ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE AMONG PEOPLE LIVING WITH HIV/AIDS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY IN TEMEKE MUNICIPALITY, DAR ES SALAAM.

By

Emmanuel Lugina

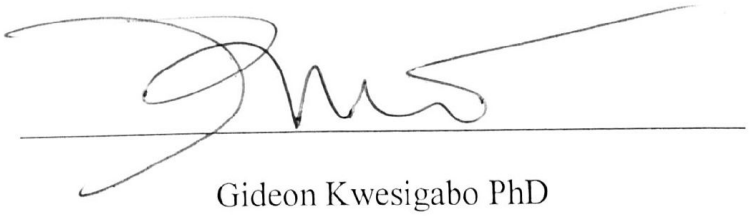
A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree of Master of Public Health of the Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that has read and hereby recommends for acceptance by Muhimbili University College of Health and Allied Sciences a dissertation entitled **Assessment of health-related quality of life among people living with HIV/AIDS on highly active antiretroviral therapy in Temeke municipality, Dar es salaam** in partial fulfilment of the requirements for the degree of Master of Public Health of the Muhimbili University of Health and Allied Sciences.



Gideon Kwesigabo PhD

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Date: 2nd November 2007

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I, **Emmanuel Lugina,** declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

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First and fore most I praise the Lord for strengthening me and for being my shepherd during the course of my studies. I could have not made it without him.

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To the staff of HIV/AIDS Care and Treatment units in Temeke, the atmosphere reigning within them made my work enjoyable.

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To my family, very deep and heartfelt appreciation for their devoted and unconditional support as well as for sponsoring me to pursue this course.

DEDICATION

To Helen and Max, my mother and father.

I say thank you.

ABSTRACT

HIV/AIDS gives rise to incurable, debilitating disease and treatments capable of prolonging survival are often associated with toxicity. When curative treatments do not exist, improvement in health-related quality of life (HRQOL) is the primary objective of therapeutic interventions.

The study aimed at investigating health-related quality of life and its predictors in people living with HIV/AIDS (PLWHA) who are on highly active antiretroviral therapy (HAART) and to make a comparison with the local general population data set.

An analytical and comparative cross-sectional study was undertaken in 200 randomly selected people living with HIV/AIDS on HAART in Temeke Municipality in Dar es salaam. The study included the SF-36 for assessing HRQOL and additional items for assessing socio-demographic and medical characteristics. The HRQOL of the PLWHA was compared to the normative data of 3802 residents in Dar es salaam using a t-test. The comparison of SF-36 mean scores of PLWHA stratified by socio-demographic and medical characteristics were done by using the t-test and one-way ANOVA. Both univariate and multivariate analyses of variance were done. The relationships between mean scores of SF-36 and predictors of health related quality of life was assessed using multiple linear regression.

The internal consistent coefficients (Cronbach's alpha) of the seven out of eight scales of the SF-36 ranged from 0. 72 to 0. 95. Only general health scale had a low cronbach's

alpha (0.52). The mean scores of the PLWHA for the eight scales ranged from 62.0 to 92.37 significantly lower than the mean scores of the general population in four of the eight SF-36 scales. Old age, being a female, being divorced, low education status, low religiosity, low CD4+ cell count, recent hospitalization and higher HIV/AIDS clinical stages were associated with poor HRQOL.In addition long duration since first HIV positive test and long duration of being on HAART were associated with higher HRQOL. In conclusion, HIV/AIDS deteriorates people's quality of life.

From this study, it is recommended that the use of self reported HRQOL as a monitoring and evaluation tool in addition to the conventional medical tests will provide a holistic approach of caring PLWHA.

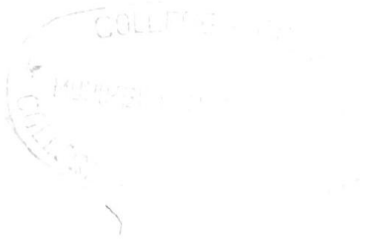


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issemination of research findings

he following bodies will be provided with a copy of this study; Muhimbili University of lealth and Allied Sciences library, Municipal Executive Director's office-Temeke lunicipality and Ministry of Health and Social Welfare.

List of abbreviations

AIDS	Acquired Immuno Deficiency Syndrome
APROCO	Antiprotease Cohort
BP	Bodily Pain
CTC	Care and Treatment Center
CDC	Centers for Disease Control and Prevention
GH	General Health
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immuno Deficiency Virus
HRQOL	Health-Related Quality of Life
MCS	Mental Component Summary measure
MH	Mental Health
MHS	Mental Health Summary
MOS-HIV	Medical Outcomes Study-HIV
NACP	National AIDS Control Program
PCS	Physical Component Summary measure
PF	Physical Functioning
PLWHA	People Living with HIV/AIDS
PHS	Physical Health Summary
QOL	Quality of Life
RE	Role Emotional
RP	Role Physical

F	Social Functioning
F-36	Short Form-36
PS	Spiritual Perspective Scale
ACAIDS	Tanzania Commission for AIDS
/T	Vitality
VHO	World Health Organization

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CHAPTER ONE

1.0 Introduction

1.1 An overview of HIV/AIDS epidemic

The human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) pandemic is the greatest challenge to public health all over the world. Promising developments have been seen in recent years in global effort to address AIDS epidemic including access to effective treatment and prevention programmes. However, the number of people living with HIV continues to grow, as the numbers of deaths due to AIDS. A total of 39.5 million people were living with HIV in 2006- 2.6 million more than 2004.

In many regions of the world, new HIV infections are heavily concentrated among young people (15-24 years of age). Among adults 15 years and older, young people accounted for 40% of new HIV infections in 2006. Sub-Saharan Africa continues to bear the brunt of the global epidemic. Two thirds (63%) of adults and children with HIV globally live in sub-Saharan Africa, with its epicenter in southern Africa. One third (23%) of all people with HIV globally live in southern Africa and 34% of all deaths due to AIDS in 2006 occurred here.

Access to treatment and care has greatly increased in recent years, albeit from very low starting levels in many countries. Nevertheless, the benefits are dramatic. Through the expanded provision of antiretroviral treatment an estimated two million life years were gained since 2002 in low- and middle-income countries. In sub-Saharan Africa alone,

some 790,000 life years have been gained, the majority of them in the past two years of anti retroviral scale-up. In Latin America, where wide scale treatment provision began earlier, some 830,000-life years have been gained since 2002.

In East Africa, where HIV infection levels have been lower than in the south of the continent, the general trend of a stabilizing or a declining HIV prevalence appears to be continuing. National HIV prevalence among pregnant women has declined in Kenya, as it has in Tanzania and, to a lesser extent in Rwanda (UNAIDS/WHO., 2006).

In Tanzania, the first three AIDS cases were clinically diagnosed and reported in 1983 in Kagera region. The first three cases were, however, followed by a rapid spread of epidemic, such that by 1986 all regions of Tanzania mainland had reported AIDS cases (NACP., 2004).

HIV/AIDS is a serious public health problem in Tanzania second only to malaria (Tanzania Commission for AIDS., 2005).

Tanzania being among sub-Saharan countries that are mostly affected by the epidemic had a 7% of adults aged 15-49 years infected with HIV between the period of 2003-2004 (Ministry of Health., 2004).

In 2002 Tanzania, the government in collaboration with different partners initiated activities for scaling up care treatment for PLWHA. By the end of 2006 there were approximately 49,315 people living with HIV/AIDS in Tanzania who were on HAART. This progressive expansion of access to HAART is expected to significantly increase the survival of HIV-infected individuals and therefore pose a major challenge to health

professionals, researchers and policy makers interested in mitigating the impact of HIV/AIDS.

