the clinic where the study was conducted. Table 2 below shows the categorization of study variables in relation to their references during the analysis and the variable types.

Table 2: showing the categorization of variables and variable type

Variables	Variable categorization	Variable type
Age	20-24(ref)	Categorical
	25-29	
	30-34	
	35-39	
	>=40	
Education	Pre-secondary (reference)	Categorical
	Secondary	
	Post secondary	
Marital status	Never married (ref)	Categorical
	Currently married	
	Ever married	
Religion	None (ref)	Categorical
	Catholics	
	Protestant s	
	Pentecostals	
	Others	
ART status	Experienced (ref)	Dichotomous
	Naïve	
Time Lived with HIV	NA	Continuous
Presence of Symptoms	Yes (reference)	Dichotomous
	No	
CD4 counts	>=250 (ref)	Dichotomous
	<250	
Occupation	Currently not employed (ref)	Dichotomous
	Currently employed	

Footnote, Occupation was dichotomized because of the fewer numbers in the smaller categories

5.8.3 Statistical analysis

5.8.3.1 Preliminary analysis

This included both descriptive and univariate analysis. We mainly looked at a comparison between ART-naïve and ART-experienced participants in terms of their frequency distributions of baseline characteristics for categorical variables. We also assessed their mean, median, mode, range and standard deviation for continuous variables.

5.8.3.2 Reliability, convergent and discriminant validity of the tool.

The cronbach's alpha coefficient was determined to a measure for reliability of the items for each dimension using the cronbach's formula (Cronbach et al. 1951) below.

$$\alpha = \frac{K}{K-1} \left(1 - \frac{\sum SD^2_i}{SD^2_t} \right)$$

Where:

K = Number of items for a dimension

SD²_i = Variance of scores on individual items

SD²_t = Variance of scores for all items total

Contrary to convergent validity, a successful evaluation of discriminant validity shows that a test of a dimension is not highly correlated with other tests designed to measure theoretically different dimensions. To demonstrate convergent and discriminant validity, we tested the intercorrelations among the scales for the tool. The acceptable values for intercorrelation between the scales should be between

0.4 and 0.8(Scott-Lennox et al. 1999). Attenuation of the inter-correlation was to rid the weakening effects of measurement errors using (Spearman 1904);

$$\frac{r_{xy}}{\sqrt{r_{xx} \cdot r_{yy}}}$$

Where

r_{xy} is correlation between x and y

r_{xx} is the reliability of x, and

r_{yy} is the reliability of y.

x and y are any two dimensions measured by the MOS-HIV tool.

5.8.3.3 A comparison of Health-Related Quality of Life Scores

The items of the MOS-HIV tool are measured on a likert scale, designed to elicit self-reported ratings of patient functioning and wellbeing.

Missing values were initially dealt with to compare scores of HRQoL dimensions between ART-experienced and ART- Naïve individuals using the MOS-HIV tool.

A missing value was given for a scale if over half of its items were not answered by the respondent. However the average score on the answered items in the dimension/scale was to replace the missing value(s) if less than half of the items were unanswered (McDowell, 2006).

Some items of the tool were coded such that a higher score indicated high health status(Poor 1, Fair 2, Good 3, Very good 4, Excellent 5) while as others, a higher score indicated low health status (Excellent 1, Very good 2, Good 3, Fair 4, Poor

5) At analysis, the later were reverse coded in a way that a higher score indicated high health status. The scale scoring was formed by aggregating item values for the same scale or dimension; Item 1 and 11a-11d were summed to form a 5-item general health perception scale scores, Items 4a-4f to form a 6-item physical function scale scores, Item 5 was summed to item 6 to form role function scale scores, Items 10a-10d formed the 4-item cognitive function scale scores, Item 2 was summed to item 3 to form Pain scale scores, Items 8a-8e formed the 5-item mental health scale scores, Items 9a-9d formed the 4-item vitality/energy/fatigue scale scores and Items 9e-9h formed the 4-item health distress scale scores. All one item scale scores were not altered such as item 7 for social function, Item 12 for quality of life and item 13 for health transition.

The raw scale scores were then linearly transformed into a 0-100 scale to permit comparison across the different scales using the formula below;

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

Where:

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

Max= maximum possible raw scale value if all items are answered

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

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

This transformation facilitated a ready interpretation and comparison between tools, dimensions and studies given that the primary outcome is continuous (Sloan et al. 1998).

Factor analysis of the MOS-HIV scale scores with a two-factor oblique rotation was used to estimate the physical and mental health factor scoring coefficients (weights). PHS scores were then constructed by multiplying each Z-dimension or scale score by its respective physical factor scoring coefficient and summing their products. Similarly, MHS was obtained by multiplying each Z-dimension or scale score by its respective mental factor score coefficient and summing their products. The component summary scores (Physical and mental health summary scores) were then standardized so that each had a mean of 50 and a standard deviation of 10 (Ware JE et al. 1994; Wu. 1999).

The differences between ART-experienced and ART-naïve participants based on the 11 dimensions of health-related quality of life were compared using *t*-tests. This was simply because we assessed the difference between mean scores of two independent groups.

A comparison of ART-experienced and ART-naïve participants on the basis of the basis of baseline characteristics such as sex, age groups, marital status

5.8.3.4 Factors associated with Health-Related Quality of Life

Multiple linear regression analysis was used to build a parsimonious model that could describe the factors associated with HRQoL among HIV-infected adults and to explain the maximum proportion of variability. The following steps were followed;-

1. The assumptions regarding linear regression were considered and the data prior to modelling examined.
2. Autocorrelation was tested

3. A model was created while testing for assumption validation and the adjusted R squared

4. Multi-co linearity was tested

5. Model questions for both the physical and mental health summary component.

In considering the assumptions regarding linear regression, missing values were assessed by tabulation and running a distribution of continuous independent variables with each outcome variable (PHS and MHS) using scatter plots. Having transformed the two outcome variables into a 0-100 score (continuous), linear regression was a suitable method for analysis. The linearity and independence of the explanatory variables was assessed by conducting simple linear regression. This enabled the short listing of variables for multivariable analysis. A *p*-value initially set at 0.3 to avoid exclusion of important variables was used. Bivariate analysis was not done simply because the outcome variables were continuous and a critical value for either good or poor PHS and MHS could not be established from literature. We also used a graphical diagnostic test (the standardized normal probability plot) was also used to assess normality of the PHS and MHS.

