

# National University of Rwanda



## FACULTY OF MEDICINE

QUALITY OF LIFE ASSESSMENT IN ADULTS WITH HIV  
INFECTION IN THE TREATMENT AND RESEARCH AIDS  
CENTER (TRAC) HIV CLINIC OF KIGALI.  
A CROSS-SECTIONAL STUDY

Presented by Alex HAKUZIMANA

As a partial fulfilment for the award of a Degree  
in Human Medicine

Directed by: Prof FRANCIS Edmond Lambert, MD, FRCP.  
Co-directed by: Robert W. BURGOYNE, M.Sc.  
Consultant: Rupert KAUL, MD, PhD.

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## DEDICATION

To you Claudienne Josephine Ingabire,  
To all HIV-carriers and their caregivers,  
To my cousins Marie, Pascasie, Verediana, Murenzi, and Ibyimanikora,  
my aunts, Marie and Cansilde,  
and friends especially Mathias, Ignace and Leonard,  
who were killed during the 1994 abominable atrocities of Rwandan and  
humanity history,  
the thesis is dedicated.

## ACKNOWLEDGEMENTS

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To my Claudienne Josephine INGABIRE, "Your Love Means Everything to my life".

To my parents, very deep and heartfelt appreciation for what you have done to make me what I am; to you all relatives and friends, thanks for being there for me.

**LIST OF ABBREVIATIONS**

et al	and others
WHO	World Health Organization
B.C.	Before Christ
TRAC	Treatment and Research AIDS Center
QOL	Quality of Life
HRQOL	Health-Related Quality of Life
PROs	Patient-Reported Outcomes
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immuno Deficiency Syndrome
CD4	Cluster Differentiation 4
ARC	AIDS - related complex
WHOQOL-BREF	World Health Organization Quality of Life assessment, short form Domain 1 - Physical - 7 items Domain 2 - Psychological - 6 items Domain 3 - Social - 3 items Domain 4 - Environmental - 8 items G 1 - Overall quality of life G 2 - Overall health satisfaction
ICIDH	International Classification of Impairments, Disabilities and Handicaps
FDA	Food and Drug Administration
SG	Standard Gamble
TTO	Time-Trade Offs
VAS	Visual Analog Scale
WHOQOL-100	World Health Organization Quality of Life Assessment.
STD	Sexually Transmissible Diseases.
SPSS	Statistical Package for Social Sciences
CHUK	Centre Hospitalier Universitaire de Kigali.
JAIDS	Journal of Acquired Immune Deficiency Syndromes
ART	Antiretroviral therapy
ICC	Intraclass Correlation Coefficient

ANOVA	Analysis of variance
PI	Protease Inhibitors
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
SD	Standard Deviation

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Vice Dean:	Dr MUSEMAKWERI André
Vice Dean (postgraduate program):	Prof. Dr WANE Justin
Academic Secretary:	KAMANZI Cassien

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Prof. Dr WANE Justin	Clinical Biochemistry
Dr GASAKURE Emmanuel	Cardiology
Dr MUSEMAKWELI André	Infectiology
Dr NKURIKIYIMFURA Jean Baptiste	Bacterio-Virology
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Dr MUHORA KEYE Georgette	Stomatology
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Dr WARUGABA Christine	Physiology

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Prof Dr VAN DEN ENDE Jeff	Internal Medicine
Dr Cwinya-ay Neniling	Pediatrics
Dr GAHIMBAHIRE Laetitia	Clinical Biology
Dr JIDEBAEVA Goulmara	ENT
Dr KREZDORN Walter	Surgery
DR MAKANGA Martine	Surgery
Dr MÜLLER Olaf	Internal Medicine
Dr MIDONZI Désiré	Anesthesia
Dr NGENDAHOYO Louis	Histopathology
Dr SCHOUTEN Evert Jan	Gynecology-Obstetrics

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## HIPPOCRATIC OATH

I promise that my medical knowledge will be used to benefit people's health. My patients are my first concern. I will listen to them, and provide the best care I can. I will be honest, respectful, and compassionate towards patients.

I will do my best to help any one in medical need, in emergencies. I will take every effort to ensure that the rights of all patients are respected, including vulnerable group who lack means of making their needs known.

I will exercise my professional judgment as independently as possible, uninfluenced by political pressure or by social standing of my patient. I will not put personal profit or advancement above my duty to my patient.

I recognize special value of human life, but I also know the prolongation of human life is not the only aim of health care. If I agree to perform abortion, I agree that it should take place only within an ethical and legal framework.

I will not provide treatments which are pointless or harmful, or which an informed and competent patient refuses. I will help patients find the information and support they want to make decisions on their care.

I will answer truthfully as I can, and respect patients' decisions, unless that puts others at risk of substantial harm. If I cannot agree with their requests, I will explain why.

If my patients have limited mental awareness, I will still encourage them to participate in decisions as much as they feel able. I will do my best to maintain confidentiality about all patients.

If there are overriding reasons, which prevent my keeping a patient's confidentiality, I will explain them. I will recognize the limits of my knowledge and seek advice from colleagues when needed. I will acknowledge my mistakes.

I will do my best to keep myself and my colleagues informed on new developments, and ensure that poor standards or bad practices are exposed to those who can improve them.

I will show respect for all those with whom I work and be ready to share my knowledge by teaching others what I know. I will use my training and professional standing to improve the community in which I work.

I will treat patients equitably and support a fair and human distribution of health resources. I will try to influence positively authorities whose policies harm public health.

I will oppose policies which breach internationally accepted standards of human rights. I will strive to change laws, which are contrary to patients' interests or to my professional ethics.

While I continue to keep this oath unviolated, may it be granted to me to enjoy life and practice of the art, respected by all, in all times.

## **SUMMARY**

### **Objectives**

The main purpose of the cross-sectional study in the TRAC HIV Clinic was to assess quality of life in adults with HIV infection. The hypothesis was to verify whether quality of life was negatively affected by HIV infection.

### **Method and Patients.**

The study was cross-sectional, analytical and carried out in the TRAC HIV Clinic/Kigali. A sample of 250 HIV + and 50 HIV- subjects was recruited in accordance with the World Health Organization Quality of Life instrument, short form, a questionnaire consisting of 24 items each from the WHOQOL-100 and two items one for the overall quality of life and other for overall health satisfaction. Domain values were depicted in the 0-100 mode. The internal consistency, intraclass correlation coefficients (ICC), independent sample t-tests and one way ANOVA were used to assess, respectively, Cronbach's alpha, test-retest reliability, scores according to age, gender, self-reported health status, HIV status and scores according to CD4 cell counts and WHO HIV stage.

### **Results**

250/300 (83.33%) HIV+ and 50/300 (16.67%) HIV- subjects participated in the study; 154/300 (51.30 %) and 146/300 (48.70 %) were, respectively, young and elderly adults. 174/300 (58 %) were females. Most of our participants had primary and secondary education (57 % = 171/300 and 28 % = 84/300 respectively). In the HIV+ group, 92/250 (36.80%) were married and 85/250 (34.00%) were widowed. In contrast, in the HIV- group, 23/50 (46%) were married and 10/50 (20%) were single. Ill subjects are highly represented in the HIV positive group (179/250, 71.60%) while healthy subjects are in the HIV negative group (44/50, 88.00%). The heterosexual mode is the most

frequent method of HIV transmission (235/250, 94.00%), WHO HIV stages I and II are most represented (145/250, 58.00%). The alpha values of each domain demonstrated generally good internal consistency ranging from 0.24 for social domain to 0.65 for physical domain. The intraclass correlation coefficients range from 0.5 for social domain to 0.7 for physical domain with a 2-week interval significantly high ( $p < .05$ ). Score values showed statistically significant difference in physical health in females and in younger age group compared to elderly adults ( $p < .01$ ). Illness was associated with significant impairment of QOL and health satisfaction and suggested psychological difficulty ( $p < 0.01$ ). HIV+ patients with  $CD4 < 200/\mu l$  had statistically significant physical disability as well as significant impairment of overall QOL. Patients with advanced HIV infection showed significant impairment in physical and environmental functioning as well as decreased QOL.

## **Conclusion.**

Quality of life assessment is currently considered essential for clinical trials in HIV infection because commonly used end-points are inadequate to identify the complexity of treatment outcomes. The WHOQOL-BREF has been established for these purposes.

This prospective cross-sectional study shows that HIV infection causes deterioration of quality of life.

Quality of life shows greater impairment in both sexes due to physical cause; When overall quality of life and overall health satisfaction is satisfactory, psychological health is better; overall quality of life, health satisfaction and psychological health are decreased in the HIV+ with poor physical health prominent; HIV+ patients with  $CD4 < 200$  have poorer physical health but better social relationships and overall health satisfaction; stages III and IV (WHO) have impaired physical and environmental QOL.

Further longitudinal studies are needed in the area of quality of life issues in care and treatment of HIV infection with patient-reported outcomes as clinical outcomes.

## RESUME

### OBJECTIFS

L'objectif global de cette étude était d'évaluer la qualité de vie des personnes adultes infectées au VIH. Notre hypothèse était de vérifier si la qualité de vie chez les patients adultes était négativement affectée par l'infection à VIH.

### METHODES ET PATIENTS

Cette étude prospective et transversale a été menée à la Clinique Ambulatoire du Centre de Traitement et de Recherche sur le SIDA (TRAC). On a obtenu la consistance interne par le calcul des valeurs Cronbach's alpha, la fiabilité temporelle par les coefficients de corrélation intraclasse. Nous avons utilisé le test T pour échantillons indépendants pour l'analyse discriminante selon l'âge, le sexe, l'état de santé rapporté et le statut sérologique. L'ANOVA à un facteur a été utilisée pour l'analyse discriminante selon le taux des CD4 et le stade VIH selon l'OMS.

### RESULTATS

250/300 (83.33%) VIH+ et 50/300 (16.67%) VIH- sujets ont participé dans notre étude. 154/300 (51.30%) étaient des jeunes adultes et 146/300 (48.70 %) étaient des adultes âgés. 174/300 (58 %) étaient des femmes. La plupart des participants ont un niveau d'étude primaire et secondaire (57 % = 171/300 et 28 % = 84/300 respectivement).

Dans le groupe VIH+, 92/250 (36.80%) étaient des mariés et 85/250 (34.00%) étaient des veufs. Par contre, dans le groupe des VIH-, 23/50 (46%) étaient des mariés et 10/50 (20%) étaient des célibataires. Les personnes ayant rapporté qu'elles étaient en mauvaise santé étaient plus représentées dans le groupe des VIH+ (179/250, 71.60%) alors que celles disant être en bonne santé l'étaient dans le groupe des VIH-. Le rapport sexuel entre les individus

de sexe opposé est le mode plus fréquent de transmission du VIH (235/250, 94.00%) et les stades I et II selon OMS de l'infection à VIH sont les plus fréquents (145/250, 58%).

Les valeurs alpha de Cronbach pour chaque domaine du questionnaire WHOQOL-BREF ont montré en général une bonne consistance interne variant entre 0.24 pour le domaine social et 0.65 pour celui physique.

Les coefficients de corrélation intraclasse varient de 0.50 pour le domaine social à 0.70 pour le domaine physique avec un intervalle de 2 semaines statistiquement significatif ( $p < 0.05$ ).

Les scores moyennes montrent une différence statistiquement significative pour la santé physique chez les femmes et jeunes adultes comparés aux adultes âgés ( $p < 0.05$ ).

L'état de mauvaise santé est associé à une dégradation statistiquement significative de la qualité de vie, de la satisfaction pour la santé et des problèmes psychologiques. Les patients VIH+ avec les taux des CD4  $< 200/\mu\text{l}$  avaient une incapacité physique fonctionnelle et une dégradation de la qualité de vie avec différence statistiquement significative.

On a noté une incapacité physique, une dégradation des relations avec l'environnement et une mauvaise qualité de vie chez patients au stade avancé de l'infection à VIH.

## CONCLUSION

L'évaluation de la qualité de vie est actuellement considérée comme outil essentiel dans les essais cliniques en rapport avec l'infection à VIH car les indicateurs classiques se sont révélés à eux seuls insuffisants pour identifier la nature complexe de sa prise en charge. Le questionnaire WHOQOL-BREF a été conçu et établi à cette fin.

En conclusion, notre étude a montré que l'infection à VIH entraîne une détérioration notoire de la qualité de vie. Cette dégradation retrouvée dans les deux sexes est surtout due à l'incapacité physique ; si la qualité de vie en général et la satisfaction pour la santé sont bonnes, la santé psychologique est bonne.

La qualité de vie en général, la satisfaction pour la santé et la dimension de la santé psychologique sont négativement affectées chez les personnes VIH+ ayant une santé physique dégradée. Ces mêmes personnes avec  $CD4 < 200/\mu l$  ont une mauvaise santé physique mais de bonnes relations sociales et satisfaction pour la santé. Des patients aux stades III et IV de l'infection accusent une incapacité physique et de mauvaises relations avec l'environnement.

Nous recommandons que l'on mène des études de suivi et de cohorte au site de cette étude transversale pour évaluer l'impact à long terme de la prise et du traitement de l'infection à VIH, en attachant une particulière importance sur ce que les patients rapportent eux-mêmes.

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## 1. INTRODUCTION

### 1.1. Problem statement

In recent decades, the health-related quality of life has increasingly gained importance as an outcome measure in health care (1), especially with regard to interventions for patients with various chronic diseases (2). The Human Immunodeficiency Virus (HIV) is a retrovirus which causes chronic, progressive, immunological dysfunction. Infection with HIV is characterized by a long period with no or minor symptoms, during which the virus causes declining levels of T-helper CD4-positive lymphocytes. Low levels of CD4-positive lymphocytes are associated with increased risk of the Acquired Immunodeficiency Syndrome (AIDS), defined by opportunistic infections and HIV-related cancers. The HIV infection is also associated with different psychological and neuropsychiatric disorders. Today, there is no cure for HIV infection. Treatment is concentrated on delaying the HIV's suppression of the immune system and/or preventing opportunistic infections and cancers (3, 4).