When curative treatments do not exist, improvement in HRQOL is the primary objective of therapeutic interventions.

1.2 Problem statement

In recent decades, HRQOL has gained importance as an outcome measure in health care, especially with regard to interventions for patients with various chronic diseases. HIV is a retrovirus that causes chronic, progressive immunological dysfunction. HIV infection is characterized by a long period with no or minor symptoms during which the virus causes the declining of T-helper CD4+ lymphocytes.

Low levels of T-helper CD4+ lymphocytes are associated with opportunistic infections and HIV related malignancies. Today there is no cure for HIV infection. Treatment is concentrated on delaying HIV's suppression of immune system and/or preventing opportunistic infections and cancers.

In the era of new antiretroviral treatments and prophylaxis treatment for opportunistic infections that have dramatically reduced morbidity and mortality and transformed HIV/AIDS into a chronic illness, the primary goal is to maximize function and well being in the everyday life of HIV-infected patients. To be able to do so, it would be important for clinicians and policy makers to identify factors that influence health-related quality of life (HRQOL).

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However measurement of health-related quality of life is still in evolution worldwide and especially in Africa. Very few studies have been undertaken towards understanding patients' experience of integrating HIV/AIDS as a chronic illness into ones life and impact of therapy on quality of life (Tsasis., 2000).

Besides clinical outcomes, health-related quality of life (HRQOL) and disability are important issues for persons treated for chronic diseases. At the HIV/AIDS care and treatment clinics, the monitoring of HIV/AIDS patients who are on HAART is done by using CD4+ cell count, viral load, full blood count and biochemistry. Anyhow it is not enough to assess care of people living with HIV/AIDS by using medical tests only. In order to get a holistic picture of the outcome of PLWHA care it is important to measure patient's own perception about his/her health. It is very important to monitor and evaluate care of PLWHA from a medical perspective as well as from patients themselves. Evaluation of health-related quality of life is important in any life prolonging therapy.

The concept of health-related quality of life among people living with HIV/AIDS has not yet been explored at all in Tanzania. As the government of Tanzania is in the process of scaling up HAART provision to PLWHA there is a need to investigate health-related quality of life of this population.

The SF-36 questionnaire had previously been used in diabetic patients attending the Muhimbili National Hospital diabetes clinic. However some problems were found regarding the general health scale because it showed low internal consistency (a=0.59) in this domain. This problem might have arisen because SF-36 was created for use in western countries with a different culture. It might be that further translation procedures have to be done to make it more applicable as health-related quality of life assessment tool in our setup.

The main interest of this study was to further explore the concept of health-related quality of life. In view of the above, the focus in this study was to compare health-related quality of life in two groups of people namely; PLWHA who are on HAART and the general population. Moreover this study aimed at determining predictors of health-related quality of life of PLWHA who are on HAART.

1.3 Rationale of the study

Evaluation of HRQOL makes it possible to understand the link between therapeutic effectiveness and subjective evaluation of the treatment, but also to estimate more precisely how people live and take their treatment in context of HIV/AIDS. For example, when one therapy is only marginally more efficacious than another, but has significant toxicity, HRQOL measures can facilitate the integration of these estimates of effectiveness, taking into account multiple factors, including efficacy, safety, tolerance, and direct and indirect costs and savings. HRQOL can also play an important role in

distinguishing between two treatments of apparently equal efficacy (e.g., no difference in term of primary endpoint such as progression to disease) via the identification of the one that demonstrates a greater improvement in HRQOL domains such as social function. For example, people may report missing fewer workdays, or children may exhibit fewer behavior problems with a certain treatment. Therefore, evaluation of people and families affected by HIV/AIDS is enhanced by integrating functioning and well being with clinical parameters, as well as considering the family structure, and the quality of support networks and social environment. When curative treatments do not exist, improvement in HRQOL is the primary objective of therapeutic interventions.

Assessment of HRQOL has been found to enhance communication between patients and providers and allows patient to emphasize those areas of HRQOL that most concern them. (Detmar et al., 2002)

Tracking HRQOL of PLWHA who are on HAART can identify subgroups with poor physical or mental health and therefore help in development of intervention policies and guide treatment decisions for both patients and providers.

Because development of side effects to HAART can worsen HRQOL and lead to poor adherence, (Ammasari et al., 2001) optimizing HRQOL may improve adherence to therapy and possibly overall survival.

HRQOL measures can also serve as important tools in evaluating programs and services. (Wu et al., 1992)

Given the continuing rise in number of PLWHA who survive, it is important to understand how these people negotiate the complexities of daily life living in the shadow of a foreshortened future.

Finally the study will provide more information on reliability and validity of SF-36 as tool for measuring HRQOL of PLWHA in Tanzania setup.

CHAPTER 2

2.0 Literature review

2.1 Origin of quality of life issues

In recent years, interest has grown in identifying new measures to assess health across different populations and countries (Murray et al., 1994). Traditional indicators such as infant mortality rate and life expectancy at birth have been used as indicators of health in industrialized countries and low-income countries. Although informative, these measures are limited as they evaluate only fatal outcomes and, thus provide no information about morbidity and disability. Furthermore, they do not comprehensively assess health as it is defined by World Health Organization, namely "state of complete physical, mental and social well being and not merely absence of disease or infirmity" (WHO., 1946).

Two main approaches of measuring non-fatal health outcomes exist. One approach focuses on estimating Quality-Adjusted Life Years (QALYs) defining a set of health states spanning from death to perfect health and attaching weights for time spent in each one of them. Disability-Adjusted Life Years (DALYs) have been developed as a type of QALY and have been proposed as a tool for priority setting of health intervention in developing countries (World Bank., 1993).

Another approach is the measurement of self-reported health status or health-related quality of life through standardized questionnaire.

2.2 Definition of Health-Related Quality of Life (HRQOL)

The concept of HRQOL can be traced to 1946 and WHO's definition of health (WHO., 1946).

Several key ideas define the concept of QOL. First is the notion that individuals have their own unique perspective on QOL, which depends on present lifestyle, past experience, hopes for the future, dreams, and ambitions. Second, QOL is generally conceptualized as a multidimensional construct encompassing several domains described as "the individual's perception of their position in life, in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"(WHOQOL Group.,1993). Third, QOL includes a range of perspectives from the more objective to the more subjective. The objective assessment of QOL focuses on what the individual can do. The subjective assessment includes the individual's perception of QOL. Differences in perceptions account for the fact that individuals with the same "objective health status" can report very different subjective QOL. As put forward by WHO that patient's perceptions of, and attributions about the dysfunction are as important as their existence (WHOQOL Group.,1993).

Just as the WHO definition of health transcends the medical model, so too does the term "quality of life" that defines all aspects of patients' well being (including environmental, spiritual and economic health). For purposes of clinical and public health research and practice, however, HRQOL is specific to health and more appropriate, it refers to patients' assessments of their current level of health-related functioning and well being.

2.3 Assessment of HRQOL

There are two distinct approaches to assessing HRQOL: profile and utility based measures (Kaplan.,1998), as summarized below.

Profile-based measures

Generic instruments aim at measuring HRQOL irrespective of the disease or patient population involved. With these instruments, it is possible to compare HRQOL between patient populations (e.g. between HIV-infected patients and patients with cancer). Examples of generic instruments are the SF-36 for adults and the Pediatric Quality of Life Questionnaire (PedsQL) for children.

Disease-targeted instruments are tailored to populations with a specific disease, such as HIV infection or epilepsy. Theoretically, these types of instruments have the main advantages of being more responsive to disease- or treatment-related changes and being more sensitive to group differences within a particular patient population. Examples of these instruments are the Pediatric Oncology Quality of Life Scale targeted at cancer in children and Medical Outcomes Study HIV (MOS-HIV) targeted at HIV disease in adults.