There was need to ensure a low correlation between any selected pair of continuous independent variables for instance age as these would affect the stability of the model. This was achieved by determining the correlation coefficient of the pair of continuous variables prior to modelling.

In creating a parsimonious model, a stepwise selection (both backward and forward variable selection) was used and a series of at least four (4), putting into consideration the principles of logical model building. All variables which were

significant at simple linear regression (above) were included into the model. The 95% confidence intervals and P-values < 0.05 of the regression coefficients were assessed simultaneously.

The models were stratified on basis of ART status (ART-naive and ART-experienced) for PHS and MHS to establish the effect of ART on the outcome variables.

An estimation of the variance inflation factor (VIF) was determined to test for multi-co linearity. After an iterative logic model building, a multiple linear regression for both physical and mental health summary score was developed

$$E [\mathbf{PHS} | \mathbf{x}] = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \dots + \beta_n x_n$$

$$E [\mathbf{MHS} | \mathbf{x}] = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \dots + \beta_n x_n$$

Where $x_1, x_2, x_3, \dots, x_n$ are independent variables/ predictor variables

The regression coefficients for each of the predictor variables indicates the amount of change one would expect in the outcome variable with a one-unit change in the value of that predictor variable, given that all other predictor variables in the model are held constant. It can also be the expected average change in the outcome variable for two adults that differ by a one-unit change in the value of that predictor variable, given that all other predictor variables in the model are held constant.

5.9 Ethical considerations

Ethical clearance to carry out the study was sought from Uganda National Council of Science and Technology (UNCST) through Makerere University School of Public Health Higher Degrees Research and Ethics Committee. Permission to collect data was also obtained from head of research departments, JCRC.

There were no tangible benefits such as gifts and money from the study to the participants but the information given was presumed to be necessary in improving the planning activities by the policy makers and clinicians in the provision of care. Cotrimoxazole and Dapsone were dispensed to the participants as they were out of stock at the facility. This research would cause a negligible risk, because there was no foreseeable risk of harm or discomfort that would impact on the participants other than the time spent being interviewed.

Written informed consent was also sought from all respondents before participation in the study. Confidentiality was assured throughout the study by use of code numbers instead of individual names for identification of participants and access to data collected was restricted to only the principle investigator.

CHAPTER 6: RESULTS

6.1 Socio-Demographic Characteristics the study population

A sample of 187 adults greater or equal to 20 years of age with a mean age of 37.6 years, standard deviation (SD) 9.55 and a medium age of 38years (IQR: 31-43) was interviewed for the overall response rate of 93.5%. One person did not respond to the study thus a reduction to 187 participants. This sample was obtained from the sampling frame by simple random sampling. Findings from this cross sectional study conducted at JCRC in December 2009 included 97(51.9%) ART-experienced and 90(48.1%) ART-Naïve adults among which, 132 (70.6%) were females and 55(29.4%) were males.

Respondents who had never married were 48(25.7%), currently married were 79(42.3%) and those who had been previously married were 60(32%). In the sample, 69(36.4%) had pre-secondary education, 85(45.5%) had secondary education and 33(17.6%) had post secondary education. Other demographic characteristics are summarized in the Table 3 below.

Table 3: Baseline demographic characteristics of respondents

Total Population N =187	(n)	(%)
Sex		
Male	55	29.4
Female	132	70.6
Age		
20-24	12	6.4
25-29	25	13.4
30-34	38	20.3
35-39	35	18.7
>=40	77	41.2
Religion		
None	13	6.9
Catholics	82	43.9
Protestants	67	35.8
Pentecostals	5	2.7
Muslims	19	10.2
Others	1	0.5
Education		
Pre-secondary	69	36.9
Secondary	85	45.5
Post-secondary	33	17.6
Marital status		
Never married	48	25.7
Currently married	79	42.3
Ever married	60	32.0
Occupation		
Unemployed	110	58.8
Employed	77	41.2
Presence of Symptoms		
Yes	117	62.6
No	70	37.4

Table 4 shows the comparison of baseline characteristics for both ART-Naïve and ART-Experienced among study participants. Variables such as age groups, education, marital status and occupation were comparable while as sex, CD4 counts and presence symptoms were not.

Results show that in both ART-experienced and ART-naïve participants, there were more females than males, 78.35% and 62.22% respectively. However, the proportion of females was significantly higher among the experienced than Naïve ($p = 0.016$). Majority of the participants were 40 years and older. There were no significant differences by age distribution.

The proportions of the participants who had attained pre secondary and those with secondary education between ART-experienced and ART-naïve were comparable. However, only 10% of the ART-naïve participants compared to 24% of ART-experienced had attained post secondary education.

Result show that among the 9% of ART-naïve participants had their CD4 counts less than 250 cells per milliliter while as 45.36% of ART-experienced had their CD4 counts less than 250 cells per milliliter.

In both groups (ART-experienced and ART-naïve), majority of the participants were unemployed; 61.86% for ART-experienced and 55.56% for ART-naïve with no statistical difference.