Globally, the estimated number of persons infected with HIV, since the beginning of the pandemic, is 39.4 million, of whom over 15 million have developed AIDS (5). The reported HIV prevalence rates in Rwanda vary from 4% in rural to 11% in urban areas, peaking at 13 % in Kigali City (6).

HIV infection affects several Health-Related Quality of Life (HRQOL) domains, and studies of HIV and quality of life have shown that, compared with patients with various other chronic conditions, patients with symptomatic HIV scored their HRQOL as poorer, while patients with asymptomatic HIV scored it better (7,8). Of the HIV patients in different disease stages, asymptomatic patients scored their HRQOL better than symptomatic HIV carriers (7-9). The most affected group seemed to be the group of patients with AIDS-related complex (ARC) (9). In a qualitative study of 25 HIV patients, Laryea and Gien found indications that the investigated patients felt doubly stigmatized and that "the HIV diagnosis had a profound impact on the individual's psychosocial aspects of life" (10). Similarly, Ragsdale and Morrow found in their study of 95 HIV patients in various disease stages that the psychosocial dimension seemed to be the most affected (9).

Several studies have focused on the quality of life of HIV-positive individuals (11-13) but comparisons with general population samples have been unusual.

Most HIV-carriers are treated in outpatient clinics and many of them are judged as symptom free. Therefore the aim of the present study is to assess the quality of life of an outpatient sample of HIV-infected persons visiting the Treatment and Research AIDS Center (TRAC) HIV Clinic of Kigali and to relate these results to the general population. As a corollary, this thesis will evaluate the applicability of the World Health Organization Quality of Life Assessment instrument, the short form (WHOQOL-BREF) to the Rwandan HIV positive population. The WHOQOL-BREF has shown, from studies already done, the accuracy and relevancy of its psychometric properties (14).

## **1.2. Hypothesis statement**

To verify whether quality of life is negatively affected in adults with Human Immunodeficiency Virus infection.

## **1.3. Objectives**

### **1.3.1. Global objective**

To evaluate quality of life of adults with HIV infection in the TRAC HIV Clinic of Kigali.

### **1.3.2. Specific objectives**

- To evaluate the WHOQOL- BREF properties in a Rwandan HIV-positive and HIV-negative population ;
- To identify and compare contributing factors for poor QOL in the HIV-positive versus HIV-negative persons.

## 2. LITERATURE REVIEW

### 2.1. BACKGROUND

#### 2.1.1. Introduction

*“We should set the highest value, not on living, but on living well.”* Socrates (15).

In contrast to quantity, (i.e. the amount, number, size), quality may be understood as a value, attribute or the essential nature of objects or phenomena. Hence, it has a certain definiteness, or particularity by which a given phenomenon as a whole differs from another whole (16).

Could such an approach be applied with respect of people and their lives?

Quantity might include longevity - the length of an individual’s life in years. Quality is more difficult to define.

The question of how life gains its quality has been raised by philosophers throughout history. As early as the fourth century B.C., Socrates declared that there were some things he feared more than death. It is not life itself but the quality of that life that counts (17). Other eminent philosophers (18-21) have debated whether there are universal aspects that give life its value.

The last quarter of the 20<sup>th</sup> century has seen a dramatic increase in interest in quality of life (QOL). It is now difficult to identify a sphere of life or area of academic study where the term is not used. For many Western societies QOL has become an accepted colloquialism used in everyday language (22). In academia, questions of definition, methodology, and motives for its measurement have been heatedly debated from the perspectives of a variety of disciplines. Aiken (23) observes that the popularity of QOL in contemporary debates has crossed diverse areas such as medical ethics, environmental ethics, moral issues in law and social justice. Häyry (24) and Bubolz (25) report on the divergent interests in QOL among social scientists, psychologists, economists, moral philosophers, environmentalists, and political scientists. In particular, Häyry reports that social scientists and psychologists are predominately interested in definitions and methods. Moral philosophers have concentrated on the motives for defining and

measuring human QOL and on the ethical questions that arise from such measurement.

Advances in medical technology and improvements in public health may have reduced the significance of many life-threatening infectious diseases in the developed world. Western health and social care systems are now increasingly concerned with treatment of chronic, disabling conditions associated with an aging population. In addition, patients' perceptions of the impact of treatment are being given greater emphasis.

Where medical interventions and health care programs are designed to make life more comfortable for patients, interest now focuses on QOL outcomes.

The first clinical publications incorporating the term QOL appeared in the 1960s. Wider acceptance was gained in the 1970s when QOL was introduced as a heading on MEDLINE in 1975. The number of MEDLINE publications using QOL as a keyword has grown exponentially since then (26).

This vast interest in QOL belies the fact that the idea is still beset by theoretical disagreement. Definitions of QOL, methods of assessment, and the quality of investigation vary widely. In many cases, the term is applied inappropriately. This has led some authors to conclude that current disagreements on the meaning of QOL are indicative of a lack of direction rather than of a healthy diversity of opinion (22).

Despite this, it seems self-evident, also, that health is a precondition of a "good" life, but it may not be the only one.

In resource-constrained settings, such as in Rwanda, where society is underdeveloped or is developing, is it useful to compare parameters with those of developed countries?

If one refers to quality of life indicators as enumerated by the Calvert-Henderson (27), such as education, employment, energy, environment, health, human rights, income, infrastructure, national security and public safety, one could assume that talking about quality of life for Rwandans makes no sense.

### **2.1.2. Defining Patient-Reported outcomes**

For researchers involved in clinical studies and trials, it is common to describe anything that they have measured as related to quality of life (28) - simply because the information was collected from patients. It should be noted that

“patient-reported” implies that the instrument used is completed by the patient. It should not be inferred that the information gained is necessarily relevant. So it is valuable to define the patient-reported outcomes (PROs) that can be measured and comment on their applicability in the context of clinical studies and trials.

**i. Impairment, disability, and Handicap.**

Impairment, disability, and handicap have been defined in the International Classification of Impairments, Disabilities and Handicaps (ICIDH) (29) and are widely accepted. Recently, the term disability has been replaced by “activity”. Handicap now refers to participation, defined as “the nature or extent of a person's involvement in life situations in the manner to be expected.” These changes have been largely driven by problems with the acceptability of the original terms and difficulties with the handicap classifications (30). However, the original terms are more useful for defining outcome and are employed below.

➤ **Impairment**

Impairment is any loss or abnormality of psychological, physiological, or anatomical structure or function which may be associated with symptoms. Common disturbances include anxiety, depression, pain, and problems with sleep. Impairment is seen as representing some deviation from the norm. The value of the construct lies in the determining of the impact of disease from a clinical viewpoint. As such, the value of the construct in the context of a clinical trial is reasonably clear and rarely questioned. Its relevance to QOL is a different matter. Impairments that patients are unaware of cannot influence QOL directly. Even where the patient is aware of impairment it may not concern them in the least.

➤ **Disability (Activity)**

A disability is any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human. Examples include problems with dressing, walking, or personal care. Disability is seen as being a deviation and there is no need for an individual to be aware that they have a restriction. Such a definition introduces cultural bias to the classification. For example, behaviour considered uncooperative in one culture may be seen

acceptable in others. Despite this, disability constructs play a major part in the assessment of health-related Quality of Life (HRQOL).

➤ **Handicap**

Handicap is the disadvantage arising from impairment or disability that prevents fulfilment of the normal or the expected role for that person. What is normal takes into account the individual's age, gender, and social and cultural background. Six main types of handicap are listed in the ICIDH: orientation, physical independence, mobility, occupation, social integration, and economic self-sufficiency. Categorization is dependent on the extent to which the individual is restricted; to bed, chair, room, dwelling, neighbourhood, or levels of immobility. Physical dependence handicap is also related to the frequency with which the individual can be left alone.

Handicap represents deviation of the individual's behaviour from that of the group. As this deviation may be from the choice, handicap may be judged from the perspective of society. It is not a personal but a social problem. But, of course, it is also a personal problem. Thus, handicap represents the impact of disease on society rather than on the individual patient. Therefore, it cannot be considered to be directly relevant to QOL. The construct is of value in determining the need for provision of social services such as education, housing, or social security.

ii. **Well-being**

The concept of well-being has a checkered history and now appears to be used as catch-all term. Subjective well-being was first formally assessed in the 1960s and 1970s. It has been defined as a decent standard of living (31), the extent to which pleasure and satisfaction characterize human existence (32), and as happiness (33). Well-being is generally related to mood. Dupuy (34) conceived of well-being as reflecting an individual's inner personal state. His widely used scale, the General Well-Being Schedule, includes items such as anxiety, depression, general health, positive well-being, self-control, and vitality.

Scandinavian researchers have considered aspects of well-being to constitute QOL. For example, Naess (35) defined QOL as an individual's inner affective state. Nordenfelt (36) identified QOL with subjective happiness-with-life. These various definitions of well-being all suggest that the construct describes

predominantly mood (impairment). As such, its measurement may add little to the assessment of relevant symptoms in a clinical trial.

### **iii. Health-Related Quality of Life (HRQOL)**

HRQOL, as defined by different authors, equates primarily to impairment and disability. It has its origins in the functionalist approach of Durkheim in the late-19<sup>th</sup> century (37), who analyzed social and cultural phenomena in terms of the functions they perform in a sociocultural system. Function-based measures appeared particularly attractive to a medical world in the 1950s and 1960s. This concept was developed by Parsons (38) who defined health as the state of optimum capacity for the effective performance of valued tasks. In this system, illness becomes a problem when it affects role performance and health (39-40). Thus, functionalist definitions of health focus on the main social roles considered “normal” for people in Western society. Following from this, HRQOL has been defined as the capacity to perform the usual daily activities for a person’s age and major social role (1).

There is general agreement that HRQOL is multidimensional, although there is no formal consensus on the domains that should be included (41-43). Torrance (44) argues that it is inappropriate to include social functioning as a dimension of HRQOL. Some researchers suggest that it is only necessary to assess those domains that are relevant to the study (45). Taken to its extreme, studies have been criticized for using a single variable such as employment, happiness, or sexual functioning as ad hoc indicators of HRQOL. Spilker has pointed out the pitfalls of such an approach (46).

Recently, QOL has been seen as going beyond the impairment-disability-handicap continuum assessed by HRQOL instruments (47-49). Bradley argues that “clinicians may be misled into thinking that findings based on a health-status instrument indicate that treatments do not damage QOL when all the data reveal is that treatments do not damage perceived health” (50).

In summary, HRQOL focuses on those aspects of life that are considered to be the province of health professionals. Its emphasis is on the measurement of symptoms and functions. Consequently, the main value of HRQOL measurement is in the assessment; levels of impairment, disabilities, and, to a lesser extent, handicap. Such information is valuable to clinical assessment of outcome.



However, the focus on fulfilment of normal roles creates problems in that groups, such as the unemployed or disabled, are automatically devalued. The emphasis on physical functioning found in HRQOL instruments suggests that disabled people cannot have a good QOL.

#### **iv. Quality of Life**

It is clear that QOL goes beyond the continuum suggested by the World Health Organization (47). The consequences of disease and its treatment represent only one group of influences on QOL. However, there are many more aspects including personality, economic status, environment, social relationships, and culture. The extent to which an impairment or disability influences QOL is dependent on other influences. For example, the impact of a skin disease will depend on whether the lesions are hidden by clothes, the climate, and quality of personal relationships, stage of life, and many other factors. Patients may give up functions that become problematic, such as swimming or sun-bathing and take up other activities in order to maintain their QOL. Function-based measures are unable to cope with such adaptation making it difficult for severely ill or disabled patients to show improvements, even following effective interventions. Figure 1 (27) shows a simplified representation of how disease relates to some of the other influences on an individual's QOL. To obtain a complete picture of the impact of disease and of the effectiveness of treatment, it is essential to measure QOL. Focusing on impairments and disability alone is insufficient. Handicap is omitted from this model as it is the disadvantage arising from impairment and disability from the perspective of society rather than the individual.

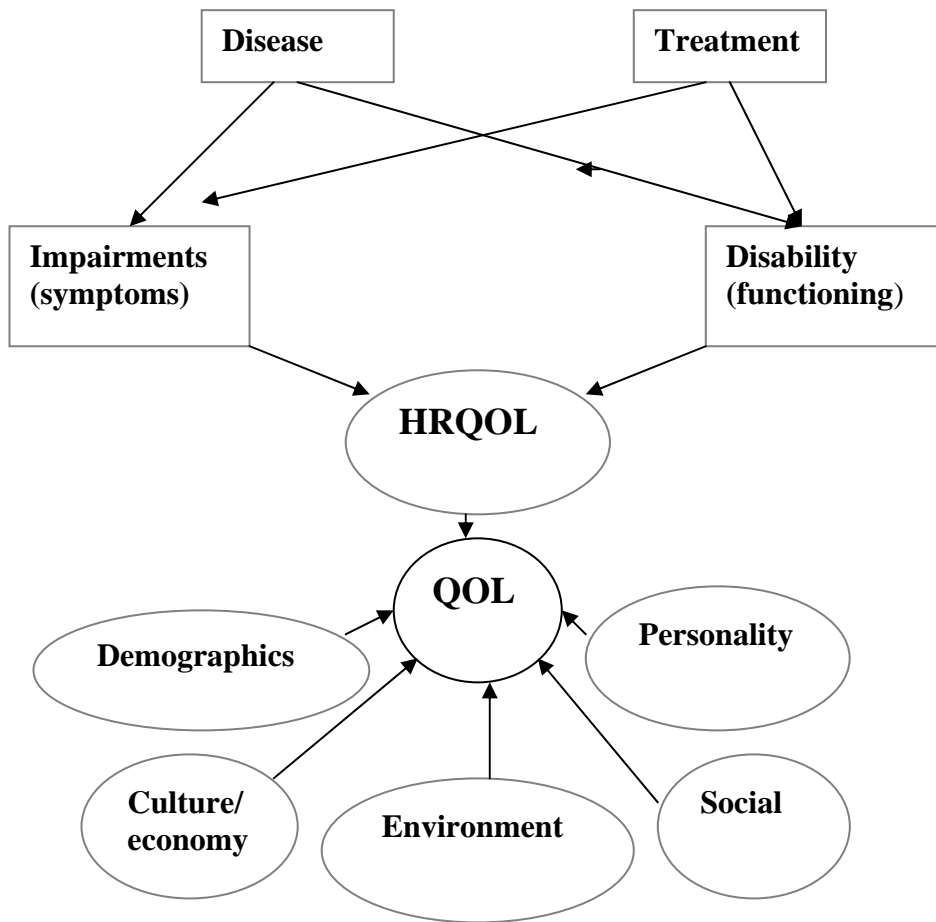


Figure 1. Influences of QOL

### **2.1.3. QOL assessment**

QOL is usually assessed by means of a physician's assessment or a QOL instrument that consists of a number of questions (51). The global physician's assessment, such as an analogue scale ranging from 0 to 10, is easy to apply by simply asking the question "How is your QOL?" However it cannot capture the whole spectrum of QOL. In addition, if the therapy does improve QOL, no information as to which domain of QOL is provided. The global physician's assessment generally produces large variability and low reproducibility. For a QOL instrument, the questionnaire may be assessed by patients, their spouse/significant others, reviewers (e.g., nurses or social workers), and/or physicians through direct observation or face-to-face or telephone interview. It can be self-administered or be supervised and self-administered.