It is not uncommon for a combination of generic and disease-targeted instruments to be used in the assessment of HRQOL. The advantage of these instruments is that they can be used to compare the HRQOL of different patient populations, yet are still sufficiently

sensitive to measure disease-specific changes. Example of the combined approach include the General Health Assessment for Children (GHAC), a combination of generic scales plus an HIV-related symptomatology module (Testa.,1995).

Another approach that has been used to assess HRQOL is to combine scales measured by separate instruments into a comprehensive battery. This approach has the advantage of using psychometrically sound scales that may be best tailored to the research questions at hand. However, batteries tend to be lengthier than single measures and thus may be more burdensome to patients. In addition, the individual scales may employ different response categories, which may be confusing to patients. An example of a battery is the HRQOL instrument developed by Cleary and colleagues for use in AIDS patients (Cleary.,1993).

Depending on the research questions at hand, HRQOL can be measured with a generic instrument (e.g., when the primary goal is to compare the HRQOL of AIDS patients and cancer patients), a disease-targeted measure (e.g., when the aim is to describe the HRQOL among AIDS patients or to evaluate the relative efficacy of 2 AIDS treatments) or a combined instrument (e.g. when both questions are to be addressed).

Preference-based measures

Preference-based measures are based on utility and decision analytical theory and include the assessment of individual preferences for various health states or treatment

outcomes. Utility scores, the ultimate variety of preference-based measures, allow morbidity and mortality data to be combined in a single weighted measure, and thus, have broad applications for evaluation of health care policies and intervention. One example of a preference-based approach is the Quality-Adjusted Time Without Symptoms and Toxicity (Q-TWiST) method, by which treatments are compared in a threshold utility analysis (Gelber.,1992). In this analysis, assumed weights are assigned that reflect the reduction in quality of life associated with adverse events and disease progression.

2.4 How to evaluate HRQOL instruments?

To select an appropriate HRQOL instrument for a particular population, we need to take into consideration both psychometric properties and feasibility of the instrument. Psychometric properties of the instrument include two major concepts: reliability and validity. For self-reported instruments, test-retest reliability and internal consistency reliability can be estimated. Test-retest reliability is the extent to which the instrument generates the same results when administered in a stable patient on more than one occasion. This type of reliability test is more appropriate for measuring traits or characteristics that are relatively stable over time (Patrick.,1989). Internal consistency reliability is the extent to which items in the same composite or scale reflect the same underlying construct. In other words, this indicator measures the extent to which individuals give consistent responses across items belonging to the same scale (de Boer.,1995). Internal consistency is generally deemed adequate when Cronbach's

alpha coefficient (which ranges from 0-1) is 0.7 or higher (Nunnaly.,1978).

Validity is the extent to which measurements reflect the true values of the theoretical construct that the observed variable is supposed to measure (i.e., the correctness of the measurements with respect to the intent of the investigators). Three main types of validity are distinguished (Nunnaly.,1978):

1. Content validity refers to adequate representation of a range of relevant concepts in an instrument
2. Criterion validity refers to the correlation of a new measure with a "gold standard" or to its relationship with an external criterion.
3. Construct validity pertains to the capacity of an instrument to measure the underlying theoretical constructs.

To investigate construct validity, a scale is examined to determine how it correlated with other measures or scales that measure similar (convergent validity) or different (divergent validity) constructs. Another method (the known group method) is to examine whether an instrument can distinguish between groups that are known to differ in clinical status (e.g. asymptomatic and symptomatic patients) (Kerlinger.,1973).

Responsiveness is the aspect of construct validity referring to the ability of an instrument to detect change over time.

Given that application is an integral and dynamic part of the scientific process, selecting an instrument must not only be guided by scientific standards but also by issues that are tangible and pragmatic. Instruments are determined as 'feasible' if participants can complete them within a reasonable period without or with minimal assistance and generate a minimal number of missing values. This property is of particular importance for a self-administered instrument (de Boer et al.,1995).

2.5 The SF-36 instrument

The SF-36 is a multi-purpose, short-form health survey with only 36 questions. It yields an 8-scale profile of functional health and well being as well as psychometrically based health utility index. It is a generic measure, as opposed to those that target a specific disease, age, or treatment group. Accordingly, the SF-36 has proven useful in surveys of general and specific populations, comparing relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments (Ware JE et al., 1993).

SF-36 is one of the widely used HRQOL instrument that has demonstrated a high-level of reliability and validity in diverse patient populations (Ware et al., 1996). The reliability of the eight scales and two summary measures has been estimated using both internal consistency and test-retest methods. With rare exceptions, published reliability statistics have exceeded the minimum standard of 0.70 recommended for measures used in group comparisons in more than 25 studies (Ware et al., 1996); most have exceeded

0.80(Ware et al., 1993). Reliability estimates for physical and mental summary scores usually exceed 0.90(Ware et al., 1994). A review of the first 15 published studies revealed that the median reliability coefficient for each of the eight scales was equal or greater than 0.80 except for SF, which had a median reliability across studies of 0.76 (Ware et al., 1993).

A study was done in Tanzania to assess the validity of the Kiswahili version of SF-36 Health Survey (SF-36) among an urban population in Tanzania using the method of known-groups validation. A total of 3802 individuals were randomly selected from a demographic surveillance system in Dar es salaam. Health status differences were hypothesized among groups, who differ in sex, age, socio-economic status and self reported morbidity. The results showed that women had significantly lower mean SF-36 scale scores than men on all scales and scores were lower for older people than the younger on all domains as hypothesized. On five of the eight SF-36 scales, means were higher for people of higher socio-economic status. People who reported an acute or chronic illness scored significantly lower on all scales compare to those who were healthy. The median internal consistency reliability of the eight scales was 0.84 (range 0.70-0.92). Furthermore, it was pointed out that floor effects were low, but on five of eight scales ceiling effects were high. The authors raised questions whether this is related to translational issues or cultural norms or whether this reflects good health status of a comparatively young population. However, ceiling effects on these scales where much lower for people with an acute illness, disability or chronic conditions sustaining

the hypothesis that SF-36 scale score in the subgroup of health people echo sound levels of health. The study concluded that mean scale scores of people in this sample might serve as the normative values for this adult, urban population (Wyss et al., 1999).

SF-36 is the only HRQOL assessment tool ever to be used in Tanzania. It was used to assess HRQOL in people with diabetes and people without diabetes living in Tanzania. Patients with diabetes reported poorer health and had significantly lower scores than the people without diabetes in seven out of eight health scales. The highest scores in patients with diabetes were found in the physical function scale, while poorest health was reported in the general health scale (Msoka et al., 2006).

2.6 Predictors of HRQOL in HIV/AIDS

The goal of therapy in HIV/AIDS is to improve HRQOL in addition to reduction of symptoms, suppression of virus and extension of survival (Murdaugh et al., 1998). However adverse effects of potent anti retroviral therapies can worsen HRQOL (Douaihy et al., 2001) In addition, symptoms associated with HIV infection and HIV medication side effects can decrease medication adherence, in addition to diminish HRQOL (Ammasari et al., 2001).

A cross-sectional study was done in London to compare health-related quality of life of HIV positive patients with general population data set and to determine the relation between health-related quality of life and markers of disease progression in the era of

highly active antiretroviral therapy (HAART). The study used HRQOL, as measured using Medical Outcome Study HIV Health Survey (MOS-HIV) and EuroQol self report (EQ-5D) questionnaires as the main outcome measure. Responses on EQ-5D were compared with general population data set. Relationship between scores on MOS-HIV and EQ-5D questionnaire and a number of independent variables including CD4+ cell count and viral load were also assessed. After adjusting for differences in age and gender, it was reported that individuals with HIV reported lower health-related quality of life compared with the general population. However further analysis revealed few significant association between markers of disease progression and HRQOL (Miners et al., 2001).