Table 4: Comparison between ART-Naïve and ART-Experienced

	<u>ART-Experienced</u> n = 97(%)	<u>ART-Naïve</u> n = 90(%)	P-value
Sex			
Male	21 (21.65)	34(37.78)	0.016
Females	76(78.35)	56(62.22)	
Age			
20-24	5(5.15)	7(7.78)	0.050
25-29	8 (8.25)	17(18.89)	
30-34	15(15.46)	23(25.56)	
35-39	20(20.62)	15 (16.67)	
>=40	49 (50.52)	28(31.11)	
Education			
Pre-secondary	33(34.02)	36(40.00)	0.300
Secondary	40(41.24)	45(50.00)	
Post-secondary	24(24.74)	9(10.00)	
Marital status			
Never married	20(20.62)	28(31.11)	0.259
Currently married	44 (45.36)	35(38.89)	
Ever married	33 (34.02)	27 (30.00)	
CD4 counts			
>=250	53 (54.64)	82(91.11)	0.000
<250	44(45.36)	08(8.89)	
Presence of symptoms			
Yes	53 (54.64)	64(71.11)	0.020
No	44(45.36)	26(28.89)	
Occupation			
Unemployed	60 (61.86)	50(55.56)	0.382
Employed	37(38.14)	40(44.44)	

6.2 Reliability, Convergent and Discriminant Validity of the adopted MOS-HIV tool in assessing HRQoL in an urban HIV clinic

Usually cronbach's α coefficient with value of greater than or equal to 0.7 indicates adequate reliability. In the analysis all the multi-item scales had a cronbach's α coefficient of greater than 0.80 (between 0.835 and 0.8979) as indicated diagonally in Table 6 below. This demonstrated that the translated and adopted MOS-HIV has good reliability. The inter-correlations between HRQoL dimensions in Table 5 were attenuated to do away with the weakening effects of measurement errors. In assessment of discriminant and convergent validity of the adopted and translated MOS-HIV tool attenuated inter-correlations less than 0.85 shows that discriminant validity likely exists between the two scales. This implies that the two scales measure theoretically different constructs. On the other hand a result greater than 0.85, shows that the two constructs overlap greatly and they are likely measuring the same construct. Therefore, discriminant validity can't be claimed between them. Table 5 indicates that most of the inter-correlations between any two scales were less than 0.85, with the exception of mental health and vitality dimensions which demonstrated some degree of overlap by an inter-correlation of 0.877. This indicates that the tool has a good discriminant and convergent validity

Table 5: Attenuated inter-correlations between HRQoL dimensions

A.I	GH	PF	CF	Pain	MH	VT	HD	RF
GH	(0.898)							
PF	0.677	(0.887)						
CF	0.468	0.666	(0.805)					
Pain	0.733	0.744	0.484	(0.805)				
MH	0.612	0.673	0.615	0.645	(0.825)			
VT	0.726	0.757	0.603	0.766	0.877	(0.835)		
HD	0.651	0.737	0.691	0.680	0.789	0.831	(0.883)	
RF	0.629	0.784	0.456	0.687	0.561	0.662	0.605	(0.859)

AI- Attenuated inter-correlation

N.B The internal consistency reliability or cronbach's alpha coefficient are reported diagonally in brackets for the dimensions/scales.

6.3 Comparison of Scores of HRQoL Scales between ART-experienced and ART-Naïve adults attending an Urban HIV Clinic

Results in Table 5 below show a significant difference in general health (difference [diff]: 27.4, 19.4-35.4, $p < 0.001$) quality of life (difference [diff]: 25.9, 18.5-33.2, $p < 0.001$) and health transition (difference [diff]: 25.7, 18.5-33.3, $p < 0.001$). There was also a significant difference of 2.8; 95% C.I 0.6- 5.0; $p < 0.012$) and 4.9; 95% C.I 2.1-7.7; $p = 0.005$ in the physical and mental health components of HRQoL respectively for ART experienced and ART naïve adults.

There were no significant differences in other HRQoL dimensions like pain, physical functioning, role functioning, social functioning, mental functioning,

vitality, health distress, and cognitive functioning in both ART experienced and ART naive adults attending an urban HIV treatment clinic in Kampala.