Based on the collected data, the HRQOL can be quantified. Generally, HRQOL may be described by a number of major domains (or dimensions). The most commonly considered QOL domains include physical functioning and morbidity, emotional or psychological status, well-being, functioning in social and role activities, general perceptions of health and well-being, disease-specific symptoms, somatic discomfort, and cognitive function. Other domains, such as intimacy and sexual functioning, economic status, personal productivity, employment, and laboratory test values, are less often used.

In the QOL instrument, for each patient, scores associated with each questionnaire are usually referred to as items. In practice, there may be a large number of items, and it is not practical to analyze the data by item. Thus, items are usually grouped to form subscales, which are often used to evaluate different components of QOL.

However, analysis of individual subscales often produces inconsistent results across subscales; consequently, no overall conclusion can be made. As an alternative, these subscales may be combined to form the so-called composite scores, which can be used to assess major domains of QOL.

As a result, QOL may be assessed by analyzing items, subscales, composite scores, and/or total score. Tandon (52) applied global statistics to combine the results of univariate analysis of each subscale. As an alternative approach,

Olschewski and Schumacher (53) proposed the use of aggregated measures to reduce the dimension of the measurements. Their method uses the standardised scoring coefficients from factor analysis as data-oriented weights for combining subscales which neglect small coefficients. The disadvantage of their method is that the selected coefficients are neither unique nor have optimal properties. To overcome these problems, Ki and Chow (54) suggest the use of factor analysis in conjunction with the analysis of principal components for combining subscales. The proposed method provides statistical justification for the use of composite scores.

## **2.2. QUALITY OF LIFE MEASUREMENT**

### **2.2.1. Purpose of measuring quality of life**

#### *✓ In medical practice*

In clinical practice quality of life rating scales may be used with other forms of assessment, giving valuable information that can indicate areas in which a person is most affected and help the practitioner in making the best choices in patient care. In addition they may be used to measure change in quality of life over the course of treatment.

#### *✓ Improving the doctor-patient relationship*

By increasing the physician's understanding of how disease affects a patient's quality of life, the interaction between patient and doctor may change and improve. This gives more meaning and fulfilment to the work of the doctor and leads to the patient being provided with more comprehensive health care. Because a more complete form of assessment covering different aspects of patients' functioning is being carried out, patients themselves may find their health care more meaningful.

✓ *In assessing the effectiveness and relative merits of different treatments*

Quality of life ratings can form a part of the evaluation of treatments. For example, chemotherapy for cancer may prolong a person's life, but may only do so at considerable cost to their quality of life. By using the quality of life instruments to look at changes in the person's well being over the course of treatment, a much fuller picture can be gained.

Measuring the quality of life is then useful in scientifically assessing the relationship between the quality of life and the development of illness. It is difficult and somewhat vague to establish what is meant by feeling good and being ill. It is an in-between, grey zone of discomfort, dissatisfaction and slight disability that is difficult to put into words and hence not very well understood. A quality of life scale enables a population group to be monitored for a number of years, and psychosocial and other factors prior to illness established.

✓ *In health services evaluation*

In the periodic review of the completeness and quality of medical services, the patients' concerns are of importance. The instruments provide an invaluable supplementary appraisal of health care services, by yielding a measure of the relationship between the health care service and patients' quality of life, and also by directly presenting a measure of patients' perception of the quality and availability of health care.

✓ *In research*

The QOL instruments provide new insights into the nature of disease by assessing how disease impairs or impacts the subjective well being of a person across a whole range of areas. Quality of life ratings can therefore be used as a scientific gauge in controlled clinical trials. The physician assesses how the person functions after he or she has undergone medical intervention. The person, then, has to fill out a questionnaire stating how they feel and describe their quality of life in other ways.

✓ *In policy making*

When health providers implement new policies it is important that the effect of policy change on the quality of life of people in contact with health services is evaluated. The QOL instruments allow monitoring of policy.

✓ *Drug advertising*

Quality of life not only can provide information as to how patients feel about drug therapies, but also appeals to the physician's desire for the best clinical practice. It can be used as a predictor of compliance of the patient. In addition, it may be used to distinguish between therapies that appear to be equally efficacious and equally safe at the stage of marketing strategy planning. The information can be potentially used in advertising for the promotion of the drug therapy.

Several FDA staffers take into account of QOL studies before promoting any drug on the market (51).

## **2.2.2. Types of QOL instruments**

### **2.2.2.1. Introduction**

Quality of life is usually assessed by a questionnaire, which may consist of a number of questions. This thesis refers to such a questionnaire as the QOL instrument. Unlike the analytic instrument, there exist no known standards that can be used as reference.

The QOL instrument is a very subjective tool, which is expected to have a large variation. It is then a concern as to whether the adopted QOL instrument can accurately and reliably quantify patients' QOL. To ensure the accuracy and reliability of QOL assessment in clinical trials, the adopted QOL instrument is necessarily validated. In practice, a QOL instrument is usually validated based on some classic validation parameters such as validity, reliability, test-retest reproducibility, responsiveness, and sensitivity. However, it is not clear whether classic validation can actually verify the instrument. In other words, it unclear

whether classic validation addresses whether the questions are the right ones for assessment of QOL. Several statistical issues regarding the validation for utility analysis of QOL and calibration have been considered.

#### **2.2.2.2. Types of QOL instruments**

A number of different QOL instruments are being used in clinical studies and trials (56).

##### **I. Generic health profiles**

These instruments are comprehensive, have established reliability and validity, may be generalized, and may detect unanticipated effects. On the other hand, they may not be adequately focused and thus not be responsive to small but clinically meaningful differences. They are also, often, lengthy and time consuming. In addition, an effect may be difficult to interpret.

##### **II. Generic utility measures.**

These instruments can be used with any population. They generally cover perceptions on overall health and also questions on social, emotional and physical functioning, pain and self-care. The Standard Gamble (SG) or the Visual Analogue Scale (VAS) or the time trade-off (TTO) techniques (57), are examples. They attempt to ascertain a judgment of the value and worth of life. They perceive health as a continuum, and thus cost-utility analyses are possible. They may result, however, in diverse scores between patients and may not be responsive.

##### **III. Disease-specific instruments**

These instruments focus on the target and are clinically sensible, but do not allow cross-condition comparisons and are narrow in scope and deliberately non comprehensive. Study-specific instruments may be very focused to the specific drug under investigation, but are generally not adequately validated, cannot detect unexpected effects, and are feasibly bogus since the sponsor decides what it wants to ask, and thus can emphasize areas where the product should

excel and deemphasize potentially troublesome areas. There are also individual instruments where each patient, with guidance, states at the beginning which areas of his impairment are most troublesome to them. Individualized forms can increase responsiveness because they emphasize what matters to the patient, but they are difficult to analyze and comparison of subjects is tricky since they respond to different concerns. A clinically sensible method is to give both a generic and a disease-specific instrument, which combines broad coverage with responsiveness to small changes in specific areas. This may be time consuming, however, and could possibly lead to contradictory results.

### **2.3. REQUIREMENTS FOR QOL INSTRUMENTS IN CLINICAL RESEARCH**

There are a number of requirements that any instrument intended to collect information from patients should meet (58-59). As the importance of a number of these has only recently been recognized, it is unlikely that many existing measures will meet them all. Although failure in some of the requirements may not be serious enough to preclude their use in a clinical trial, it may affect the way data are analyzed and limit inferences that can be drawn from these analyses. These requirements refer to the psychometric properties of the instrument leading to its validation. Of course, besides content derivation and acceptability to respondents, the following are criteria most frequently mentioned for selecting instruments to measure human attributes.

#### **2.3.1. Validity**

The validity of a QOL instrument is defined as the extent to which the QOL instrument measures what it is designed to measure. In other words, it is a measure of bias of the instrument. The bias of an instrument can reflect the accuracy of the instrument.

There exist three basic types of validity mostly frequently found in the use:

- The content validity is the extent to which a particular method of measurement includes all of the dimensions of the construct one intends to measure. For example, a scale for measuring pain would have content



validity if it included questions about aching, throbbing, burning, and stinging, but not about pressure, itching, nausea, and tingling.

- a) The face validity represents a subjective assessment by a panel of expert judges, users, or the developers of the measure, regarding whether the instrument appears to measure what it is said to measure.
  - b) The sampling validity consists of identifying the important dimensions of the instrument, e.g. physical or social health, and including items that cover each of the relevant categories within those dimensions.
- The construct validity is present to the extent that the measurement is consistent with other measurements of the same phenomenon, that is, it is measuring the intended construct. Three prerequisites of this are that the instrument is based on a coherent theory or definition, that the scale is unidimensional, and that it has good reproducibility. For example, the researcher might show that responses to a scale measuring pain are related to other manifestations of the severity of pain such as sweating, moaning, writhing, and asking for pain medications.
  - Criterion validity including concurrent and predictive ones refers to the timing of the assessment.

### **2.3.2. Reliability**

The reliability of a QOL instrument refers to the freedom from random error. It is the extent to which repeated measurements of a stable phenomenon- by different people and instruments, at different times and places- get similar results (59). Reproducibility and precision are other words for this property. The reliability of an instrument measures the variability of the instrument, which directly relates to the precision of the instrument.

### **2.3.3. Reproducibility**

Reproducibility is defined as the extent to which repeat administrations of the same QOL measure yield the same result, assuming no underlying changes have occurred. The assessment of reproducibility involves expected and/or

unexpected variabilities that might occur in the assessment of QOL. It includes inter-time point and inter-rater reproducibility.

For the assessment of reproducibility, the technique of test-retest is often employed. The same QOL instrument is administered to patients who have reached stable conditions at two different time points. These two time points are generally separated by a sufficient length of time that is long enough to wear off the memory of the previous evaluation but not long enough to allow any change in environment. The Pearson's product moment correlation coefficient,  $\rho$ , of the two repeated results is then studied. In practice, a test-retest correlation of 80% or higher is considered acceptable.

#### **2.3.4. Responsiveness and Sensitivity**

The responsiveness of a QOL instrument is usually referred to as the ability of the instrument to detect a difference of clinical significance within a treatment.

The sensitivity is a measure of the ability of the instrument to detect a clinically significant difference between treatments. A validated QOL instrument should be able to detect a difference if there is indeed a difference and should not wrongly detect a difference if there is no difference. Chow and Ki proposed precision and power indices to assess the responsiveness and sensitivity of a QOL instrument when comparing the effect of drug on QOL between treatments. The precision index measures the probability of not detecting a false difference and the power index reflects the probability of detecting a meaningful difference.

## **2.4. HEALTH-RELATED QUALITY OF LIFE AND HIV INFECTION.**

Advances in drug therapy and the use of HAART have dramatically extended the life expectancy of patients with HIV infection (60); however, adherence to effective antiretroviral therapy is also necessary to delay disease progression (61). HRQOL for patients living with HIV disease has become increasingly important, with the goals of therapy now including improvement of HRQOL in addition to the reduction of symptoms, suppression of the virus, and extension of survival (62). However, adverse effects of potent antiretroviral therapies can worsen HRQOL (63). In addition, symptoms associated with HIV infection and HIV medication side effects (nausea, anxiety, confusion, vision problems, sexual dysfunction, anorexia, insomnia, taste perversion, and abnormal fat distribution/lipodystrophy) can decrease medication adherence, in addition to diminishing HRQOL (64-65).

Medical issues associated with HIV infection also negatively affect HRQOL. Malnutrition, which can predate immune deficiency, is correlated with decreased functional performance (66), with progressive malnutrition strongly associated with the risk of death (67). Chronic diarrhoea affects up to 50% of HIV-infected persons (68) and may result in significant deterioration in social activity, activities of daily living, energy, and general health (63). Anaemia, which occurs in nearly half of HIV-infected patients, (69) is a common cause of fatigue (70). Predictably, anaemia and fatigue demonstrate a strong negative correlation with HRQOL (71-72). Treatment of anaemia is associated with improved HRQOL and increased hematocrit levels (72).

Lipodystrophy, sexual dysfunction, and sleep disturbances, as a result of both disease and treatment, are common in HIV-infected patients and can have both physical and emotional ramifications. The lipodystrophy syndrome consists of metabolic abnormalities and body fat redistribution in patients infected with HIV. The latter typically includes loss of subcutaneous adipose tissue (lipoatrophy) and accumulation of visceral adipose tissue (lipohypertrophy), resulting in an appearance resembling that seen in a wasting syndrome. This can limit physical and social activities, lower self-esteem, and lead to depression

(74). Sexual dysfunction is reported to affect more than 50% of HIV-symptomatic gay men (75-77) and, not surprisingly, negatively affects HRQOL. Interestingly, sexual dysfunction may have a psychogenic cause twice as often as an organic cause in this population (78). Sleep disturbances frequently reported in persons living with HIV infection include difficulty in both falling and staying asleep, and can be caused by psychological factors (anxiety and depression) as well as by physical symptoms (pain, diarrhoea, fever, night sweats, and cough) (79).