A similar kind of cross-sectional study was conducted by Eriksson et al., (2000) among Swedish HIV positive gay men which also aimed at comparing health-related quality of life between HIV infected men and general population as well as to investigate relation between social and demographic variables with HRQOL.The participants answered Swedish health-related quality of life questionnaire and the health index. The results showed a more negative impact on HRQOL and subjective health status in HIV-positive subjects, compared with male population group. The dimensions of emotional well being were most affected. When comparisons were made according to medical and demographic variables for different subgroups within the HIV sample, differences in the physical dimension scales were most prominent. Symptomatic HIV infection, anti-

retroviral treatment, sick leave or disability pensions, low income and basic education were associated with worst HRQOL and health status.

Findings from the study done by O'Keefe EA., (1996) correlate with the above findings. This was a cross-sectional study with the aim of documenting quality of life in South African HIV subjects, using SF-36 instrument, and to determine whether this was affected by gender, race or clinical stage. The study showed that HIV subjects scored significantly lower than controls on all scales ($p<0.01$); the majority of decline in function occur early in the disease by WHO clinical stages one and two. Furthermore, the impact of HIV on quality of life was independent of racial origin.

Psychosocial, social-demographic and psychological factors can affect HRQOL in HIV infected patients. The diagnosis of HIV infection, in and of itself, can have deleterious ramifications; including discontinuation of work, limitation in social activities, dependence on others, limited social support and poor coping skills can negatively affect HRQOL (Douaihy et al., 2001).

Similar findings were obtained by Hays et al., (2000) who concluded that Social-demographic factors such as old age, female gender, unemployment and low income have been associated with poor HRQO. The aim of this study was to compare the health-related quality of life of adults with HIV with that of the general population and with

patients with other chronic conditions; and to determine the associations of demographic variables and disease severity with health-related quality of life. A battery of 28 items covering eight domains of health (physical functioning, emotional well-being, role functioning, pain, general health perceptions, social functioning, energy, disability days) was administered. The eight domains were combined into physical and mental health summary scores. SF-36 physical functioning and emotional well-being scales were compared with the US general population and patients with other chronic diseases on a 0 to 100 scale. Physical functioning was about the same for adults with asymptomatic HIV disease as for the US population but was much worse for those with symptomatic HIV disease or who met criteria for the acquired immunodeficiency syndrome. Emotional well-being was comparable among patients with various stages of HIV disease, but was significantly worse than the general population and patients with other chronic diseases except depression. In multivariate analyses, HIV-related symptoms were strongly associated with physical and mental health, whereas race, sex, health insurance status, disease stage, and CD4 count were at most weakly associated with physical and mental health.

Another study done in North India with the aim of determining impact of HIV/AIDS on HRQOL also concluded that HRQOL was associated with education, income, occupation, family support and clinical categories of the patients. This was also a cross-sectional study in which HRQOL was evaluated using the WHOQOL-Bref (Hindi) instrument. There was a significant difference of quality of life in the physical domain

between asymptomatic patients and patients with AIDS defining illnesses ($p<0.001$) and asymptomatic and early symptomatic patients ($p=0.014$). QOL in the psychological domain was significantly poorer in early symptomatic ($p<0.05$) and AIDS patients $p<0.006$) as compared to asymptomatic individuals. A significant difference in QOL scores in the psychological domain was observed with respect to the educational status ($p<0.037$) and income of patients ($p<0.048$). Significantly better QOL scores in the physical ($p<0.040$) and environmental domain ($p<0.017$) were present with respect to the occupation of the patients. Patients with family support had better QOL scores in environmental domain.

In another study that sought to further understand how sociodemographic and clinical factors impact the health-related quality of life (HRQL) of people living with HIV/AIDS (PLWHA) it was shown that these factors influenced HRQOL of PLWHA. This study utilized an illness specific measure of HRQOL called Functional Assessment of Human Immunodeficiency Virus Infection (FAHI). Four subscales from the FAHI, physical, emotional, social, and functional/general well being were analyzed as dependent variables. Men reported better physical well being ($p < 0.001$) and better functional well being ($p < 0.05$). Women appear to be particularly vulnerable to adverse quality of life impacts in the physical domains (Rao et al., 2007)

Meng et al., (2007) also had similar findings pertaining the impact of socio-demographic characteristics on HRQOL.The objective of this study was to test the reliability and validity of the SF-36 in assessing the quality of life of people living with HIV in Sichuan province. The quality of life of 114 people living with HIV was assessed against 1604 rural residents in Sichuan province. The internal consistent coefficients (Cronbach's alpha) of the eight scales of the SF-36 ranged from 0. 75 to 0. 92. The respondents who reported worse health scored significantly lower in all of the eight scales. The average scores of the people living with HIV for the eight scales ranged from 21. 4 to 61. 0 significantly lower than the norm of the general rural residents. Age, gender, and length of infection were the major factors that impacted the quality of life of people living with HIV.

In a longitudinal study to assess the long term efficacy of HAART on HRQOL it was shown that immunodepresion and self reported adverse effects were found to be negative predictors of both PCS and MCS. AIDS clinical stage was found to affect physical HRQOL (Protopopescu et al., 2007).

There were no significant differences in QOL when stratified according to CD4 cell count, age groups and CDC staging classification. These were the findings of a descriptive cross sectional study done in Los Angeles, America. The purpose of the study was to describe health-related quality in a multicultural AIDS setting. This study suggested that in the presence of HAART therapy patient CD4+ cell increase and their

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viral loads decrease allowing patients to return to those activities that improved their quality of life. However, depression, fatigue and especially pain seem to continue to be an important component in diminishing HRQOL of persons living with HIV (Johnson et al., 2000).

Similar findings regarding CD4+ cell count were observed by a study done in Italy among HIV positive patients with nonadvanced disease. This study was intended to present evidence for the reliability and validity of an Italian version of the MOS-HIV Health Survey and to identify important disease-related factors associated with health-related quality of life (HRQOL) in people with nonadvanced HIV. In this cross-sectional study, HRQOL was measured using an Italian version of the MOS-HIV Health Survey questionnaire. The level of internal consistency of the Italian version of the MOS-HIV Health Survey was high (Cronbach's alpha, 0.80-0.93), and items demonstrated acceptable discrimination across scales. The study showed that number of pills required to be taken was the only significant factor associated with with HRQOL while no relation was found with CD4+ cell count (Murri et al., 1997).

However a study done by Gill CJ et al., (2002) showed that CD4+ cell count was significantly associated with HRQOL. The objective of this cross sectional study was to understand the relationship of viral load (VL), CD4+ cell counts, and highly active antiretroviral therapy (HAART) use to health-related quality of life (HRQOL). Primary outcomes were four domains of HRQOL: physical functioning (PF), role function (RF),

energy levels (EL), and health perceptions (HP). In univariate analyses, compared with patients with CD4+ > 500, those with CD4+ < 200 (p =0. 001) or 200 to 500 (p =0.002) had lower PF and RF scores, and patients with undetectable VL had higher PF scores than patients with VL log10 2.6 to 4.0 (p =0.02) and > log10 4.0 (p =0.01). In multivariate analyses, compared with patients with CD4+ > 500, patients with CD4+ < 200 had lower PF (p <0.01), RF (p <0.01), and HP (p <0.001). Patients with log10 VL 2.6 to 4.0 had lower PF scores (p <0.01) versus undetectable VL. After adjusting for VL and CD4+counts, HAART use was associated with lower PF scores (p <0.05). The study concluded by suggesting that efforts to improve CD4+ cell count are likely to improve HRQOL. HAART had negative effects on Physical Functioning (PF) that were independent of its effect on CD4+ cell count. For adherent patients these adverse effects of HAART on PF are likely to be outweighed by the positive effect that has on increasing CD4+ cell count.