Table 6: Mean differences between HRQoL dimensional scores

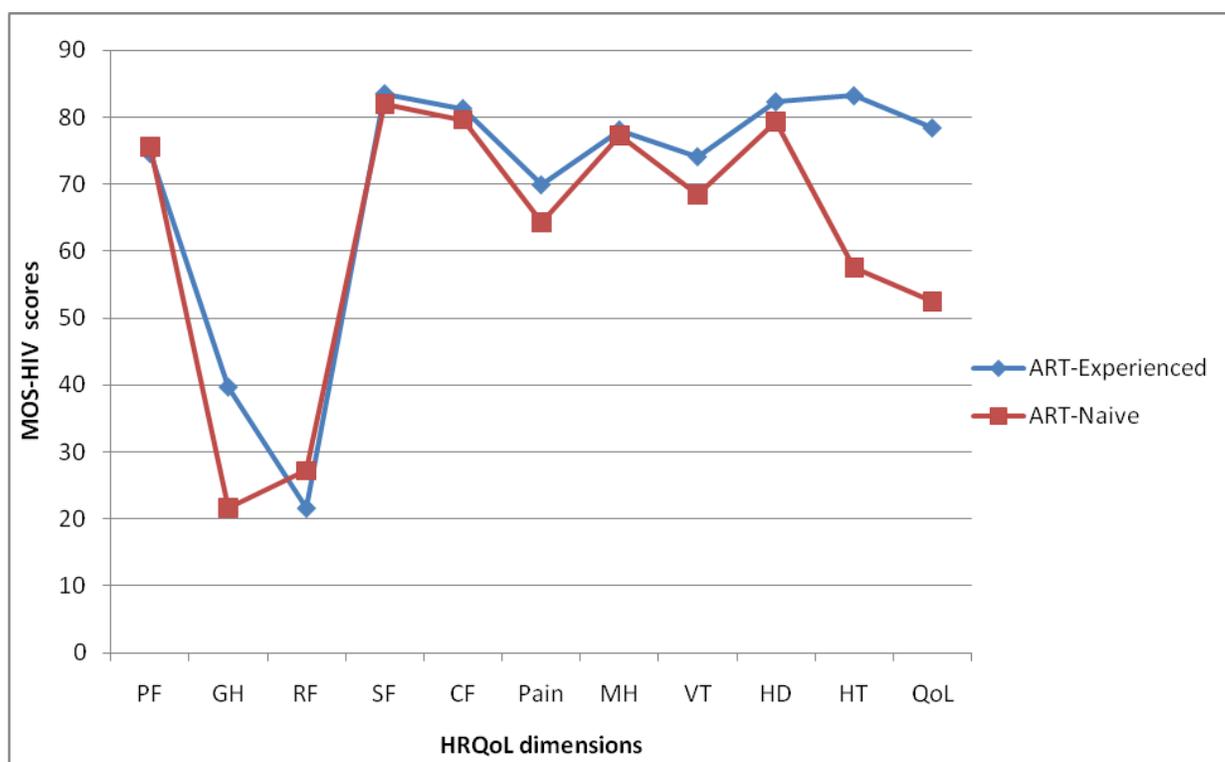
HRQoL dimensions	D	95% C.I	p-value
General health	27.4	(19.4, 35.4)	<0.001
Pain	5.6	(-2.6, 13.7)	0.180
Physical functioning	2.2	(-5.6, 9.9)	0.580
Role functioning	-5.6	(-17.2, 6.1)	0.346
Social functioning	1.7	(-5.2, 8.59)	0.624
Mental	0.8	(-4.4, 5.9)	0.768
Vitality/energy	5.6	(-0.5, 11.7)	0.007
Distress	3.0	(-2.3, 8.2)	0.262
Cognitive	1.8	(-3.4, 7.0)	0.500
Qol	25.9	(18.5, 33.2)	<0.001
Health transition	25.7	(18.2, 33.3)	<0.001
Physical health summary	2.8	(0.6, 5.0)	0.012
Mental health summary	4.9	(2.1, 7.7)	0.005

D- Mean differences for ART-experienced and ART-naïve adults.

Figure 2 below show the variation in the HRQoL mean scores across the various HRQoL dimensions between ART-experienced and ART-Naïve. The graph shows that ART-experienced adults had higher HRQoL scores than ART-naïve adults. The highest scores among ART-experienced adults were observed in Social functioning, Health transition and lowest score was observed in role functioning.

The highest scores among ART-naïve adults were observed in the social functioning dimension and lowest score was observed in role functioning dimensions. There were significant differences in the General health, Health transition and Quality of life dimension as indicated in the graph and Table 6 above.

Figure 2: A graph showing HRQoL mean scores among HIV-infected adults



6.4 Factors associated with HRQoL among HIV infected adults

The adjusted R-squared values were between 0.33 and 0.37, meaning that approximately 33% - 37% of the variability of HRQoL summary components was accounted for by the variables in the models

Table 7 below shows crude and adjusted linear regression coefficients for the PHS scores in both ART-experienced and ART-naïve adults. There was an increase of 0.52 scores in the PHS among ART-naïve adults for every year lived, assuming that all other variables in the model is held constant. In other words, an ART-naïve adult who had lived for 5 years would be expected to have a PHS score of approximately 3 higher than the value when first measured, assuming all other variables in the model are held constant.

After controlling other variables, the expected average difference in the PHS score between an ART-Experienced patient who had attained post secondary education and one with pre secondary education was 4.78 and this was not so different from the crude coefficient of 5.66.

The expected average difference in the PHS score between an ART-Naive patient who had employment and one who did not have employment was 4.01 assuming that all other variables in the model are held constant. Similarly, the adjusted coefficient was not so different from the crude coefficient indicating some degree of consistency in the model.

The model shows that the expected average difference in the PHS between an ART-Naïve patient who did not present with symptoms and one who presented with symptoms was 6.5. It further shows that the expected average difference in the PHS between an ART-Experienced patient who did not present with

symptoms and one who presented with symptoms was 5.94 holding other variables constant.

Table 7: Crude and adjusted linear regression coefficients for PHS scores

	<u>ART- Naïve</u>		<u>ART-Experienced</u>	
	Crude	Adjusted	Crude	adjusted
Age				
20-24	1		1	
25-29	0.96	1.73	-3.37	-0.55
30-34	-2.09	-2.29	-7.00	-3.44
35-39	1.48	2.54	0.66	1.67
>=40	-2.91	-2.12	-3.64	-0.47
Time lived with HIV	0.52	0.52*	-0.34	0.28
Education				
Pre-secondary	1		1	
Secondary	3.11	0.59	0.15	-0.38
Post secondary	2.15	0.77	5.66**	4.78*
Employed				
Not employed	1		1	
Employed	4.30**	4.01***	-1.44	-1.11
Presence of symptoms				
Yes	1		1	
No	7.96***	6.5 ***	5.94***	6.77***

*** p<0.001

** 0.001<p<0.01

* 0.01<p<0.05

Coef- regression coefficients

Table 8 below shows crude and adjusted linear regression coefficients for the MHS scores in both ART-experienced and ART-naïve adults. A bivariate analysis of time lived with the HIV and MHS scores among ART-experienced shows significant increase of 0.64 per year lived. However, the changes when other variables are held constant.

The MHS model shows the expected average difference in the MHS score between an ART-Experienced patient who had attained post secondary education and one with pre secondary education was 5.42 assuming that all other variables in the model are held constant. This is consistent with results from the bivariate analysis on the other hand the coefficients of an ART-naïve adult (4.34) are statistically insignificant upon adjustment for other variables.