In addition, psychosocial, sociodemographic, and psychological factors can affect HRQOL in HIV-infected patients. The diagnosis of HIV infection, in and of itself, can have deleterious ramifications, including the discontinuation of work, limitations in social activity, and dependence on others. Limited social support and poor coping skills also can negatively affect HRQOL (63, 71). Sociodemographic factors, such as older age, female gender, unemployment, and low income, have been associated with poor HRQOL (71, 80). Limited social support, unemployment, low CD4<sup>+</sup> cell counts, and HIV-related symptoms are associated with depression in persons living with HIV infection (81). Interestingly, the degree of physical limitations appears to predict depression better than does disease severity (82). Other stressors associated with HIV infection include those of disclosure, decision making regarding privacy issues, the negotiations of safer sex, and the fear of violence (real or perceived) resulting from disclosure of HIV status (83-84).

## **3. METHODS AND PATIENTS**

### **3.1. Design and setting**

This study was cross-sectionally conducted in the HIV Clinic of the Treatment and Research AIDS Center (TRAC) of Kigali. The study protocol was presented to the research unit of the University Central Hospital of Kigali for revision and approval. Ethics approval was obtained from the TRAC direction and each subject provided signed an informed consent to participate in the study.

### **3.2. Translation process**

The translation of the English version into Kinyarwanda consisted of three phases: translation, back-translation, and harmonization. Translation into Kinyarwanda was carried by a Bachelor's degree in Arts holder who graduated from the National University of Rwanda. After a critical inspection by the author and a clinical psychologist, a first version of the translation was agreed upon. This was back-translated into British English by an independent bilingual translator. All items which showed differences between the original and the back-translated version were thoroughly discussed with the author and the translator. After several changes in the first version of the translation, we obtained the Rwandan WHOQOLBREF version used in the study.

### **3.3. Period**

The study extended from August 2004 to May 2005. The translation process was completed, then, the protocol was presented to the Research Committee of Central University Hospital of Kigali who encouraged the study.

Parastudy results showed the reliability and accuracy of the questionnaire. Recruitment of subjects began at the end of March 2005 and ended at mid May of 2005.

### **3.4. Subjects**

With respect to the administration of the WHOQOL BREF (14), the sample size was 300 subjects from whom 250 were HIV positive and 50 HIV negative. All were adults, adult being older than 14 years. Quota sampling considering sex and age was used in the two groups.

### **3.5. Measures**

*Demographic and clinical variables.* The demographic variables of interest for this study included subjects' age, sex, marital status, education, and mode of transmission in the HIV positive group. Clinical measures used in the study were CD4 cell counts, prophylactic and antiretroviral therapy.

#### *Quality of life*

The World Health Organization Quality of Life assessment, short form (WHOQOL BREF) was used in this study. This questionnaire comprises 26 questions with one item from each of the 24 facets contained in the WHOQOL-100, and two additional items; one for the overall quality of life and another for general health.

### **3.6. Data assessment procedure**

All subjects signed a written informed consent before participating in the study. Then the data collector explained the purpose of the study and created an atmosphere of cooperation.

Age, sex, education, marital status, self-perceived health status, mode of HIV transmission were reported by patients and serostatus, HIV stage, CD4 count, prophylactic therapy, antiretroviral therapy were taken from medical records and lab results.

The interviewer read the questions aloud to the patient who could at the same time see the text of the questions and tell the interviewer to repeat and explain for more clarification.

A subsample of 45 HIV+ subjects was interviewed a second time by the same interviewer approximately 2 weeks later for retest. This convenience sample consisted of patients who were appointed for medical visits.

### **3.7. Statistical analysis**

The SPSS software package was used for data entry and analysis. The author did data entry and Robert William BURGOYNE did statistical analysis.

Domain values were depicted in the 0-100 mode.

The internal consistency of WHOQOL-BREF domain scores was calculated using the Cronbach's alpha. Intraclass correlation coefficients (ICC) were used to calculate the 2-week test-retest reliability of WHOQOL-BREF domain scores and overall quality of life and health satisfaction items.

Independent sample t-tests were used to determine domain scores and overall quality of life and health satisfaction items according to age, gender, self-reported health status, and to HIV status.

The one-way analysis of variance (ANOVA) was used to determine domain scores and overall quality of life and health satisfaction items according to CD4 count and to WHO disease stage.

## 4. RESULTS

This study was cross-sectional and analytical.

According to this literature review, there are many similar studies that have been done worldwide in persons with HIV disease. Many of these studies have shown that several factors have an impact on the quality of life of HIV-infected persons.

### 4.1. Characteristics of the population

#### 4.1.1. Distribution according to HIV serostatus

The following figure shows distribution according to tested HIV serostatus. 83.33% (250/300) are HIV-positive and 16.67% (50/300) are HIV-negative.

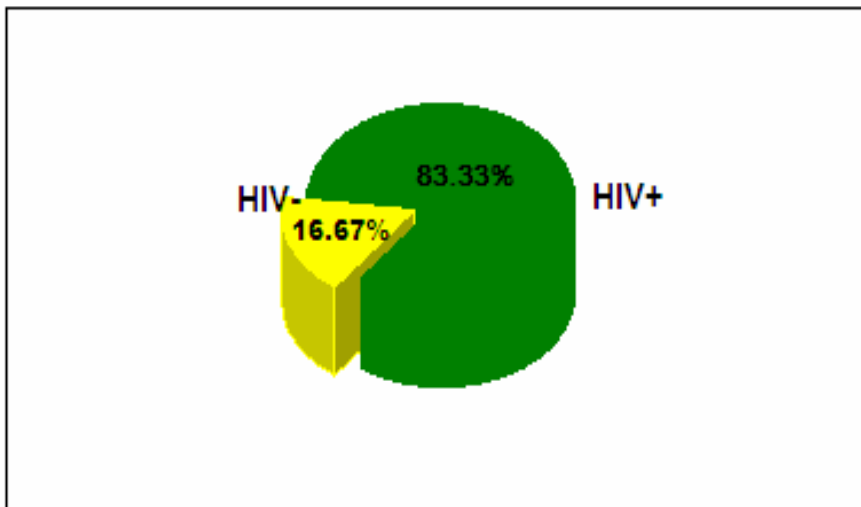


Figure 2 showing distribution according to HIV serostatus.



#### 4.1.2. Age distribution

As shown in the table, all patients were adults > 14 years of age. Arbitrarily, aged patients were > 35 years. 134/300 (51.30 %) were < 35 years; 146/300 (48.70 %) were older than 35 years. In the HIV+ group, 129/250 (51.60 %) were under age of 35 years and 121/250 (48.40) were over age 35.

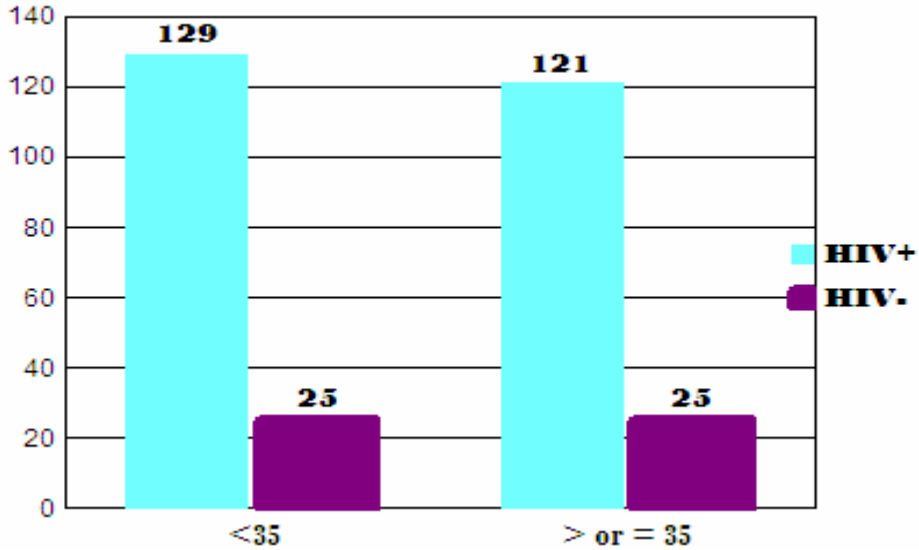


Figure 3 showing age distribution in the two groups.

#### 4.1.3. Gender distribution

Of the 300 patients in the study, 174/300 (58 %) were female and 126/300 (42 %) were male. 146/250 (58.4 %) of females were HIV+ and 104/250 (41.60 %) of males were HIV+. Male/female occurrence in both groups is approximately equal. However, there were more females in the study, and more females were HIV+. HIV- persons were 28/50 (56%) female and 22/50 (44 %) male.

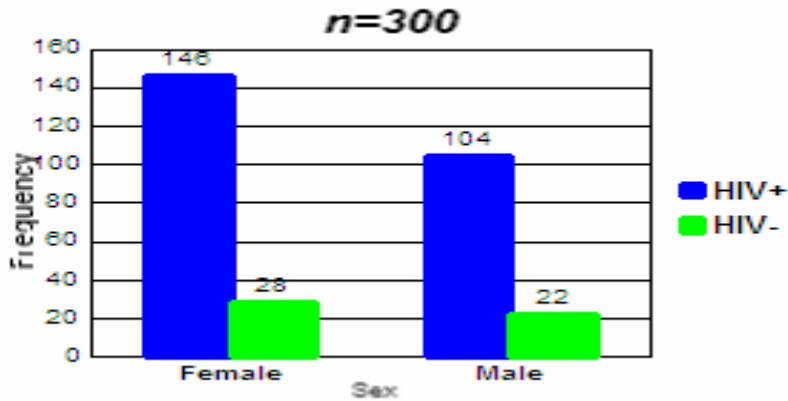


Figure 4 showing gender distribution.

#### 4.1.4. Distribution according to level of education

Of the 300 participants in the study, 171/300 (57 %) had primary education and 84/300 (28 %) had secondary education. In the HIV+ group, 149/250 (59.60 %) had primary and 68/250 (27.20 %) had secondary education. In the HIV- group, 22/50 (44 %) had primary and 16/50 (32 %) had secondary education. In the HIV+ group, 149+68 (217)/250 (87 %) had both primary and secondary education.

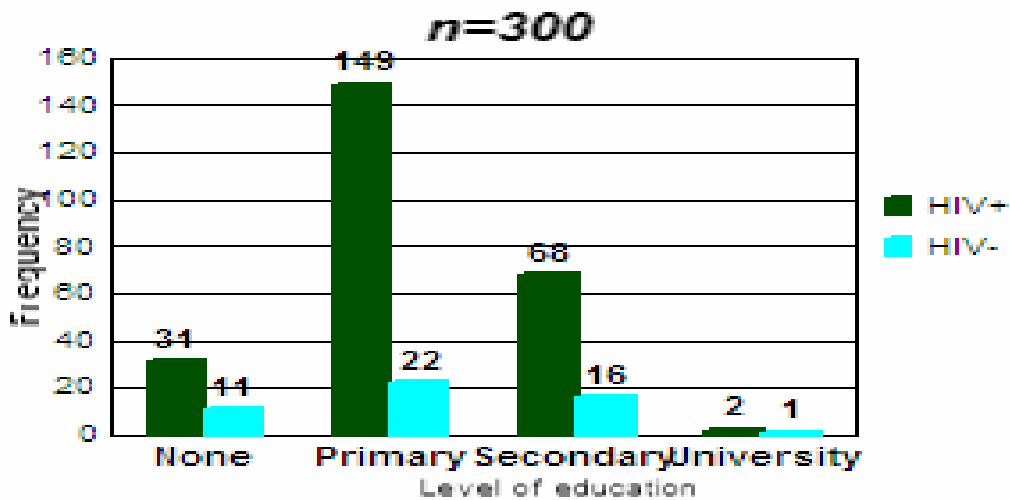


Figure 5 showing distribution according to level of education.

**4.1.5. Distribution according to marital status**

Of the 300 cases in the study, 92+23 (115)/300 were married (38.30%); 85+5 (90)/300 (30 %) were widowed and 32+9 (41)/300 (13.60 %) were separated. In the HIV+ group, 92/250 (36.80 %) were married, 85/250 (34 %) were widowed and 32/250 (12.80 %) were separated. In contrast, in the HIV- group, 23/50 (46 %) were married and only 5/50 (10 %) were widowed.

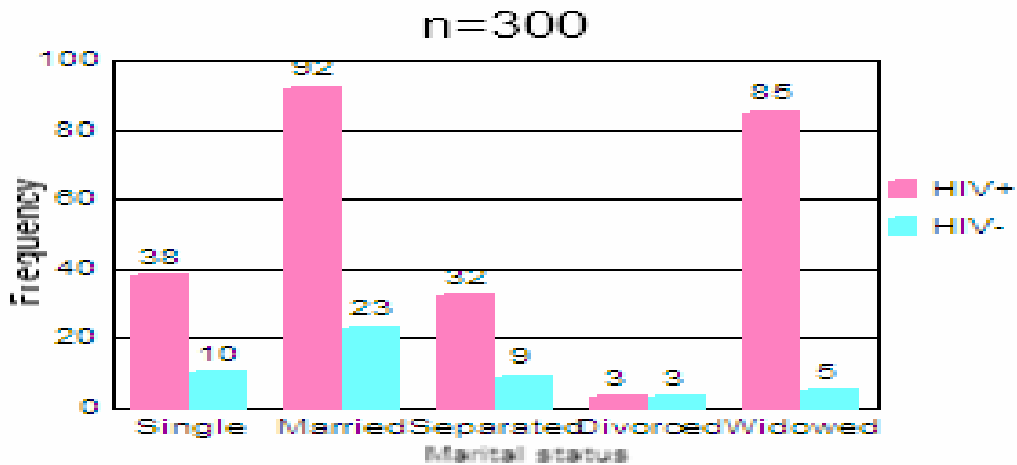


Figure 6 showing distribution according to marital status.

**4.1.6. Distribution according to the self-reported health status**

Of the 300 participants, 115/300 (38.30 %) perceived themselves as healthy and 185/300 (61.70 %) considered themselves ill.