Another study also showed the association between CD4+ cell count and HRQOL. The objective of this multicentre prospective cohort study was to identify determinants of HRQOL in a cohort of Italian HIV-infected patients, the majority of whom were taking highly active antiretroviral therapy (HAART). The MOS-HIV Health Survey (summarized using two scores, physical health (PHS) and mental health (MHS)), and an HIV-related symptom scale were administered at enrolment and six months later. At baseline, low CD4+ cell count, hospitalization during the three months before the enrollment and symptoms were independently related to poor PHS; hospitalization

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during the three months before the enrollment, symptoms and poor satisfaction with information from providers were independently related to MHS. Predictors of PHS at six months included the stage of HIV infection, baseline CD4+ cells count, PHS and symptom score; while age, baseline MHS, symptom score and education predicted six-month MHS. Among these factors, symptoms, recent hospitalization and satisfaction with information are most amenable to clinical intervention (Murri et al., 2003).

Patrizia et al., (2003) also investigated the impact of the first year of HAART on HRQOL. Medical data for patients in the French APROCO cohort were collected at enrollment and month 12 (M12). A self-administered questionnaire gathered information about HRQOL (Medical Outcome Study 36-Item Short Form Health Survey) and toxicity-related symptoms. Using the twenty-fifth percentile of HRQOL scales in the French population as a threshold, patients with normal values in at least three mental and three physical scales were considered to have a "normal HRQOL. "Of the 1053 patients followed through month 12, HRQOL data at baseline and month 12 were available for 654. Among the 233 patients with a normal baseline HRQOL, 63 (27.0%) experienced a deterioration of HRQOL at month 12. Among the 421 patients with a low baseline HRQOL, 121 achieved a normal HRQOL at month 12. Logistic regression showed that factors independently associated with a normal HRQOL at M12 were normal baseline HRQOL, baseline CD4+ count <500 cells/mm^3, time since HIV diagnosis <8 years, undetectable HIV-RNA at M12, and lower number of self-reported symptoms at month 12.

Grimsley et al., (2006) did a study on the effects of spirituality on quality of life on the lives of HIV positive persons. This was a cross-sectional study in which spirituality was assessed using Spiritual Perspective Scale and health-related quality of life was measured by using WHO QOL short- form BREF instrument. Demographic data on age, ethnicity, gender, education, and marital status were examined in relation to responses on the Spiritual Perspective Scale (SPS) and the WHO QOL short- form BREF instrument. The author analyzed the results using correlation analysis. There was a positive and significant relationship between spirituality and overall QOL score. The author tested the results of independent t or F tests, comparing scores on the BREF and on the SPS composite scales between categories of gender, education level, and ethnicity. Scheffe's multiple group comparisons were examined to compare means in cases where the F ratio, or overall test, was significant at the .05 level or less. Educational differences suggested that advancing education was related to higher levels of spirituality, but the differences were not statistically significant. QOL levels differed as measured by the BREF comparing those with less than high school education and those with high school or greater than high school education. An inspection of the comparative data for the BREF did show that the differences between levels of education and QOL were significant, and Scheffe's multiple comparison method was employed on individual group differences. The average score on QOL for patients completing less than high school was significantly different from the mean score on QOL for patients completing high school. These data clearly suggest that education had

an independent positive effect on patient perceptions of QOL. The more education, the higher the HIV-positive persons assessed their overall QOL. The analysis also showed that, there was no difference in levels of spirituality or QOL based on marital status. Moreover, there was no significant difference between men and women on QOL.

2.7 Objectives

2.7.1 Broad Objective

Assessment of Health Related Quality of Life of People Living with HIV/AIDS who are on Highly Active Antiretroviral Therapy.

2.7.2 Specific Objectives

1. To compare HRQOL of PLWHA on HAART and the local general population data set.
2. To compare HRQOL of PLWHA on HAART by their different social-demographic and medical characteristics.
3. To determine the association between HRQOL of PLWHA on HAART and its medical predictors.

CHAPTER 3

3.0 Research methodology

3.1 Study design

This was an analytical and comparative cross sectional study.

According to literature review, this approach has been used worldwide in persons with HIV disease to investigate several factors that have an impact on HRQOL of PLWHA.

3.2 Study population

The target populations of this study were PLWHA aged 18 years and above who were seeking care at HIV/AIDS care and treatment centers and who were on standard HAART regimen recommended by the Tanzania National Guidelines for clinical management of HIV/AIDS.

3.3 Sample size

The sample size was determined by using one of sample size estimation methods for SF-36 outcomes. The formula chosen was the one for estimating sample sizes for comparing two independent means using a t-test assuming the outcome of interest is a continuous variable and follows a normal distribution pattern. (Fayers et al., 2000)

$$N = \frac{4[Z_{1-\alpha/2} + Z_{1-\beta}]^2}{\Delta^2}$$

Where $N = n_1 + n_0$ (assuming equal samples)

n_1 = number of sample size in the index group

n_0 = number of sample size in the comparison group

Δ = effect size: difference among group means divided by standard deviation

$= (\mu_1-\mu_2)/\sigma$

$\alpha= 0.05$

$\beta= 0.20$

Assuming $\Delta= 0.2$ (smallest effect size worth detecting.)

then $N = 784$

Since the samples are not of equal sizes and $n_1 = 3802$

then the formula for estimating sample size of the index group is

$$N = 4\, n_1\, n_0 / (n_1 + n_0)$$

$n_0 = 200$

Therefore the minimum sample size was 200.

3.4 Sampling method

Two care and treatment centers were randomly selected out of a list of 8 centers in Temeke Municipality. A name list of female and male people living with HIV/AIDS on HAART obtained from site coordinator of the selected care and treatment center formed a sampling frame. Systematic sampling method was used to select names of participants. Sampling was carried out as explained in the following steps;

First, sampling frame and size of study population was determined by obtaining a total number of clients in each of the two care and treatment centers, which add up to 8037. Considering minimum sample size of 200(n), sampling interval k=N/n

K=8037/200=40

The random sampling technique was applied to select one client from individuals in the first sampling interval. Then, for each list, participants were chosen according to the first random number picked plus the sampling interval. The sampling procedure was carried out for the two care and treatment centers involved in this study.

3.5 Study area

The study was conducted in Temeke Municipality, Dar es salaam region. The Temeke Municipality is among three municipals, which make Dar es salaam City, the others being Kinondoni and Ilala.Temeke Municipality has a total of 8 HIV/AIDS care and treatment clinics namely; Temeke District Hospital, Mbagala Health Center, Pasada, Tanzania Occupational Health Services, Police Barracks Hospital, Prison Hospital, JKT Mgulani and IDC clinic.

3.6 Selection of study area

Temeke Municipality was conveniently selected to participate in the study.

3.7 Research Instrument

Interviewer administered structured questionnaire which consisted of two parts (A and B) was used. The questionnaire had a total of 53 questions. Section A contained questions which covered the socio-demographic and medical information (17 items) and Section B contained questions which assess HRQOL (36 items of SF-36). All questions were closed ended.

Medical records of the respondents were requested and reviewed to determine stages of illness i.e., current WHO clinical functioning classification and the highest stage of the illness the respondent ever experienced; the most recent CD4+ cell count and type of HAART taken. This data was used to evaluate the extent to which they correlate with HRQOL scores.