The expected average difference in the MHS score between an ART-Naive patient who had employment and one who did not have employment was 4.47 assuming that all other variables in the model are held constant.

Further still, the model shows that the expected average difference in the MHS between an ART-Naïve patient who did not present with symptoms and one who presented with symptoms was 8.09. It also shows that the expected average difference in the MHS between an ART-Experienced patient who did not present with symptoms and one who presented with symptoms was 8.44 holding other variables constant. These results to some extent are consistent with those in the bivariate analysis.

Table 8: Crude and adjusted linear regression coefficients for MHS scores

	<u>ART- Naïve</u>		<u>ART-Experienced</u>	
	Crude	Adjusted	Crude	Adjusted
Age				
20-24	1		1	
25-29	4.01	5.47	-6.72	-2.16
30-34	3.70	4.12	-7.20	-1.07
35-39	7.06	9.04	-0.05	1.96
>=40	1.86	4.37	-2.14	2.60
Time lived with HIV	-0.304	0.17	0.64*	0.53
Education				
Pre-secondary	1		1	
Secondary	4.34*	2.11	1.48	1.66
Post secondary	3.21	2.43	5.56*	5.42*
Employed				
Not employed	1		1	
Employed	5.13**	4.47*	-3.56	-3.83
Presence of symptoms				
Yes	1		1	
No	9.61***	8.09 ***	8.857***	8.44***

*** p<0.001

** 0.001<p<0.01

* 0.01<p<0.05

Coef- regression coefficients

CHAPTER 7: DISCUSSION

7.1 Introduction

This section interprets the results, how our results relate to findings from other research and the limitations of this study. The study shows that the MOS-HIV is reliable and valid. Overall ART-experienced adults had higher HRQoL scores than ART-naïve adults and that there were significant association in a number of factors with HRQoL.

7.2 Discussion of findings and relation to other research

In Table 4, the high proportion of female in both the ART-experienced and ART-naïve participants further indicates that women have better health seeking behaviors than males. This may also be an indicator in the level of HIV susceptibility and prevalence levels of HIV between males and females. A high proportion of participants (91.11%) with greater or equal to 250 cells per milliliter among ART-naïve were indicative of early infection or proper management of patients on prophylactic treatment. However, the proportions of participants with CD4 counts less than 250 or greater than 250 is approximately equally distributed, this may indicate treatment failure or recent recruits of patients on ART. In both ART-experienced and ART-naïve patients, it's not clear why there were a significant number of participants who presented with disease symptoms in the study.

In table 5, of the cronbach's alpha coefficients were greater than 0.8 indicating that the degree of consistency is largely satisfactory (Bland et al. 1997). These results are consistent with findings from studies conducted in rural settings in

Uganda (Mast et al. 2004; Stangl et al. 2007) and those in the developed setting (Cowdery et al. 2002; Schifano et al. 2003).

An attenuated intercorrelation less than 0.85 tells us that discriminant validity likely exists between the two scales meaning the two scales measure theoretically different constructs. Conversely, a result greater than 0.85, tells us that the two constructs overlap greatly and that they are likely to be measuring the same construct. Therefore, we cannot claim discriminant validity between them (Scott-Lennox et al. 1999).

A tool with convergent validity is able to provide convergence when used to measure similar constructs while a tool with discriminant validity should show differences between different constructs. Most of the attenuated intercorrelation coefficients were less than 0.8 showing evidence of discriminant validity in an urban setting in Uganda. However there was a small degree of overlap observed in the mental and vitality scale with an attenuated intercorrelation coefficient of 0.877. This could likely be due to the relationship between an individual's mental status and liveliness and may suggest further assessment and restructuring of the mental and vitality items. Overall, our findings were consistent with (Schifano et al. 2003; Shahriar et al. 2003); in that there showed evidence of validity. In the treatment of HIV-infected patients that measuring the mental status of patients may see a challenge but with presence of such tools, this task is made easier. If the mental status can be assessed, designing interventions to address low mental health summary scores thus improving the quality of services health care providers avail to their clients.

The graph in figure 2 demonstrates significant differences in general health, quality of life scores, and health transition in the two groups much as there were relative similar HRQoL scores in the other number of dimensions. Generally ART-Naïve adults have lower scores probably because of stigma, denial and self condemnation in the first years of infection as compared to the ART-Experienced adults. The low HRQoL scores among ART-naïve adults further suggests of routine visits instead of clinicians seeing these patients on a monthly basis. These visits should be scheduled at least twice in a month. Most of the HIV treatment centres have support groups but studies need to be conducted to answer questions regarding the effectiveness of their strategies and the kind of HIV infected people who actually take part in these groups especially in the urban setting. For instance, results show low proportions of men who seek care as compared to females just as it has been reported by other studies. This window of opportunity is not fully utilized and yet social groups are believed to be one of the ways to improve quality of life among HIV infected adults (Bajunirwe et al. 2009). Other channels may also be utilized to improve HRQoL among ART-naïve adults such as involvement of family members in the management of these patients, continuously training of counselors, routine nutritional teachings and so on.

The time lived with HIV in the PHS model shows borderline significance in both the bivariate and regression analysis among ART-naïve adults. This value may not be reliable given that the study was not longitudinal. In the both PHS and MHS model, attainment of a post secondary level of education is consistently associated with HRQoL in both the bivariate and regression analysis among ART-experienced adults. The coefficients for employment status in both the bivariate

and regression analysis are also consistent among ART-naïve adults. A similar observation is made for presence of symptoms among both ART-experienced and ART-naïve adults in the two models. This implies that attainment of post secondary education among ART-experienced, employment status among ART-naïve and presence of symptoms among both ART-experienced and ART-naïve adults are neither effect modifiers nor confounders.