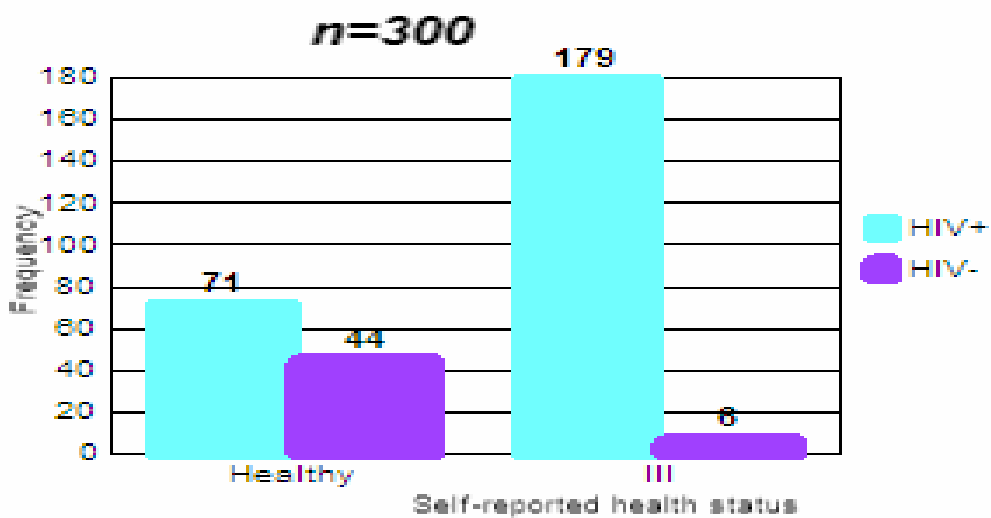


Figure 7 showing distribution according to self-reported health status.

#### 4.2. Characteristics of the HIV positive group

##### 4.2.1. Distribution according to the mode of HIV transmission

In this study, transmission of HIV was heterosexual in 235/250 (94 %), by traditional medicine in 2/250 (0.80 %) and unknown in 13/300 (5.20 %).

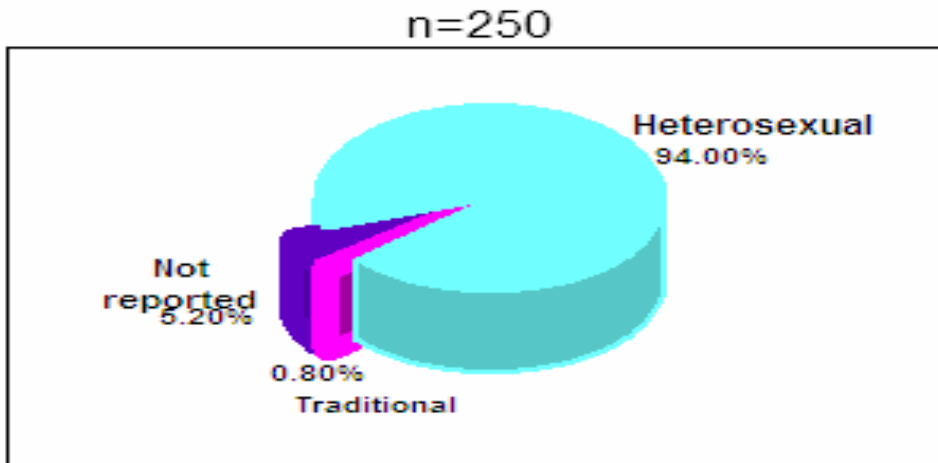


Figure 8 showing the mode of HIV transmission

##### 4.2.2. Distribution according to HIV stage

Categorization according to HIV stage indicates that 145/250 (58 %) were in WHO stage I and 63/250 (25.20 %) were in WHO stage II. 145+65 (208)/250 (83.20 %) were either in stage I or II. Only 31+11 (16.80 %) were in advanced stages III and IV.

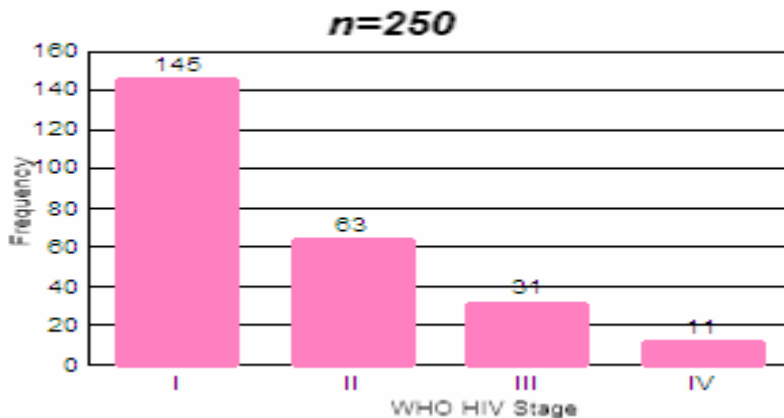


Figure 9 showing WHO HIV stage.

### 4.2.3. Distribution according to CD4 cell counts

45/250 (18 %) had CD4 count  $\leq 200/\text{mm}^3$  and 51/250 (20.40 %) had CD4 between 201-500/ $\mu\text{l}$ . 96/250 (38 %) had CD4 cell counts between 200 and 500. A large number of participants (135/250 (54.00 %) had not yet a CD4 count.

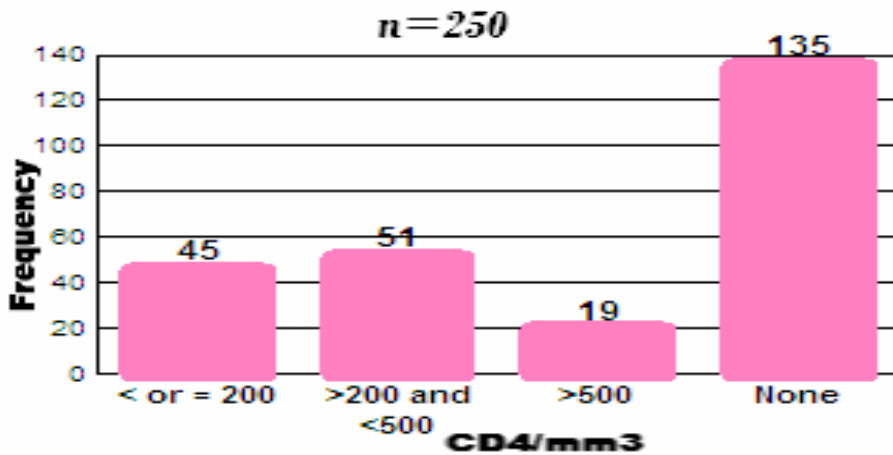


Figure 10 showing CD4 cell counts.

### 4.2.4. Distribution according to antibiotic prophylaxis

The following figure shows distribution according to antibiotic prophylaxis. Most of patients received no prophylaxis (162/250, 64.8%). 81/250 (32.4%) received bactrim.

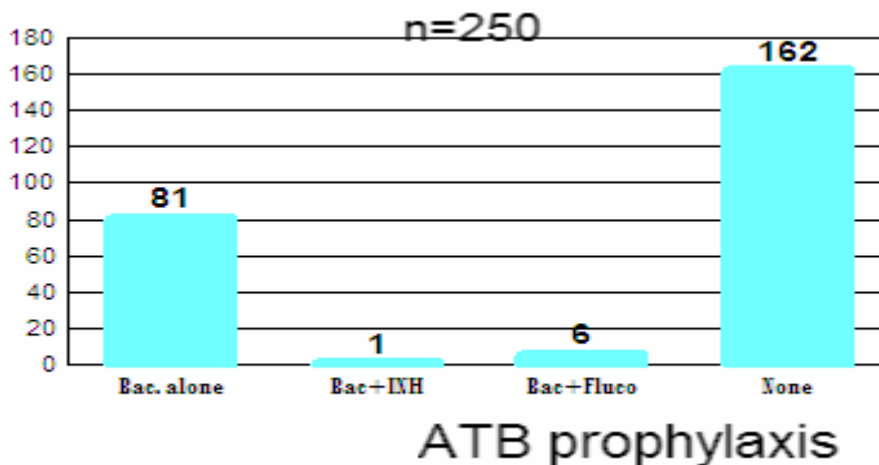


Figure 11 showing distribution according to antibiotic prophylaxis.

#### 4.2.5. Distribution according to ART regimen

Only a small proportion of patients were on ART (58/250 (23.20 %)).

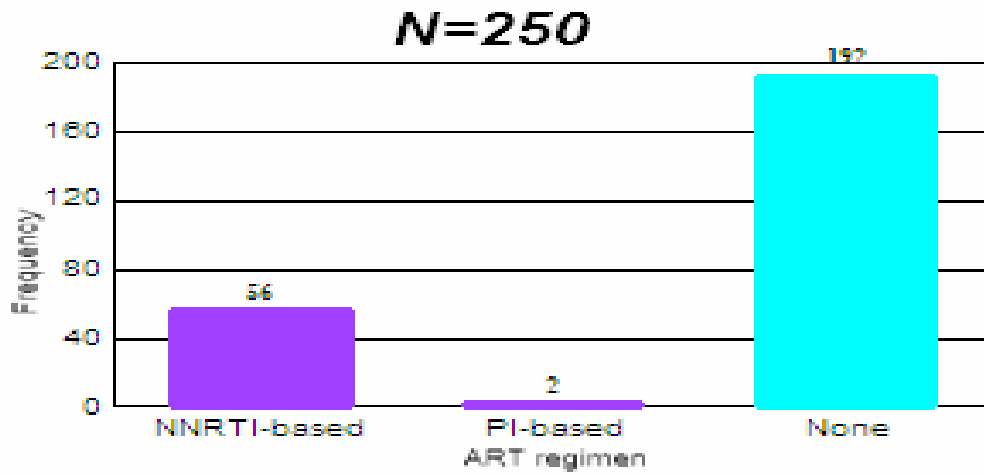


Figure 12 showing distribution according antiretroviral therapy.

**4. 3. The WHOQOL-BREF psychometric properties.**

**4.3.1. Reliability: Internal consistency (Cronbach’s alpha) of WHOQOL-BREF Domain Scores**

Cronbach’s alpha is a single summary statistic that gives some idea of reliability of the survey. It is a mathematical construct which attempts to identify the proportion of variability of responses to questionnaires. In this study, Cronbach’s alpha was calculated for both HIV+ and HIV- respondents. The test describes the lower boundary of reliability. The domain scores are almost identical in both groups, and overall score is > 0.70. Scores range between 0.24 (social) and 0.65 (physical).

<b>WHOQOL-BREF Domain</b>	<b>HIV+ (n =250)</b>	<b>HIV- (n =50)</b>	<b>Total (n = 300)</b>
<b>Domain 1</b>	<b>0.64</b>	<b>0.67</b>	<b>0.65</b>
<b>Domain 2</b>	<b>0.47</b>	<b>0.37</b>	<b>0.45</b>
<b>Domain 3</b>	<b>0.23</b>	<b>0.30</b>	<b>0.24</b>
<b>Domain 4</b>	<b>0.50</b>	<b>0.41</b>	<b>0.48</b>
<b>Total (24 items)</b>	<b>0.74</b>	<b>0.74</b>	<b>0.74</b>
<b>Total (26 scale items)</b>	<b>0.76</b>	<b>0.77</b>	<b>0.76</b>

Table 1 showing the internal consistency reliability.



**4.3.2. Reliability: 2-week test-retest reliability (ICC) of WHOQOL-BREF Domain Scores and overall quality of life and health satisfaction items for portion of HIV+ subsample.**

A 2-week test-retest reliability was done with a 45 HIV positive subsample. The numbers are short of the original 250 HIV+ sample, suggesting the possibility of bias in the subsample. So intraclass correlation coefficients (ICC) are calculated on the repeat domain scores to reduce bias, comparing test and retest data. The p values for all domains are all less than  $p < 0.05$ . This suggests a high degree of correspondence with test and retest domains.

<b>WHOQOLBREF domains</b>	<b>HIV+ (n=48)</b>	<b>p</b>
<b>Domain 1</b>	<b>0.70</b>	<b>0.00</b>
<b>Domain 2</b>	<b>0.69</b>	<b>0.00</b>
<b>Domain 3</b>	<b>0.50</b>	<b>0.01</b>
<b>Domain 4</b>	<b>0.57</b>	<b>0.00</b>
<b>G 1</b>	<b>0.69</b>	<b>0.00</b>
<b>G 2</b>	<b>0.67</b>	<b>0.00</b>

CI 95%,  $p < .05$

Table 2 showing the test-retest reliability

**4.3.3. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to gender.**

The scores of the 4 domains and overall quality of life and overall health satisfaction are practically the same except in the physical domain where there is a statistically significant difference ( $p < 0.05$ ) in the female HIV + patients. Physical disability in the females is suggested.

	<b>Male (n = 126 )</b>	<b>Female (n =174)</b>	<b>p</b>
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>68.2 (16.4)</b>	<b>63.5 (16.3)</b>	<b>0.02</b>
<b>Domain 2</b>	<b>63.4 (12.8)</b>	<b>65.6 (13.6)</b>	<b>0.16</b>
<b>Domain 3</b>	<b>53.2 (14.4)</b>	<b>56.7 (16.7)</b>	<b>0.47</b>
<b>Domain 4</b>	<b>44.5 (11.3)</b>	<b>46.7 (11.4)</b>	<b>0.1</b>
<b>G 1</b>	<b>33.7 (22.0)</b>	<b>32.6(17.9)</b>	<b>0.64</b>
<b>G 2</b>	<b>43.9 (26.4)</b>	<b>43.1 (25.1)</b>	<b>0.81</b>

*Independent sample t-tests*

$P < .05$ .

Table 3 showing domain scores and overall quality of life and health satisfaction items according to gender.

**4.3.4. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to age.**

The scores in the physical domain is higher in the younger age group with a statistically significant difference ( $p < .01$ ). This would suggest more physically robust health in the younger age group compared to the more elderly HIV patients who may have increasing physical disability.