SF-36 measures eight health concepts with multi-item scales. It has 8 scales containing a total of 36 items (Ware et al., 1992).

The scales are;

1. Physical functioning (PF)-10 items
2. Role limitation due to physical health problem (RP)-4 items
3. Bodily pain (BP)-2 items
4. General Health (GH)-5 items
5. Vitality (VT)-4 items
6. Social Functioning (SF)-2 items

7. Role limitation due to emotional health problems (RE)-4 items

8. Mental health (MH)-5 items

The different items and response alternative are represented in Table 1

Table 1: Items and response alternatives included in the eight SF-36 health scales

Health scale/ items	Response alternatives
Physical functioning (PF) Participate in traditional dances Fetch water/ wash closes Carry a bag with potatoes or maize during half an hour Walk up a hill Walk down a hill Bending, kneeling Walk for half an hour Walk for 15 minutes without rest Cross a football ground Bathing, dressing	"Limited a lot/limited a little/not at all"
Role physical (RP) Due to physical health Cut down time for work Accomplishing less Limited in kind of work Difficulty performing work	Yes/No
Bodily pain (BP) Bodily pain Interference with work	"None-very mild/mild/moderate/severe/very severe" "Not at all/a little bit/moderately/quite a bit/extremely"
General health (GH) General health Getting sick easier As healthy as anybody else Expect health to get worse Excellent health	"Excellent/very good/good/fair-poor" "Definitely true/mostly true/don't know/mostly false/definitely false"
Vitality (VT) Full of pep Lot of energy Feel worn out Feel tired	During the past 4 weeks have had the feeling: "all of the time/most of the time/a good bit of the time/some of time/ A little of the time/none of the time"
Social functioning (SF) Interference of social activity Time of interference	Any perceived limitation: "not at all-slightly-moderately-quite a bit-extremely"
Role emotional (RE) Due to emotional problems Cut down time for work Accomplishing less	Yes/No
Mental health (MH) Nervous Felt down in dumps Calm, peaceful Downhearted and blue Happy	Positive and negative feeling during the last 4 weeks: "all of the time-most of time-a good bit of the time-some of the time-a little of the time-none of the time"

3.8 Recruitment and training of research assistants

Two medical students were recruited as research assistants. Prior to the actual fieldwork, research assistants were trained for one day. The training comprised of briefing of the study, familiarized them with questionnaires and WHO HIV/AIDS clinical staging system for adults. Research ethics and administrative issues such as work schedule and logistics were also part of the training. During fieldwork, feedback meetings between the research assistants were conducted on the same day after data collection for evaluation of what has been done as well as discussing the problems encountered.

3.9 Pretesting of questionnaire

Kiswahili structured questionnaire was used to gather information in this study. The Section A of the questionnaire was originally written in English and translated to Kiswahili. Section B contained the validated Kiswahili version of SF-36 (Wyss et al., 1999). Prior to the main study, pretesting of research instruments was done at Ilala District Hospital HIV/AIDS care and treatment center in Ilala Municipality. Pretesting of questionnaires was useful as some of the unclear questions in the section A of the questionnaire were reworked.

3.10 Data Collection

The clients of HIV/AIDS care and treatment centers usually attend the clinics on a monthly basis for refill of their medications. The interviewers waited for the selected

participants to come to the interview according to their appointments. Data collection was through face-to-face standardized interviews.

3.11 Quality control of data collection.

After finishing each interview, the answer sheets were collected from the interviewers and were assessed by the investigator. Feedbacks of problems of filling the questionnaire were reported to the investigator for further improvement before the next interview. Meetings between the interviewers and the investigator were held regularly to discuss the problems encountered during interviews. Necessary changes were made to improve the process of data collection. For example, due to busy nature of the clinics, we decided to interview the respondents while they were waiting to go to the pharmacy rather than in other waiting stations because they spent relatively more time there.

3.12 Variables

The independent variables were age, sex, education status, marital status, employment status, religion, religiosity, duration since first HIV positive test, duration of being on HAART, history of hospitalization in the previous three months, CD4+ cell count, HIV/AIDS clinical stage and type of HAART taken.

The dependant variables were mean scores of SF-36 scales and the two summary measures.

3.13 Data Management

The questionnaire was coded prior to data entry. The coded data were entered into the computer using Epi Info 6.04 on a daily basis. To reduce the possible errors made during the data entry process, Check function of Epi Info including logic check, possible ranges and legal value set-up were employed. Furthermore, two independent data entry operators were used to detect data-entry errors. The approved data file was converted to SPSS format for analysis.

3.14 Data analysis

Prior to the analysis, transformation of the multi-item scales scores to a possible 0-100 range was done using SF-36 scoring software.

Scales are constructed by recording items that need to recoded, summing the response choice values of their respective items and transforming scores to a 0-100 scale (where 100 indicates best health on each scale), according to standard scoring algorithm (Ware et al., 1993).

In more than seven countries studied to date, SF-36 scale scores follow a two-dimensional structure that has been characterized as representing physical and mental health constructs (Ware et al., 1994).

The first five scales make up the "physical health" dimension, and the last five form the "mental health" dimension. The scales vitality and general health are parts of both dimensions. Hence, each dimension includes three specific and two overlapping scales. The SF-36 also includes a question about self-evaluation of change in health during the past year (reported health) that does not belong to any score or dimension or the total SF36 score. The scores of the two dimensions and the total SF36 score are based on mathematical averaging of the scale components.

Mean scores, standard deviations, ranges and percentages of scoring the highest (ceiling) and lowest (floor) possible scores were calculated.

The analysis was divided into four parts;

In the first part, the internal consistency SF-36 scales containing multiple items was examined using Cronbach's alpha statistics, because it is generally regarded that items within a particular scale should be moderately correlated with each other and with the total scale score.

In the second part of the analysis, comparison between completed SF-36 questionnaires and Dar-es-salaam general population data set that was collected by Wyss et al., (1999), (n=3802) was done. Statistical differences between the two were examined using student t-test. The unadjusted mean scores were used in this comparison.

In the third part the mean scores of eight SF-36 scales of the study population were compared in relation to socio-demographic and medical characteristics. Student t-test was used where only two groups were compared and one-way ANOVA was used where more than two groups were compared. Bonferroni multiple group comparison test was used to compare means in cases where overall one way ANOVA yielded significant differences at 0.05 significance level. Both univariate and multivariate analyses were done.

Finally the examination of the relationship between various scores of health related quality of life scales and a number of independent variables was done using multiple linear regression analysis to associate the extent to which Health Related Quality of Life is associated with its predictors.

However, only Mental Component Score (MCS) and Physical Component Score (PCS) subscales of the SF-36 were used in this part of the analysis to reduce probability of Type 1 error.

3.15 Ethical issues

Ethical approval was sought from research and publication committee of Muhimbili University College of Health Sciences. The approval to conduct the study was received from Municipal Executive Director.

The participants were informed of the study objectives, its jurisdiction and benefits expected.

Written informed consent for participating in the study was obtained from participants before being interviewed. First participants read informed consent form. After agreeing to participate they put a signature on the informed consent form. The informed consent form contained full description of the study, its objectives, procedures, benefits, risks, confidentiality, and contact details in case of any queries.

Through the informed consent participants were briefed about the right to agree or disagree to participate in the study. Participants were informed that, the information they provide will strictly be treated confidentially and information collected will be used for study purposes only.

CHAPTER 4

4.0 Results

4.1 Demographic characteristics of respondents

A total of 200 respondents were involved in this study out of whom 134(67.0%) were females. Most of the respondents were in the 25-44 years age category (43.5%). The overall mean age of the respondents was 37.3 years (median 37.0 years) with the oldest respondent being 63 years old and the youngest being 18 years old. Men were older than women (mean 39.5 years for men versus 36.2 years for women) (Table 2).