7.3 Study Limitations

The study utilized quantitative methods and not qualitative methods. This implies that a deeper understanding of the factors associated with lower HRQoL in HIV-infected adults was not obtained as methods like focus grouped discussions and key informant interviews were not used. Probably this is why the models only explain 37% of the variation in the two component health summary scores.

This study had a limitation that Health-related quality of life data is to a large extent subjective. A number of factors are likely to influence the participant reported data given the prevailing circumstances. For instance, the loss of a loved one can cause depression and this would impact on HRQoL of an individual. Hence some degree of information bias specifically reporting bias is likely to be encountered. The missing values for some items and calculated averages may also impact on our outcome measures. Randomization to some extent makes the two groups comparable as a way of minimizing such effects. Bias was also reduced by carefully paying attention to the various stages of the study.

CHAPTER 8: CONCLUSIONS

1. The MOS-HIV tool is a reliable, valid and suitable for measuring Health-related quality of life among HIV-infected adults in both rural and urban resource limited setting in Uganda.
2. ART is associated with high HRQoL scores among HIV infected adults attending an urban clinic.
3. Low levels of education among ART experienced adults, employment status among ART-naïve adults and presences of symptom among HIV infected adults are associated with low Health-related quality of life scores.

CHAPTER 9: RECOMMENDATIONS

1. This study recommends that the Ministry of Health adopts measuring of HRQoL among people living with HIV/AIDS and that prior to this, health care providers be trained to use MOS-HIV.
2. Health care providers are encouraged to measure HRQoL among HIV infected adults in routine HIV care. This would facilitate them to provide holistic care and improves the quality of services provided by physicians. This is partly what Health Services Research is about.
3. Health care providers encourage their patients to engage in income generating activities especially the ART-naïve adults much as they also need to endeavor and address all patients' disease symptoms.
4. Further research pertaining the reliability and validity of the MOS-HIV tool be conducted among children and adolescents.

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APPENDICES

Appendix 1: English version of the culturally adopted MOS-HIV tool

HEALTH RELATED QUALITY OF LIFE

I am from Makerere University School of Public Health and we are conducting a study to measure the health related quality of life among ART experienced and ART naïve patients in Kampala district. The information from this study will facilitate clinicians to improve on the provision of care and policy makers in their planning activities . Your participation in this study is voluntary and all the data provided will be treated as confidential and anonymous. You have a right to withdraw from the study anytime. Thank you

Date_____

Questionnaire number_____

Name of Interviewer_____

ART Experienced_____ ART Naïve _____

Patient Identifiers

P-Number

Clinic Number

BASELINE CHARACTERISTICS

1. Sex____|____| {Qb1}
2. What is your age in years? ____ |____| {Qb2}
3. Do you have a religious belief?
 1. Yes
 2. No|____| {Qb3}

4. What is the highest level of education you attained?
 - 1.No education
 - 2.Primary
 - 3.Secondary
 - 4.Tertiary University
 - 5.Others|___| {Qb4}

5. Have you ever disclosed to you partner about your HIV status
 1. Yes
 2. No |___| {Qb5}

6. From which part of Uganda do you come from?
 1. Eastern
 2. Western
 3. Northern
 4. Southern |___| {Qb6}

7. Do you have a regular source of income or are you employed?
 1. Yes
 2. No |___| {Qb7}

8. What is your marital status?
 1. Married
 2. Living together
 3. Single
 4. widowed
 5. Divorced |___| {Qb8}

9. How long have been with the HIV? _____|____| {Qb9}

10. How long have you been on ART? ____|____| {Qb10}

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

[INTERVIEWER: Q1_ Q14 ARE PROMPTED]

1. In general, would you say your health is:

Excellent. . .1

Very good. .2

Good . . .3

Fair. . . 4

Poor. . .5 _____|____| {Q1}

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

None. . .1

Mild. . .2

Moderate. . 3

Severe. . .4

Very Severe ..5 _____|____| {Q2}

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

Not at all. . .1

little bit. . .2

Moderately. . .3

Quite a bit. . .4

Extremely . .5 _____|____| {Q3}

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

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

a. The kinds or amounts of vigorous activities you can do like, digging, fetching water from a well, carrying a big bunch of matooke, splitting firewood.

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4A}

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

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4B}

c. Walking up hill, climbing stairs.

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4C}

d. Bending, lifting light objects or kneeling.

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4D}

e. Walking a distance, like the length of a football pitch, about 100 meters.

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4E}

f. Eating, dressing, bathing or using the latrine.

1. YES, Limited a Lot
2. YES, Limited a Little
3. NO, Not Limited at All |___|{Q4F}

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

Yes. . .1

No. . .2 |___|{Q5}

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

Yes. . .1

No. . .2 |___| {Q6}

For each of the following questions, please tell me the answer that comes closest to the way you have been feeling in the past thirty days.

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

7. How much of the time, during the past thirty days, has your health limited your social activities, like visiting with friends or family?

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___| {Q7}

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

a. Have you been a very nervous person?

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___|{Q8A}

b. Have you felt calm and peaceful?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___|{Q8B}

c. Have you felt depressed?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___|{Q8C}

d. Have you been a happy person?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___|{Q8D}

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

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|____|{Q8E}

9. How often during the past thirty days:

a. Did you feel full of life and energy?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|____|{Q9A}

b. Did you feel totally without energy?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|____|{Q9B}

c. Did you feel tired?

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___|{Q9C}

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

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___|{Q9D}

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

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___| {Q9E}

f. Were you discouraged by your health problems?

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___|{Q9F}

g. Did you feel despair over your health problems?

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___| {Q9G}

h. Were you afraid because of your health?