	<b>&lt; 35 (n =154 )</b>	<b>≥ 35 (n =146)</b>	<b>p</b>
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>68.8 (14.1)</b>	<b>61.9 (18.1)</b>	<b>0</b>
<b>Domain 2</b>	<b>63.4 (13.3)</b>	<b>66.0 (13.2)</b>	<b>0.1</b>
<b>Domain 3</b>	<b>54.2 (15.8)</b>	<b>56.3 (15.8)</b>	<b>0.27</b>
<b>Domain 4</b>	<b>45.9 (11.3)</b>	<b>45.53 (11.5)</b>	<b>0.75</b>
<b>G 1</b>	<b>30.0 (19.0)</b>	<b>36.3 (19.9)</b>	<b>0.01</b>
<b>G 2</b>	<b>40.1 (24.5)</b>	<b>46.9 (26.4)</b>	<b>0.02</b>

*Independent sample t-tests*

Table 4 showing domain scores and overall quality of life and health satisfaction items according to age.

**4.3.5. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to self-reported health status.**

Scores in the psychological domain and overall quality of life and health satisfaction were high in the self-reported “healthy” and showed statistically significant difference ( $p < .01$ ). Compared to the “ill”, scoring for psychological domain is improved and possibly reflects a more “stable” psychological state with higher quality of life and health satisfaction in the healthy group. However, not all “healthy” patients are HIV- since only 50 HIV- persons were recruited. So, it is so possible that  $115 - 50 = 60 / 300$  (21.90 %) “healthy” patients are HIV+.

	<b>Ill (n =185 )</b>	<b>Healthy (n = 115)</b>	<b>p</b>
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>64.8 (16.0)</b>	<b>66.5 (17.3)</b>	<b>0.4</b>
<b>Domain 2</b>	<b>61.4 (12.9)</b>	<b>69.9 (12.2)</b>	<b>0</b>
<b>Domain 3</b>	<b>53.4 (15.5)</b>	<b>58.2 (15.9)</b>	<b>0.01</b>
<b>Domain 4</b>	<b>45.8 (10.5)</b>	<b>45.6 (12.7)</b>	<b>0.9</b>
<b>G 1</b>	<b>28.4 (17.8)</b>	<b>40.7 (20.3)</b>	<b>0</b>
<b>G 2</b>	<b>39.1 (23.7)</b>	<b>50.4 (27.1)</b>	<b>0</b>

*Independent sample t-tests*

$P < 0.01$

Table 5 showing domain scores and overall quality of life and health satisfaction items according to self-reported health status.

**4.3.6. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to HIV status.**

Of the 300 cases recruited, 250/300 (83.3%) were HIV positive and 50/300 (16.6%) HIV negative. Differences in domain scores were seen in domain 1, G 1 and G 2. No differences were seen in psychological, social and environmental domains. So, based on HIV status, the HIV+ patient has statistically significant physical disability as well as significant impairment of overall QOL and satisfaction with health.

	<b>HIV+ (n = 250)</b>	<b>HIV- (n = 50)</b>	<b>p</b>
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>63.9 (16.6)</b>	<b>73.5 (13.5)</b>	<b>0</b>
<b>Domain 2</b>	<b>64.8 (13.4)</b>	<b>64.2 (12.7)</b>	<b>0.8</b>
<b>Domain 3</b>	<b>54.9 (15.6)</b>	<b>57.2 (16.9)</b>	<b>0.37</b>
<b>Domain 4</b>	<b>45.9 (11.3)</b>	<b>44.8 (11.9)</b>	<b>0.54</b>
<b>G 1</b>	<b>30.6 (19.0)</b>	<b>45.5 (18.7)</b>	<b>0</b>
<b>G 2</b>	<b>42.8 (25.0)</b>	<b>46.5 (28.6)</b>	<b>0.4</b>

*Independent sample t-tests*

*P<0.01*

Table 6 showing domain scores and overall quality of life and health satisfaction items according to HIV status.

**4.3.7. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to CD4 count (cells/ $\mu$ L)**

Of the HIV+ cases (250/300, 83.3%), only 115/250 (46%) had CD4 counts done. While numbers were small in all categories (< or = 200, 200-500, >500), differences were seen in domains 1, 3, and G 2. Impairment of physical health was seen with CD $\leq$  200 (domain1), but inexplicably, social functioning and overall health satisfaction was improved compared to higher CD4 counts. Differences were statistically significant compared to CD4>200.

	$\leq$ 200 (n =45)	201-500 (n = 51)	> 500 (n = 19)	<i>p</i>
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>48.7 (16.8)<sup>a,b</sup></b>	<b>59.5 (13.4)</b>	<b>66.2 (11.0)</b>	<b>0.00</b>
<b>Domain 2</b>	<b>67.1 (12.4)</b>	<b>68.8 (12.2)</b>	<b>65.2 (15.6)</b>	<b>0.56</b>
<b>Domain 3</b>	<b>60.5 (15.3)<sup>a,b</sup></b>	<b>53.6 (11.2)</b>	<b>52.0 (18.3)</b>	<b>0.03</b>
<b>Domain 4</b>	<b>43.8 (13.6)</b>	<b>45.8 (11.0)</b>	<b>47.8 (12.2)</b>	<b>0.47</b>
<b>G 1</b>	<b>32.8 (19.1)</b>	<b>32.8 (16.2)</b>	<b>30.3 (10.5)</b>	<b>0.83</b>
<b>G 2</b>	<b>56.1 (27.8)<sup>a,b</sup></b>	<b>46.1 (18.3)</b>	<b>36.8 (24.1)</b>	<b>0.01</b>

*One-way analysis of variance; missing n = 35*

<sup>a</sup> *CD4  $\leq$  200 compared to CD4 201-500 (P < .05)*

<sup>b</sup> *CD4  $\leq$ 200 compared to CD4 > 500 (P < .05)*

<sup>c</sup> *CD4 201-500 compared to CD4 >500 (P < .05)*

Table 7 showing domain scores and overall quality of life and health satisfaction items according to CD4 count (cells/ $\mu$ L)

**4.3.8. WHOQOL-BREF domain scores and overall quality of life and health satisfaction items according to WHO disease stage (I, II, and III & IV combined)**

HIV positive patients at stages III and IV had their physical and environmental dimensions negatively affected compared to early stages. In early stages, those in stage II had their psychological dimension impaired compared to stage I. In stages III and IV, overall quality of life was impaired as well as impairment of physical and environmental health.

	I (n = 145)	II (n = 63)	III & IV (n = 42)	p
<b>WHOQOL-BREF Domains</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	
<b>Domain 1</b>	<b>68.4 (13.3)<sup>b</sup></b>	<b>64.1 (18.7)<sup>c</sup></b>	<b>48.0 (14.0)</b>	<b>0.00</b>
<b>Domain 2</b>	<b>66.5 (12.3)<sup>a</sup></b>	<b>61.5 (16.0)</b>	<b>63.4 (12.0)</b>	<b>0.04</b>
<b>Domain 3</b>	<b>54.4 (14.9)</b>	<b>52.9 (18.6)<sup>c</sup></b>	<b>59.6 (11.7)</b>	<b>0.08</b>
<b>Domain 4</b>	<b>47.7 (10.5)<sup>b</sup></b>	<b>45.8 (11.8)<sup>c</sup></b>	<b>40.2 (11.6)</b>	<b>0.00</b>
<b>G 1</b>	<b>31.9 (18.0)</b>	<b>29.8 (24.1)</b>	<b>27.4 (12.2)</b>	<b>0.37</b>
<b>G 2</b>	<b>41.4 (22.1)<sup>b</sup></b>	<b>40.5 (28.6)<sup>c</sup></b>	<b>51.2 (27.6)</b>	<b>0.06</b>

*One-way analysis of variance*

<sup>a</sup> Stage I compared to Stage II ( $P < .05$ )

<sup>b</sup> Stage I compared to Stage III and IV combined ( $P < .05$ )

<sup>c</sup> Stage II compared to Stage III and IV combined ( $P < .05$ )

\* Stage III (n = 31); Stage IV (n = 11)

Table 8 showing domain scores and overall quality of life and health satisfaction items according to WHO disease stage.

## 5. DISCUSSION

In our series, sampling followed recommendations of WHOQOL-BREF (14).

Age distribution was comprehensive for most adults. 51.30 % were young adults < 35 years, and 48.70 % were elderly. Similar proportions were reported by Giovanni (85) and Shekhar (86).

Education level appeared satisfactory and reached 87.00 % in the HIV+ group. Thus, there is reasonable expectation that candidates would understand instruction and complete questions. Primary and secondary education levels of adults were also reported by Fang and others (82%), Giovanni and others (87.40 %), Temsak and others (68 %) and Casado and others (68 %) (85, 87-89). Probably, high figures in this series could be accounted for by the locale of sampling which was situated in the heart of Kigali, capital of Rwanda, where candidates could, at least, attend school.

Most candidates were married (38 %) but 34 % were widowed. Other studies showed larger numbers of married candidates 41.70 % (90), 50 % (91) and 66.70 % (88). While speculative, the high percentage of widows may be related to the 1994 Rwandan genocide and marital separation due to HIV.

It appears that perception of health is a relative term, and not necessarily related to HIV status. 115/300 (38.30 %) perceived themselves healthy, but since only 50/300 were HIV negative, a proportion of healthy persons were HIV positive. This underlines that perception of health is very subjective and does not necessarily indicate chance of disease. Fang and others (87) showed 80 % reporting they were healthy and Starace and others (90) reported 82 % reporting they were healthy.

The majority of the population in both series was on antiretroviral therapy and was HIV+. In 235/250 (94 %), the mode of HIV transmission was heterosexual. In 2/250 (0.80 %), mode of transmission was unknown and in 13/250, transmission was “traditional”. Our study supports the premise that heterosexual transmission is chief mode of transmission in Sub-Saharan Africa. Traditional medicine is not infrequently seen in Kigali, and while not demonstrated here, experience indicates that the frequent use of sharp instruments, razor blades, knives is not uncommon in traditional medicine.



A peculiarity of our series is the high percentage of patients who were in early HIV stages I and II (83 %). Possibly this reflects tendency of patients to test HIV serostatus early, but the exact explanation is unclear.

Only 45/250 (18 %) had a CD4 count done. Since CD4 counts are requirements for inclusion in treatment, it is possible that CD4 had not been obtained for the vast majority of candidates at the commencement of the study. Similarly, only 23 % were receiving ARV drugs and this is related to costs and only recent availability of ARV through international organizations and drug companies for our patients. It is also possible that, absence of ARV therapy reflects processing of HIV+ patients who yet require eligibility testing to be done.

Psychometric properties indicate good internal consistency (reliability) but Cronbach's alpha summary statistic showed impaired reliability in the physical, psychological, and environmental domains but with acceptable overall quality of life and health satisfaction. A reliability score of 0.70 or greater is considered "acceptable" (93). Overall quality of life was 0.74 and overall health satisfaction 0.76.

2-week test-retest reliability shows intraclass correlation coefficients  $p$  for domain scores to be less than  $p < 0.05$  for all domains indicating good correlation between test and retest values. Cronbach's alpha is, however, still lower in social and environmental domains but acceptable in physical and psychological domains.

Using independent sample t tests, impairment in the physical domain is present in the females, which is statistically significant ( $p < 0.02$ ). Scoring is also higher in the younger age group, in general, compared to the elderly with statistically significant difference ( $p < 0.01$ ).

Patients who consider themselves "healthy" have higher scores in the psychological domain and overall quality of life and overall health satisfaction with statistically significant differences ( $p < 0.01$ ).

In the HIV+, impairment of physical health, overall quality of life and health satisfaction is present which is statistically significant.

Using one way ANOVA, patients with  $CD4 < 200/\mu l$  have poorer physical health, but better social relationships and better health satisfaction with statistically significant differences ( $p < 0.05$ ) compared to those with  $CD4 > 200/\mu l$ .

HIV patients in stages III and IV have impairment of physical and environmental dimensions compared to early stages.

## 6. CONCLUSION AND RECOMMENDATIONS

### 6. 1. CONCLUSION

In this study, 38 % were married, but almost an equal percentage was widowed (34 %). Some HIV+ subjects reported good health indicating that perception of health is very subjective and does not exclude the probability of HIV infection. The principal mode of transmission of HIV is heterosexual, but in 5.20 %, transmission is via implement used in practice of traditional medicine. For reasons somewhat unclear, 83 % of cases of HIV infection are in WHO stages I and II.

Psychometric properties of this study show good internal consistency reliability. Cronbach's alpha statistic shows "unacceptable" reliability in physical, psychological, social and environmental domains but acceptable quality of life and overall health satisfaction.

Test-retest reliability (2 weeks) shows good correlation between test and retest, but Cronbach's alpha scores are still low in social and environmental domains. Independent sample *t* tests indicate impairment of the physical domain in the female and probably in the aged. Overall, the HIV+ individual has impairment of physical health, and overall quality of life and health satisfaction. HIV+ patients in WHO stages III and IV have impairment of physical health and environmental functioning compared to earlier stages.

ANOVA shows HIV+ patients with CD4<200/ $\mu$ l have poorer physical health but better social relationships and better health satisfaction.

## **6.2. RECOMMENDATIONS**

1. Health care professionals are encouraged to become familiar with the full spectrum of predictors of HRQOL, which may eventually contribute to the development of multiple entry points for interventions in promoting improved QOL in patients with HIV infection.
2. Social support, coping and other psychiatric factors need particular attention in care of HIV-carriers.
3. Identifying variables influencing QOL among diverse groups, particularly women, and old persons, and designing effective interventions specific to the social and psychological well-being of HIV-infected individuals are areas for research.
4. Longitudinal studies should be encouraged in QOL issues and quality of life assessment ought to be included in studies of efficacy of drugs as outcome measures.
5. Nutrition and social welfare should be implied in the care and management of HIV infection and donors are particularly recommended to take into account such an issue in their funding programmes.