Regarding marital status, majority of the respondents were married (51.5%). About 57% of respondents were Muslims, 24% were Catholics and 19% were Protestants. Most of the Protestants were born again Christians. Concerning religiosity, majority of the respondents (37 %) attended religious activities more than once in a week (Table 2).

Table 2: Demographic characteristics of the respondents (n=200)

Characteristics	Number	Percentage (%)
Sex		
Female	134	67.0
Male	66	33.0
Age group		
15-24	7	3.5
25-34	71	35.5
35-44	87	43.5
45-54	31	15.5
55-64	4	2.0
Marital status		
Married	103	51.5
Single	17	8.5
Divorced	33	16.5
Widowed	32	16.0
Cohabiting	15	7.5
Religion		
Catholic	48	24.0
Protestant	38	19.0
Muslim	114	57.0
Religiosity		
More than once a week	74	37.0
Once a week	56	28.0
1-3 times a month	17	8.5
Rarely	9	4.5
Never	44	22.0

4.2 Socio-economic characteristics of respondents

A large proportion of the respondents were petty traders (38.0%).

Most of the respondent had primary school education (70.5%) and most had studied for 5-9 years (72.9%). Refer to Table 3 for further details.

Table 3: Socio-economic characteristics of respondents (n=200)

Characteristics	Number	Percentage (%)
Education level		
No formal education	21	10.5
Primary 1-4	10	5.0
Primary 5-7	141	70.5
Secondary, post secondary	28	14.0
Duration of studying (years)		
0-4	30	15.0
5-9	145	72.5
10-15	25	12.5
Employment		
Peasant	19	9.5
Government employee	3	1.5
Private sector employee	38	19.0
Petty business	76	38.0
Unemployed	59	29.5
Others	5	2.5

4.3 Medical characteristics of respondents

Duration since first HIV positive test was categorized in months. Most of the respondents were in 38-74 months category (45.0%) and the mean duration since first HIV positive test was 19 months (Table 4).

Duration of being on HAART was also categorized in months. Majority of the respondents were in the 15-28 months category (41%) and the mean duration of being on HAART was 13 months (Table 4).

Almost all of the respondents (90.0%) had no history of hospitalization in the previous three months (Table 4).

Concerning CD4+ cell count, majority of the respondents (48.5%) belonged in the lowest category of CD4 cell count (0-200 cells/mm^3).

Regarding HIV/AIDS clinical stage, majority of the respondents (40.5%) were in stage two (Table 4).

Almost all of the respondents (98.0%) were on first line Highly Active Antiretroviral therapy while only 2% were on second line (Table 4).

Table 4: Medical characteristics of respondents (n=200)

Characteristics	Number	Percentage (%)
Duration since first HIV positive test (months)		
1-37	37	18.5
38-74	90	45.0
75-111	62	31.0
112-148	6	3.0
149-185	5	2.5
Duration of being on HAART (months)		
1-14	58	29.0
15-28	82	41.0
29-42	57	28.5
43-56	1	0.5
57-70	2	1.0
Recent CD4+ cell count (Cells/mm^3)		
0-200	97	48.5
201-500	86	43.0
501 and above	17	8.5
HIV/AIDS clinical stage		
Stage 1	49	24.5
Stage 2	81	40.5
Stage 3	61	30.5
Stage 4	9	4.5
Type of HAART		
First line	196	98.0
Second line	4	2.0
Hospitalization within the last three months		
Yes	20	10.0
No	180	90.0

4.4 Characteristics of respondents by mean scores of SF-36

Table 5 shows that the mean score in the physical function scale was the highest and lowest in the general health scale. The mean score of the physical component summary measure was slightly higher than the mental summary measure. The internal consistent coefficient (cronbach's alpha) of seven of the eight SF-36 scales ranged from 0.72 to 0.95 indicating high internal consistency reliability. Only one scale (GH) showed low internal consistency (Cronbach's alpha= 0.52). The floor effects were low, but on five of the eight scales ceiling effects were high.

Table 5: Characteristics of respondents by mean scores of eight scales of SF-36 (n=200)

Scale	Mean Score	Standard Deviation	Minimum Score	Maximum Score	% Scoring Of floor	% Scoring Of Ceiling	Cronbach's Alpha
Physical Function	90.30	16.83	15	100	0.5	60.0	0.84
Role Physical	76.05	40.47	0	100	18.5	71.5	0.95
Bodily pain	92.37	17.85	12	100	1.0	79.5	0.77
General Health	62.20	21.47	5	100	1.0	1.0	0.52
Vitality	79.20	21.68	0	100	0.5	24.5	0.77
Social Function	83.15	26.81	0	100	2.5	66.5	0.72
Role emotional	70.65	43.66	0	100	25.0	67.0	0.95
Mental Health	80.17	49.01	8	100	0.5	25.0	0.77
Physical Component Summary	79.82	16.94	10	100	0.0	0.5	
Mental Component Summary	75.02	17.47	10	100	0.5	26.0	

All scales 0-100. A high score indicates better health.

4.5 Comparison of mean scores of eight SF-36 scales between study population and normative data from local general population

Table 6 shows that the study population had lower mean scores than the general population in five of the eight SF-36 scales but these mean differences were significant in only four of these five scales. On the other hand the study population had higher mean scores than the general population in general health, mental health and vitality scales but the differences were significant in only two of these scales. Generally the general population had a higher health-related quality of life than the study population.

Table 6: Comparison of mean scores of eight SF-36 scales between study population and normative data from local general population

		Mean scale score (standard deviation)							
	n	**Physical Functioning**	**Role Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Social Functioning**	**Role Emotional**	**Mental Health**
Study Population	200	90.3 (16.8)	76.1 (40.5)	92.4 (17.9)	62.2 (21.5)	79.2 (21.7)	83.2 (26.8)	70.7 (43.7)	83.2 (49.0)
General Population	3,802	93.8 (12.3)	84.2 (30.8)	82.8 (24.7)	62.9 (18.6)	74.9 (18.5)	88.2 (18.5)	86.3 (30.8)	82.2 (18.5)
t		3.85	336.46	5.4	1.12	3.176	3.67	6.63	0.63
P value		**<0.01**	**<0.01**	**<0.01**	**0.6**	**<0.01**	**<0.05**	**<0.01**	**0.52**

All scales 0-100. A high score indicates better health.

4.6 Comparison of mean scores of eight SF-36 scales stratified by respondents' characteristics (HIV/AIDS sample)

The mean scores of SF-36 scales were compared in relation to socio-demographic and medical characteristics of the respondents.

4.6.1 Comparison of mean scores of eight SF-36 scales of study population by socio-demographic characteristics

There were no significant mean differences in all SF-36 scales by sex except in the scale of role limitation due to emotional problems where men scored higher compared to women (Table 7). The same results were obtained in multivariate analyses. This indicated that men had fewer problems with work or other daily activities as a result of emotional health problems during the previous month.

Comparison of eight SF-36 scales stratified by age as shown in Table 7 shows that at least one age group had a mean score which differ from the other age groups by more than would be expected by sampling variation in the social functioning scale only. Respondents in the 15-24 and 55-64 age categories were very few (less than seven). The same results were obtained in multivariate analyses. A multiple comparison procedure (Bonferroni t Test) was carried out and it revealed that there was significant difference between the 15-24 years and 55-64 years age groups in the social functioning scale. The older respondents scored less in social functioning scale. This indicated older

respondents perceived to be more limited in the social activities than the younger respondents.