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___|{Q9H}

10. How often during the past thirty days:

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

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___| {Q10A}

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

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___|{Q10B}

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

- 1.All of the Time
- 2.Most of the Time
- 3.A Good Bit of the Time
- 4.Some of the Time
- 5.A Little of the Time
6. None of the Time|___|{Q10C}

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

1.All of the Time

2.Most of the Time

3.A Good Bit of the Time

4.Some of the Time

5.A Little of the Time

6. None of the Time|___| {Q10D}

11. Please tell me the answer that comes closest to describing whether the following statement is

True or false for you. The answers are: [INTERVIEWER: READ RESPONSES BELOW].

1. Definitely True

2. Mostly True

3. Don't Know

4. Mostly False

5. Definitely False

a. You are somewhat ill.

1. Definitely True

2. Mostly True

3. Don't Know

4. Mostly False

5. Definitely False |___|{Q11A}

b. You are as healthy as other people you know.

1. Definitely True
2. Mostly True
3. Don't Know
4. Mostly False
5. Definitely False |___|{Q11B}

c. Your health is excellent.

1. Definitely True
2. Mostly True
3. Don't Know
4. Mostly False
5. Definitely False |___|{Q11C}

d. You have been feeling bad recently.

1. Definitely True
2. Mostly True
3. Don't Know
4. Mostly False
5. Definitely False |___| {Q11D}

12. How has the quality of your life been during the past thirty days? That is, how have things been going for you? Very well; could hardly

Better. . .1

Pretty good. . .2

Good and bad parts about equal. . .3

Pretty bad. . .4

Very bad; could hardly

be worse. . .5 |___| {Q12}

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

Much better. . .1

A little better. . .2

About the same. . .3

A little worse. . .4

Much worse. . .5|___| {Q13}

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

1) Yes

2) No |___| {Q14}

If yes, which one

From medical record:

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

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

1) > 250

2) < 250 |___| {Q15}

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

1) > 10,000 copies/ml

2) < 10,000 copies/ml |___| {Q16}

THANK YOU VERY MUCH FOR YOUR PRECIOUS TIME

Appendix II: Luganda version of the culturally adopted MOS-HIV tool

1. Okutwarila awamu, wandigambye nti embeera y' obulamu bwo:

- 1 .Nungi nyo nyo
- 2 .Nungi nyo
- 3 .Nungi
- 4 .Bwetyo bwetyo
5. Mbi {Q1}

2. Okutwalira awamu ofunye okulumizibwa mumubiri kwenkanawa mu naku amakumi asatu eziyise?

1. Tewali
2. Kutono ddala
3. Kutono
4. Kwakigero
5. Kwamaanyi
6. Kwamaanyi ddala {Q2}

3. Munaku amakumi asatu eziyise okulumizibwa kutaataganyizza (kwataataganya kyenkanawa emirimu gyo egyabulijjo, nga otwalidemu egyawaka n'egitali gyawaka)?

- 1.Tewali
2. Katono ddala
3. Kwakigero
4. Nyo
5. Nyo ddala {Q3}

4. Ebibuuzo ebiddako bikwata ku bintu omuntu byayinza okukola mulunaku. Embeera y'obulaamu bwo kati eziyeeza/ekendeeza kyenkanawa munkola yo eyemirimu/ebintu bino wamanga?

a. Emirimu/ebintu by'okola nga byetaagisa amaanyi amangi gamba nga okulima, okukima amazzi kuluzzi, okwetikka enkota y'etooke ennene, okwasa enku

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono {Q4A}

b. Emirimu/ebintu by'okola nga byetaagisa amaanyi agekigero gamba nga okwoza engoye, okujjulula ekidomolera kyamazzi oba ekinywa ky'enku okuva mukifo ekimu okukissa mu kilala.

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono |__|{Q4B}

c. Okulinya akasozi / amadaala

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono |__|{Q4C}

d. Okufukamira, okukutama/okweweta oba okusitula ebintu ebiwewuka.

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono |__|{Q4D}

e. Okutambula akabanga akenkana nga obuwanvu bw'ekisaawe ky'omupiira.

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono |__|{Q4E}

f. Okulya, okwambala, okunaaba, oba okugenda mu kabuyonjo.

1. Eziyiza nyo
2. Eziyiza Katono
3. Teziyiza n'akatono |__|{Q4F}

5. Embeera y'obulaamu bwo ekuziyiza/ekugaana okugenda ku mirimu gyo oba okukola emirimu egy'awaka, oba okugenda ku somero?

1. Yee
2. Nedda |__|{Q5}

6. Olw' embeera y'obulamu bwo, wakendeezako ku nkola y' emirimu gyo ng'otaddeko n' egyawaka oba n' egyokusomero?

1. Yee
2. Nedda |__|{Q6}

Kubili kibuzo wamanga nsaba ombulire embeera esinga okwefananyiriza kweyo gyobaddemu mu naku amamkumi asatu eziyise

7. Mu naku amakumi asatu eziyise embeera y'obulamu bwo eziyizizza kyenkanawa kubudde/kubiseera by'okolagana n'abantu, gamba nga okukyaalira abemikwano

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q7}

8. Mu naku amakumi asatu eziyise embeera y'obulamu bwo eziyizizza kyenkanawa kubudde/kubiseera by'okolagana n'abantu, gamba nga okukyaalira abemikwano

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali

a. By' obadde nga owulira toterera /okutyemukirira?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q8A}

b. By' obadde nga owulira emirembe?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q8B}

c. By' obadde nga owulira enaku enyingi/enyiike?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q8C}

d. By' obadde nga olimusanyufu?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q8D}

e. By' obadde nga owulira enaku nyingi / enyiike nga tewali kisobola kukusanyusa?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q8E}