## 7. REFERENCES

1. GUYATT GH, FEENY DH, PATRICK DL. Measuring HRQOL. *Annals of Internal Medicine*, 1993, 118, 622-629.
2. PATRICK DL, ERICKSSON P. Health Status and Health Policy. QOL in Health Care Evaluation and Resource. 1993, 4, 56-61.
3. CATALAN J. Psychiatric manifestations of HIV disease. *Bailliere's Clinical Gastroenterology*, 1993, 4, 547-562.
4. SAAG MS. Natural History of HIV-1 disease. In *Textbook of AIDS Medicine* (Broder et al.), Williams & Wilkins, Baltimore, 1994, 45-53.
5. UNAIDS/WHO WORKING GROUP ON GLOBAL HIV/AIDS AND STD SURVEILLANCE. Report on the Global HIV/AIDS Epidemic, December 2004, UNAIDS/WHO, Geneva. 2004.
6. MINISTRY OF HEALTH, GOVERNMENT OF THE REPUBLIC OF RWANDA. Health indicators: HIV/AIDS and other epidemics. [Online]. [http://www.moh.gov.rw/health\\_indicator.html](http://www.moh.gov.rw/health_indicator.html). Accessed June 2, 2005.
7. WU AW, MATHEWS WC, BRYSK LT, et al. QOL in placebo-controlled trial on Zidovudine in patients with AIDS and AIDS - related complex. *Journal of Acquired Immune Deficiency Syndromes*, 1990, 3, 683-690.
8. WACHTEL T, PIETTE J, MORE V, et al. QOL in persons with HIV infection: measurement by the MOS instrument. *Annals of Internal Medicine*, 1990, 116, 129-137.
9. RAGSDALE D, MORROW JR. QOL as a function of HIV classification. *Nursing Research*, 1990, 39, 355-359.
10. LARYEA M, GIEN L. The impact of HIV-positive diagnosis on the individual, Part 1. *Clinical Nursing Research*, 1993, 2, 245-266.
11. HAYS RD, SHAPIRO MF. An overview of generic HRQOL measures for HIV research. *Quality of Life Research*, 1992, 1, 91-97.
12. WU A, RUBIN HR. Measuring health status and QOL in HIV/AIDS. *Psychology and Health*, 1992, 6, 251-264.
13. HOLZEMER WL, WILSON HS. QOL and the spectrum of HIV infection. *Annual review of Nursing Research*, 1995, 13, 3-29.
14. WHOQOL Group: Development of the WHO WHOQOL-BREF quality of life assessment. *Psychological Medicine*, 1998, 28, 551-558.

15. PLATO. Euthyphro, Apology, Crito. Church FJ, trans. New York: Bobbs-Merrill.1956, 12-78.
16. KOVAC D. QOL: a megaconcept of coming époque. *Psychology Science*, 2004, 46(I), 167-186.
17. COHEN C. On the QOL: some philosophical reflections. *Circulation. Suppl III*, 29-33.
18. ARISTOTLE. Nicumachean ethics. Ostwald M, trans. New York: Bobbs-Merrill, 1962. Cited in Aiken W. *The QOL Applied Philosophy*, 1982, 1, 26-36.
19. BENTHAM J. Deontology: Together with a table on the springs of action and article on utilitarianism. Goldworth A, ed. Oxford: Clarendon Press. 1834/ 1983, 23-30.
20. MORE T. Utopia. London: Chatto and Windus Publishers, 1516/1908, 20-26.
21. ROYCE J. The philosophy of loyalty, Lecture IV, section IV. New York: Macmillan. 1908.
22. DRAPER P. QOL as quality of being: an alternative to the subject-object dichotomy. *Journal of Advanced Nursing*, 1992, 1, 965-70.
23. AIKEN W. The QOL. *Applied Philosophy*, 1982, 1, 26-36.
24. HAYRY M. Measuring the QOL: why, how and what? *Theory of Medicine*, 1991, 12, 97-116.
25. BUBOLZ M, EICHER JB, EVERS SJ et al. A human ecological approach to QOL: conceptual framework and results of a preliminary study. *Social Indicators Research*. 1980, 7, 103-36.
26. SUZANNE MS, KATHRYN AO. Measuring quality of life in HIV and AIDS: a review of the recent literature. *Psychology and Health*, 2003, 18, 3, 331-350.
27. The Calvert Henderson Quality of Life Indicators. On line at [www.calvert-henderson.com/index.htm](http://www.calvert-henderson.com/index.htm). Accessed May 12, 2005.
28. LYNDA CD, STEPHEN PM. Defining PROs. *Value in Health*, 2004, suppl. 1, 7, S4-S8.
29. WHO. The International Classification of Impairment, Disabilities and Handicaps. Geneva: WHO.1980.
30. WHO. International Classification of Functioning and Disability: ICFIDH-2. Stationary Office Books. November 1999.

31. CANTRIL H. The pattern of human concerns. New Brunswick: Rutgers University Press. 1965, 1-10.
32. ANDREWS FM. Social indicators of perceived life quality. *Social Indicators Research*, 1974, 1, 279-99.
33. BRADBURN NM, CAPLOVITZ D. Reports on happiness: a pilot study of Behaviour related to mental health. Chicago: Aldine, 1965.
34. DUPUY HJ. The psychological general well-being index (PGWB). In: WENGER NK, MATTSON ME, FURBERG CD et al, eds, *Assessment of QOL in clinical trials of cardiovascular therapies*. New York: LeJacq Publishing, 1984, 123-150.
35. NAESS S. The concept of QOL. In: BJORK S, VANG J, eds, *Assessing QOL*. Linkoping, Sweden: Health Service Studies, 1989, 47-58.
36. NORDENFELT L. Towards a theory of happiness: a subjectivist notion of QOL. In: NORDENFELT L, ed., *Concepts and measurement of QOL in health care*. London: Kluwer Academic Publishers, 1994.
37. DURKHEIM ES, SPAULDING JA, SIMPSON G, trans. New York: The Free Press, 1897/1951, 1-5.
38. PARSONS T. Definition of health and illness in the light of American values and social structure. In: GARTLY GE, ed., *Patients, physicians and illness: A sourcebook in behavioural science and health*. New York: Free Press, 1958, 34-41.
39. ROKEACH M. The nature of human values. New York: Free Press, 1973, 1-8.
40. KAPLAN RM, FEENY D, REVICKI DA. Methods for assessing relative importance in preference based outcome measures. *Quality of life research*, 1993, 2, 467-75.
41. Van DAM F. QOL: methodological aspects. *Cancer Bulletin (Paris)*, 1986, 73, 607-13.
42. WENGER NK, MATTSON ME, FURBERG CD et al. *Assessment of QOL in clinical trials of cardiovascular therapies*. New York: LeJack, 1984, 130-139.
43. PATRICK DL, BERGNER M. Measurement of health status in 1990s. *Annual Review of Public Health*, 1990, 11, 593-600.
44. TORRANCE GW. Utility approach to measuring HRQOL. *Journal of Chronic Diseases*, 1987, 40, 593-600.

45. LEVINE S, CROOG SH. QOL and the patient's response to treatment. *Journal of cardiovascular Pharmacology*, 1985, 7 (suppl 1), S132-S136.
46. SPILKER B. Adopting higher standards for QOL trials. In: Spilker B, ed., *QOL assessment in clinical trials* (2<sup>nd</sup> ed.). New York: Raven Press, 1996, 371-378 and 729-732.
47. TENNANT A, MCKENNA SP. Conceptualising and defining outcome. *British Journal of Rheumatology*, 1995, 34, 899-900.
48. HEINMANN AW, WHITENECK CG. Relationships among impairment, disability, handicap and life satisfaction in persons with traumatic brain injury. *Journal of Head Trauma Rehabilitation*, 1995, 10, 54-63.
49. WHITENECK GG. Measuring what matters: key rehabilitation outcomes. *Archives of Physical Medicine and Rehabilitation*, 1994, 75, 1073-6.
50. BRADLEY C. Importance of differentiating health status from QOL. *Lancet*, 2001, 357, 7-8.
51. SHEIN CC, FANNY YCK. Statistical issues in QOL assessment. *Journal of Biopharmaceutical statistics*, 1996, 6 (1), 37-48.
52. TANDON PK. Application of global statistics in analysing QOL data. *Statistics in Medicine*, 1990, 9, 819-827.
53. OLSCHEWSKI M, SCHUMACHER M. Statistical analysis of QOL data in cancer clinical trials. *Statistics in Medicine*, 1995, 9, 749-63.
54. KI FYC, CHOW SC. Statistical justification for the use of composite score in quality assessment. *Drug Information Journal*, 1995, 29, 715-27.
55. SOREN V. Measuring QOL: from theory to practice [online]. Quality of life research Centre, 2004. Available on: [www.livskvalitet.org](http://www.livskvalitet.org) accessed May 2005.
56. BERGNER M, ROTHMAN ML. Health status measures: an overview and guide for selection. *Annual Review of Public Health*, 1987, 8, 191-210.
57. MEDINA AL. Quality of life assessment in HIV infection [online]. Liverpool School of Tropical Medicine, 2005. Available on: [www.who.int/entity/hiv/strategic/en/antoniotta\\_media\\_lara\\_qol.ppt](http://www.who.int/entity/hiv/strategic/en/antoniotta_media_lara_qol.ppt). Accessed May 2005.
58. LYNDA CD, DAVID MM, HANNE T. Requirements for QOL instruments in clinical research. *Value in health*, 2004, suppl 1, 7, S13-S16.
59. FLETCHER RH, FLETCHER SW, WAGNER EH. *Clinical epidemiology: the essentials*, 3<sup>rd</sup> ed., Williams and Wilkins, 1996, 21-24.



60. VAN SIGHEM AI, VAN DE WIEL MA, GHANI AC, et al. Mortality and progression to AIDS after starting highly active antiretroviral therapy. *AIDS*, 2003, 17, 2227-2236.
61. ICKOVICS JR, MEADE CS. Adherence to antiretroviral therapy among patients with HIV: a critical link between behavioural and biomedical sciences. *JAIDS*, 2002, 31(suppl 3), S98-S102.
62. MURDAUGH C. Health-related quality of life in HIV disease: achieving a balance. *J Assoc Nurses AIDS Care*, 1998, 9, 59-71.
63. DOUAIHY A, SINGH N. Factors affecting quality of life in patients with HIV infection. *AIDS Reader*, 2001, 11, 450-454, 660-661, 475
64. AMMASSARI A, MURRI R, PEZZOTTI P, et al. Self-reported symptoms and medication side effects influence adherence to highly active antiretroviral therapy in persons with HIV infection. *JAIDS*, 2001, 28, 445-449.
65. GALLANT JE. Strategies for long-term success in the treatment of HIV infection. *JAMA*, 2000, 283, 1329-1334.
66. KOTLER DP. Management of nutritional alterations and issues concerning quality of life. *Journal of Acquired Immune Deficiency Syndromes*, 1997, 16(suppl 1), S30-S35.
67. BABAMETO G, KOTLER DP. Malnutrition in HIV infection. *Gastroenterol Clin North Am*, 1997, 26, 393-415.
68. WILCOX CM, RABENECK L, FRIEDMAN S. AGA technical review: malnutrition and cachexia, chronic diarrhoea, and hepatobiliary disease in patients with human immunodeficiency virus infection. *Gastroenterology*, 1996, 111, 1724-1752.
69. FERRI RS, ADINOLFI A, ORSI AJ, et al. Treatment of anaemia in patients with HIV infection, part 1: the need for adequate guidelines. *J Assoc Nurses AIDS Care*, 2001, 12, 39-51.
70. SULLIVAN PS, DWORKIN MS, for the Adult and Adolescent Spectrum of HIV Disease Investigators. Prevalence and correlates of fatigue among persons with HIV infection. *J Pain Symptom Management*, 2003, 25, 329-333.
71. ELLER LS. Quality of life in persons living with HIV. *Clinical Nursing Research*, 2001, 10, 401-423.
72. REVICKI DA, BROWN RE, HENRY DH, et al. Recombinant human erythropoietin and health-related quality of life of AIDS patients with anaemia. *JAIDS*, 1994, 7, 474-484.
73. LEFKOWITZ M. Pain management for the AIDS patient. *J Fla Med Assoc*, 1996, 83, 701-704.
74. MARTEDNEZ E, GARCIA-VIEJO MA, BLANCH L, et al. Lipodystrophy syndrome in patients with HIV infection: quality of life issues. *Drug Safety*, 2001, 24, 157-166.
75. CATALAN J, KLIMES I, DAY A, ET AL. The psychosocial impact of HIV infection in gay men: a controlled investigation and factors associated with psychiatric morbidity. *Br J Psychiatry*, 1992, 161, 774-778.
76. DUPRAS A, MORISSET R. Sexual dysfunction among HIV-positive gay males. *Sex Marital Therapy*, 1993, 8, 37-45.

77. TINDALL B, FORDE S, GOLDSTEIN D, et al. Sexual dysfunction in advanced HIV disease. *AIDS Care*, 1994, 6, 105-107.
78. CATALAN J, MEADOWS J. Sexual dysfunction in gay and bisexual men with HIV infection: evaluation, treatment and implications. *AIDS Care*, 2000, 12, 279-286.
79. LASHLEY F. Sleep alterations. In: Ropka ME, Williams AB, eds. *HIV Nursing and Symptom Management*. Boston: Jones and Bartlett Publishers, 1999, 471-483.
80. HAYS RD, CUNNINGHAM WE, SHERBOURNE CD, et al. Health-related quality of life in patients with human immunodeficiency virus infection in the United States: results from the HIV Cost and Services Utilization Study. *Am J Med*, 2000, 108, 714-722.
81. KATZ MH, DOUGLAS JM JR, BOLAN GA, et al. Depression and use of mental health services among HIV- infected men. *AIDS Care*, 1996, 8, 433-442.
82. GRIFFIN KW, RABKIN JG, REMIEN RH, et al. Disease severity, physical limitations and depression in HIV-infected men. *J Psychosom Res*, 1998, 44, 219-227.
83. NILSSON SCHONNESSON L. Psychological and existential issues and quality of life in people living with HIV infection. *AIDS Care*, 2002, 14, 399-404.
84. National Coalition of Anti-Violence Programs. *AntiLesbian, Gay, Bisexual and Transgender Violence in 2002. A report of the National Coalition of Anti-Violence Programs*. 2003.
85. GIOVANNI DE GIROLAMO, PAOLA RUCCI, PAOLO SCOCCO et al. La valutazione della qualita della vita : validazione del WHOQOL-Breve. *Epidemiologia e Psichiatria Sociale*, 2000, 9, 1, 45-55.
86. SHEKHAR S, DAWN C, REX B et al. The WHO quality of life assessment instrument (WHOQOL-Bref): The importance of its items for cross-cultural research. *Quality of Life Research*, 2001, 10, 711-712.
87. FANG CT, HSIUNG PC, YU PC, et al. Validation of the World Health Organization quality of life instrument in patients with HIV infection. *Quality of Life Research*, 2002, 11, 753-762.
88. TEMSAK P, RACHAMOL K, SOMCHAI W, ET AL. Quality of Life Assessment in Radiotherapy Patients by WHOQOL-BREF-THAI: A Feasibility Study. *Journal of Medical Association Thailand*, 2004, 87, 12, 1459-65.
89. CASADO A, CONSIGLIO E, PODZAMCZER D, et al. Highly active antiretroviral treatment and HRQOL in naïve and pre-treated HIV-infected patients. *HIV Clinical trials*, 2001, 2(6), 477-483.
90. STARACE F, CAFARO L, ABRESCIA, et al. Quality of life assessment in HIV-positive persons: application and validation of the WHOQOL-HIV, Italian version. *AIDS care*, 2002, 14, 3, 405-415.
91. JOHN ME, NDEBBIO TJ, UDOMA EJ. Perceived psychosocial needs, social support and quality of life in subjects with HIV/AIDS. *Global Journal of Medical Sciences*, 2003, 2, 2, 171-175.
92. THE WHO AND UNAIDS. Expert group stresses that unsafe sex is primary mode of transmission of HIV in Africa. Geneva, March 2003. [Online] [www.who.int/mediacentre/news/statements/2003/statement5/en/](http://www.who.int/mediacentre/news/statements/2003/statement5/en/). Visited on May 24, 2005.
93. MIN SK, KIM KI, LEE CI, et al. Development of the Korean versions of WHO quality of life scale and WHOQOL-BREF. *Quality of Life Research*, 2002, 11, 593-600.

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## **9. APPENDICES**

### **i. ASSESSMENT OF QOL USING WHOQOL-BREF INSTRUMENT**

The WHOQOL-BREF and similar instruments were designed to obtain information about quality of life outside biological markers such as viral load, CD4 counts, and occurrence of opportunistic infections. However, it might be construed, that in chronic diseases such as HIV or cancers, that many aspects of life that might be disturbed such as physical ability, psychological functioning, social relationships, relationship with environment and spiritual concerns.

In our present state of knowledge, information about these aspects needs to be obtained from the patients (patient-reported outcomes (PROs) usually by questionnaire. Assessment instruments are beset with difficulties. Obtaining reliable and valid responses to questions may be difficult especially if the patient is unaware of difficulty. Scores may be difficult to interpret, because with large samples, many comparisons may reach statistical significance.

There are no gold standards by which one can compare instrument scores and it is unknown how much change in instrument scores represents a detectable change in patient status. Finally, despite analytic instruments, the method is subjective.

In the WHOQOL-BREF, after sampling and demographic information have been obtained, the questionnaire and its results need evaluation.

There are 24 questions, all of which were obtained from the much larger WHOQOL-100, which are placed in 4 categories or domains - physical, psychological, social and environmental - presumably because answers to these questions will assist in elaboration of difficulties in these areas. The number of questions in each domain differs - 7 physical, 6 psychological, 3 social and 8 environmental. The reason for these differences appears to be that they provide similar information that could be obtained from larger number in WHOQOL-100. The candidate scores these questions according to a 5-point scale, to the degree that they are true for them. Agreement varies between 1-5 (disagree to completely agree, very dissatisfied to very satisfied) and are quantified (1 (0%), 2(25%), 3(50%), 4(75%), 5(100%).

2 more questions are added (WHOQOL-BREF) related to quality of life and life satisfaction. The scores are then transformed for statistical analysis.

The results are compiled and scores for each domain obtained.

There are no gold standards for either questions or domains. The scores will be low where there is disagreement with individual questions or cumulative questions in each domain; and conversely scores will be high with agreement. Since there are no gold standards to compare results, then there are no true values for evaluation. As a result, one settles for the lesser goal of assessing reliability or reproducibility to obtain some sense of the quality of measurements to each other rather than comparing them with true values.

**ii. The WHOQOL-BREF domains and facets**

<b>Domain</b>	<b>Facets incorporated within domains</b>
<b>Physical health</b>	<ul style="list-style-type: none"> <li>➤ <b>Activities of daily living (Q3)</b></li> <li>➤ <b>Dependence on medicinal substances and medical aids(Q4)</b></li> <li>➤ <b>Energy and fatigue (Q10)</b></li> <li>➤ <b>Mobility (Q15)</b></li> <li>➤ <b>Pain and discomfort (Q16)</b></li> <li>➤ <b>Sleep and rest (Q17)</b></li> <li>➤ <b>Work Capacity (Q18)</b></li> </ul>
<b>Psychological</b>	<ul style="list-style-type: none"> <li>➤ <b>Bodily image and appearance (Q11)</b></li> <li>➤ <b>Negative feelings (Q26)</b></li> <li>➤ <b>Positive feelings (Q5)</b></li> <li>➤ <b>Self-esteem (Q19)</b></li> <li>➤ <b>Spirituality / Religion / Personal beliefs (Q6)</b></li> <li>➤ <b>Thinking, learning, memory and concentration (Q7)</b></li> </ul>
<b>Social relationships</b>	<ul style="list-style-type: none"> <li>➤ <b>Personal relationships (Q20)</b></li> <li>➤ <b>Social support (Q22)</b></li> <li>➤ <b>Sexual activity (Q21)</b></li> </ul>
<b>Environment</b>	<ul style="list-style-type: none"> <li>➤ <b>Financial resources (Q12)</b></li> <li>➤ <b>Freedom, physical safety and security (Q8)</b></li> <li>➤ <b>Health and social care: accessibility and quality (Q24)</b></li> <li>➤ <b>Home environment (Q23)</b></li> <li>➤ <b>Opportunities for acquiring new information and skills (Q13)</b></li> <li>➤ <b>Participation in and opportunities for recreation / leisure activities (Q14)</b></li> <li>➤ <b>Physical environment (pollution / noise / traffic / climate)(Q9)</b></li> <li>➤ <b>Transport (Q25)</b></li> </ul>

iii. Questionnaire on QOL assessment in adults with HIV infection

1. POPULATION CHARACTERISTICS

1. ID N°:
2. Age: -  $\leq 34$    
 -  $\geq 35$
3. Sex: M/F
4. Marital status: - Married   
 - Divorced   
 - Widowed   
 - Separated   
 - Single
5. Education: None   
 Primary   
 Secondary   
 University
6. Mode of transmission: Heterosexual   
 Homosexual   
 Transfusion   
 IV drug user   
 Birth   
 None
7. Are currently ill? Yes/No
8. HIV stage: I   
 II   
 III   
 IV
9. Current CD cell count (/mm<sup>3</sup>)  $\leq 200$    
 201-500   
 > 500   
 None
10. Prophylaxis: Bactrim  Bactrim+INH :   
 Isoniazide  Bactrim+Fluconazole :   
 Fluconazole   
 None
11. Current ART: None   
 PIs-based regimens   
 NNRTIs-based regimens

## 2. WHOQOL-BREF

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer.

		Very poor	Poor	Neither poor nor good	Good	Very good
1 (G1)	How would you rate your QOL?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
2(G4)	How satisfied are you with your life?	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme Amount
3(F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8(F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9(F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last 2 weeks.

		Not at all	A little	Moderately amount	Mostly	Completely
10(F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11(F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12(F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13(F20.1)	How available to you is information that you need in your day-to-day life?	1	2	3	4	5
14(F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very Good
15(F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very Satisfied
16(F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17(F10.3)	How satisfied are you with your ability to perform your daily activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19(F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5



24(F19.3) )	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3) )	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26(F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?

How long did it take to fill this form out?

Do you have any comments about the assessment?

.....  
 .....

**THANK YOU FOR YOUR HELP.**

#### **iv.COMPARING THREE OR MORE MEANS: ANALYSIS OF VARIANCE**

To compare the mean outcomes in three or more exposure groups, the procedure used is the one-way analysis of variance (ANOVA). As in the t-test, the null hypothesis is that the groups are equivalent (they represent random samples from hypothetical source population with identical outcome means). The procedure divides the total variance among all study subjects into two portions (a. portion accounted for by the differences between the groups INTERGROUP VARIANCE and b. portion due to differences among subjects of within the same group INTRAGROUP VARIANCE). The larger the former relative to the latter (F-ratio), the less likely that the differences among group means is due to chance. The t-test for two independent group means is merely a special case of the one-way ANOVA F-test when the number of groups is two.

The primary result of a one-way ANOVA is a p value representing an overall test of the null hypothesis. If  $p < .05$ , one infers that the source population means are not equivalent.

The investigator, however, is usually interested to find out which group or groups are responsible for the overall difference. Different pairs of groups can then be compared but p values must be adjusted to account for multiple testing unless all tests are statistically independent of one another.

Should it be desired to study the effects of two or more exposures (or treatments) simultaneously (e.g. males versus females + drug) at various intervals in time, one can carry out separate t-tests for men and women. A TWO WAY ANALYSIS OF VARIANCE (ANOVA) provides both greater statistical efficiency and an opportunity to test for a sex difference independent of treatment. Analysis of the main effect, the treatment difference, is more statistically efficient because it uses data from both sexes simultaneously, instead of from just one at a time.

When two main effects are being studied, both can be assessed simultaneously without requiring doubling of sample size that would be necessary in two separate studies.

This study design is called a “two-way factorial design” and provided sample size is sufficient to yield adequate subject numbers in each subgroup formed by

combination, ANOVA methods can be extended 3-way, 4-way for larger number of study effects.

#### v. Cronbach's alpha

Reliability and reproducibility refer to the extent to which the results of measurement can be replicated. In the presence of a stable phenomenon, these terms refer to the extent that repeated measurements at different times and places get similar results.

Reproducibility also refers to some specific instrument for testing reliability ( eg test-retest).

Cronbach's alpha is a single summary statistic that gives an idea how reliable a survey is. It is a mathematical construct which attempts to define reliability in terms of the proportion of variability in responses which is a result of differences in the respondents. Thus, in a survey, answers may differ because of different opinions of respondents, and not necessarily because questions are confusing or have multiple interpretations. In this respect, it is a measurement of instrument variability. Cronbach's alpha, also, specifically identifies the lower boundary of true reliability in a survey. It is a ratio based on the number of items in a survey (k) and the average inter-item covariance to the average item covariance.

$\alpha = \frac{k \text{ cov} / \text{var}}{1 + (k-1) \text{ cov}/\text{var}}$  ( SPSS Base 9.0, Application guide; Cronbach, LJ, 1951.

Coefficient alpha and internal structure of tests.

Psychometrika 16: 3, 291-334).

In our study, Cronbach's alpha was used to calculate domain scores, 2-week test-retest reliability and internal consistency.

While there is no evidence that Cronbach's alpha is a "gold standard", investigation in QOL assessments consider 0.70 as an "acceptable" value.

In WHOQOL-HIV, alpha value was above 0.70 in 22/28 sections and between 0.53-0.68 in remaining 6 sections (90).

In WHOQOL-BREF (Taiwan), Cronbach's alpha coefficients ranged between 0.70-0.77 (87).

In WHOQOL-100 (Taiwan), Cronbach's alpha for internal consistency ranged from 0.74-0.85 across domains (87).

In Korean WHOQOL-100 and WHOQOL-BREF (93), social domain value 0.58 should be treated with caution because it is based on only 3 scores: physical, psychological, and environmental important, but not social.

#### **vi. REPRODUCIBILITY**

Reproducibility is assessment of reliability by repeated testing of the target population to determine if QOL measures will yield the same result, assuming no changes have occurred in the target population. Testing may occur with the same instrument at a later time (2 weeks, 4 weeks) separated by a sufficient length of time long enough to wear off memory of previous evaluation but not long enough to allow change in environment (test-retest). Alternatively, the same instrument could be used, but two independent observers independently assess patients (inter-rater reliability).

Split-Half testing is used where respondents are unwilling or unable to take the questionnaire a second time. The items are split into two groups then compared, as if they were two separate administrations of the same survey.

Cronbach's alpha values may be recalculated from retest scores but this is often impractical because bias may hence have been introduced in the second set of answers.

Intraclass correlation coefficients for domain scores can be calculated between the initial and retest data to assess bias. If test-retest correlation is >80 %, then retest figures are probably reliable.

In our study, "p" is significantly high and this is assessment with elevated scores in physical, psychological, social and environmental domains compared to initial Cronbach's alpha scores.

vii. *GUFATA ICYEMEZO*  
(CONSETEMENT ECLAIRE)  
(INFORMED CONSENT)

**Ubushakashatsi bwo gutohoza imibereho y'ubuzima y'abafite ubwandu bw'agakoko ka SIDA**

*(Evaluation de la qualité chez les personnes adultes vivant avec l'infection au VIH)*  
*(Quality of life assessment in adults living with HIV infection)*

Muraho Madamu, Muraho Bwana,

Turimo gukora ubushakashatsi kugira ngo dushobore kumenya neza imibereho mu buzima ku bantu bakuru bafite ubwandu bwa SIDA. Kubera iyo mpamvu, tubasaba gusubiza ibisubizo byerekeranye n'iyi mibereho bikaba byerekeye ibibazo umuntu ahura nabyo mu buzima bwa buri muni.

Turabasaba ko mwashyira umukono ahagana hasi kuri uru rupapuro niba mwemeye kugira uruhare muri ubu bushakatsi.

Tukaba tubijeje ibanga ku bisubizo muratanga.

Niba mufite ibindi ibibazo, twiteguye kubibasubiza.

Izina ry'umurwayi .....

(Nom du (de la) participant (e))

(Participant's names)

**Yego, nemeye kugira uruhare muri ubu bushakashatsi  
( Oui, je suis d'accord à participer dans cette étude)  
( Yes, I do agree to participate in the study)**

Italiki.....

(Date)

Umukono.....

(Signature du (de la) participant(e))

(Participant's signature)

Murakoze kudufasha

(Merci pour votre participation)

(Thank you for your participation)