9. Mu naku amakumi asatu eziyise, ebisera byenkana wa?

a. Wewawulirira nga ojjudde obulamu n'aamanyi?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9A}

b. Wewawulirira ng'ogwereddemu ddala aamanyi?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9B}

c. Wewawulirira ng'okooye?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9C}

d. Wewabeerera nga olina amaanyi agakola ebintu byewayagala okukola?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9D}

e. Wewawulirira nga ozitooweredwa olwembeera y'obulamu bwo?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9E}

f. Wewabereera nga embeera y'obulamu bwo ekumazeemu amaanyi?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9F}

g. Wewawulirira nga oweddemu essuubi olw'embeera y'obulamu bwo?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9G}

h. Wewabereera nga embeera y'obulamu bwo ekutiisizza?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q9H}

10. Mu naku amakumi asatu eziyise, ebisera byenkana wa:

a. Byewali nga olina obuzibu mu kulowooza n'okusalaawo gamba nga okulola entegeka oba okuyiga ebintu ebipya?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q10A}

b. Byewali nga werabira/werabidde ebibaddewo mu bisera ebitono enyo emabega, gamba nga w'otadde ebintu, oba b'olangaanyiza?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q10B}

c. Byewali nga olina obuzibu mu kusaayo omwoyo okumala ebbanga ku kintu kyona ekyali kikolebwa?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q10C}

d. Byewali nga olina obuzibu okukola emirimu egyali gyetagisa okulowooza n'okusaayo enyo omwoyo?

1. Ebisera byona
2. Ebisera ebisinga obungi
3. Ebisera bingi
4. Ebisera bitono
5. Ebisera bitono nyo
6. Tewali {Q10D}

11. Nsaba ombulire kiki ekisinga okunyonyola ebikukwatako kubino wamanga oba bituufu oba bikyaamu. Njagala onziremu oba

a. Oli mulwaddelwadde

1. Kituufu nyo
2. Kituufu
3. Tomanyi
4. Sikituufu
5. Sikituufu nakamu {Q11A}

b. Oli mulamu nga abantu abalala bomanyi.

1. Kituufu nyo
2. Kituufu
3. Tomanyi
4. Sikituufu
5. Sikituufu nakamu {Q11B}

c. Oli mulamu ddala

1. Kituufu nyo
2. Kituufu
3. Tomanyi
4. Sikituufu
5. Sikituufu nakamu |___|{Q11C}

d. Obadde owulira bubi gyebuvuddeko.

1. Kituufu nyo
2. Kituufu
3. Tomanyi
4. Sikituufu
5. Sikituufu nakamu |___|{Q11D}

12. Mu naku amakumi asatu eziyise obulamu bwo bubadde butya? Ntegeeza, ebintu bibadde bikugendera bitya?

1. Bulungi ddala; nga tebusobola kusingawo
2. Bulungi
3. Bulungilungi
4. Bubi
5. Bubi nyo; nga tebusobola kusingawo |___| {Q12}

13. Ogerageranya otya embeera y'omubiri gwo n'embeera y' ebirowoozo byo kati nebwebyali enaku amakumi asatu emabega?

1. Erongokedde ddala
2. Erongosemu katono
3. Kumpi tekyuseeko
4. Ebizzemu katono
5. Ebijjidde ddala |___| {Q13}

Appendix III: Consent form

INTRODUCTION

This study is measuring health related quality of life among ART experienced and ART naïve patients in Kampala district. This informed consent explains the study and we will also discuss the study with you. After you have heard the study explained and your questions answered, and you have decided to participate in the study, you will be asked to sign a consent form and you will be given a copy to keep. Please one important thing you should remember is that this study is voluntary.

PURPOSE OF THE STUDY

This study seeks to measure health related quality of life among HIV infected adults in Kampala district using a medical outcome study HIV tool and determine its validity, As a way of improving the quality of care provided by the clinicians and guide the policy makers in their planning.

RISKS

This research will cause a negligible risk, which will not be more than inconvenience in terms of time spent. No foreseeable risk of harm or discomfort that will impact on any participants.

BENEFITS

There are no tangible benefits from the study but the information given will help to improve the planning activities by the policy makers and clinicians in the provision of care.

ALTERNATIVES TO PARTICIPATION

In case you are not interested in the study, you don't have to participate, no benefits will be lost and you will get all the treatment you are entitled to from the clinic.

SUMMARY OF YOUR RIGHTS TO PARTICIPATE IN THIS STUDY

You can withdraw from this study at any time and no penalty will be imposed.

SIGNATURE

Signing below indicates that you have been informed about the research study in which you volunteer to participate; that you have asked any questions about the study that you may have and that the information given to you has permitted you to make a fully informed and a non coercive decision about your participation in the study.

By signing this consent form, you don't waive any legal rights and the investigators aren't relieved of any liability they may have. A copy of this consent form will be provided to you

Name of respondent	Signature	Date
_____	_____	_____

Name of Principal investigator or Research assistant	Signature	Date
_____	_____	_____

Telephone contact

In case of any problem, contact the principal Investigator on the following address;

Telephone contact 0712965171 or email address sekabus@yahoo.com

Or Chairman Makerere University Higher degrees of Research and Ethics Committee, P.O Box 7072 Kampala, Uganda

Appendix IV: Visual analogue scale (VAS)

In this method (VAS), respondents are asked to rate a state of ill health on a scale from 0 to 100, with 0 representing death and 100 representing perfect health. This method has the advantage of being the easiest to use, but is the most subjective.



Appendix V: Timelines for Implementation

TASKS	Person Responsible	OCT	NOV	DEC	JAN	FEB
1.Proposal Writing	PI					
2.Designing of research tools	PI					
3.Training of Research assistants	PI					
4.Pretesting of research tools	PI &RA					
5.Data collection	PI & RA					
6.Data entry, cleaning, processing and analysis,	PI & RA					
7. Dissertation write up and submission	PI					