The mean score of at least one type of marital status differs from the other by more than would be expected by sampling variation in the social functioning scale. Similar results were obtained in multivariate analysis. A multiple comparison test (Bonferroni t Test) showed that the difference was between divorced and widowed respondents and between cohabiting and divorced respondents. Widowed respondents scored higher than divorced respondents in the social functioning scale and cohabiting respondents scored higher than divorced respondents in the social functioning scale (Table 7).

Table 7: Comparison of mean scores of eight SF-36 scales of study population by sex, age and marital status (n =200)

		Mean scale score (standard deviation)							
	n	**Physical Functioning**	**Bodily Pain**	**Social Functioning**	**Role Emotional**	**Mental Health**	**Vitality**	**General Health**	**Role Physical**
Sex									
Female	134	90.4(17.3)	91.5(18.7)	82.5(26.4)	65.9(45.4)	79.5(22.6)	79.7(21.7)	62.9(20.8)	78.7(39.1)
Male	66	90.2(15.9)	94.1(16.1)	84.5(27.7)	80.3(38.3)	90.6(78.9)	78.3(21.8)	60.7(22.9)	70.6(42.9)
t		0.09	-0.93	-0.49	-2.22	-1.51	0.43	0.69	1.34
P-value		**0.22**	**0.35**	**0.62**	**0.03**	**0.13**	**0.67**	**0.49**	**0.18**
Age									
15-24	7	98.6(2.4)	91.7(10.9)	100.0(0.0)	47.6(50.4)	85.7(14.0)	80.7(12.4)	70.7(15.2)	75.0(43.3)
25-34	71	88.9(19.1)	89.9(21.7)	83.5(28.8)	63.8(45.7)	76.4(24.6)	76.5(25.2)	60.7(22.2)	73.6(42.7)
34-44	87	90.2(16.0)	94.4(14.6)	85.4(23.9)	73.9(42.4)	86.4(69.9)	80.5(20.2)	62.1(21.2)	75.9(40.6)
45-54	31	90.5(16.2)	91.8(18.7)	76.3(30.3)	78.5(40.9)	88.5(15.1)	80.9(19.4)	63.2(22.2)	79.4(37.6)
55-64	4	100.0(0.0)	96.0(8.0)	53.3(15.6)	100.0(0.0)	87.0(21.0)	83.8(17.9)	69.0(20.6)	100.0(0.0)
F		0.87	0.66	2.68	1.77	0.53	0.45	0.48	0.46
P-value		**0.49**	**0.62**	**0.03**	**0.14**	**0.72**	**0.77**	**0.75**	**0.76**
Marital Status									
Married	103	91.2(15.9)	92.7(17.7)	82.8(27.1)	77.3(39.7)	88.6(64.0)	80.2(20.9)	62.9(22.5)	78.9(32.9)
Single	17	89.7(21.1)	87.3(24.6)	90.5(19.5)	76.47(43.7)	79.5(22.3)	82.7(25.8)	66.8(23.9)	64.7(45.1)
Divorced	33	84.4(19.8)	96.9(11.5)	69.3(32.9)	65.6(45.3)	79.0(25.2)	81.7(19.1)	59.2(20.7)	64.3(46.4)
Widowed	32	90.9(16.2)	89.9(17.2)	88.3(21.4)	53.1(48.5)	71.1(25.5)	72.0(21.3)	59.7(18.1)	80.5(37.4)
Cohabiting	15	96.7(7.9)	91.4(22.8)	96.7(12.9)	66.7(48.8)	85.1(15.0)	78.7(27.6)	64.3(20.9)	85.0(32.5)
F		1.66	1.04	3.99	2.17	0.88	1.14	0.53	1.45
P-value		**0.16**	**0.38**	**<0.01**	**0.07**	**0.47**	**0.34**	**0.71**	**0.22**

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Table 8 shows that the mean differences were not statistically significant when SF-36 scores were stratified by religion. Multivariate analyses resulted in the same findings. However the trend shows that Protestants had better health-related quality of life in seven of the eight SF-36 scales compared to other religions. Most of these Protestants were borne again Christians.

At least the mean score of one group of religiosity differ significantly from the others by more than would be expected from sampling variation in the physical function scale. Similar findings were obtained in multivariate analysis. A multiple comparison test (Bonferroni t Test) showed that the difference was between those who never attend religious activities and those who attend more than once in a week (p-value 0.01). This indicates that the respondents who attend religious activities frequently could perform all types of physical activities, including the most vigorous ones without limitation due to health than the respondents who never attend (Table 8).

Table 8: Comparison of mean scores of eight SF-36 scales of study population by type of religion and religiosity (n =200)

		Mean scale score (standard deviation)							
	n	**Physical Functioning**	**Bodily Pain**	**Social Functioning**	**Role Emotional**	**Mental Health**	**Vitality**	**General Health**	**Role Physical**
Religion									
Catholic	48	90.6(17.3)	89.2(23.9)	78.9(28.1)	69.4(43.4)	75.9(23.7)	77.3(22.4)	62.6(21.6)	77.3(40.8)
Protestant	38	92.2(17.4)	94.1(14.1)	88.8(21.3)	81.6(39.3)	84.0(21.9)	83.6(19.7)	64.9(20.1)	73.7(43.9)
Muslim	114	89.5(16.5)	93.6(15.7)	83.0(27.8)	67.6(44.9)	85.9(61.7)	78.6(22.0)	61.2(21.9)	76.3(39.5)
F		0.38	1.74	1.46	1.51	0.71	1.00	0.44	0.09
P-value		**0.68**	**0.18**	**0.24**	**0.22**	**0.49**	**0.37**	**0.65**	**0.92**
Religiosity									
More than once per week	74	93.7(11.8)	92.4(19.2)	80.6(29.9)	76.5(41.4)	81.3(23.1)	81.6(19.7)	64.9(21.8)	82.1(36.7)
Once per week	56	88.8(18.1)	92.0(18.1)	83.7(27.2)	72.0(43.9)	79.2(22.6)	74.7(35.1)	59.1(24.3)	72.9(42.7)
1-3 times per month	17	94.7(7.6)	93.1(17.2)	89.7(19.9)	58.8(47.9)	100(151.7)	80.0(15.4)	60.7(17.8)	83.8(34.2)
Rarely	9	96.7(8.3)	89.6(23.2)	82.0(27.2)	77.8(44.1)	81.8(20.4)	92.2(9.7)	61.3(22.2)	80.6(39.1)
Don't attend	44	83.5(23.2)	93.0(14.8)	84.4(23.5)	63.6(45.4)	79.4(21.7)	77.9(23.0)	62.3(18.4)	65.9(45.1)
F		3.44	0.09	0.45	0.91	1.99	1.69	0.65	1.38
P-value		**0.01**	**0.99**	**0.77**	**0.46**	**0.10**	**0.15**	**0.65**	**0.24**

All scales 0-100. A high score indicates better health

Table 9 shows that at least one category of education status had a mean score which differ significantly from the other categories in the bodily pain scale. Similar findings were obtained in multivariate analyses. A multiple comparison test (Bonferroni t Test) showed that this difference was between those with no formal education and those with primary education up to standard four (P-value 0.03). Those with no formal education had lower mean scores than those with standard 1-4 education in the bodily pain scale. This meant that bodily pain interfere with the daily activities of the respondents who have no formal education more than it did to the respondents who had standard 1-4 education.

There were no significant differences in the mean scores of the eight SF-36 scales in relation to employment status. Both univariate and multivariate analyses concluded the same way (Table 9).

Table 9: Comparison of mean scores of eight SF-36 scales of study population by socio-economic characteristics (n =200)

Mean scale score (standard deviation)

	n	Physical Functioning	Bodily Pain	Social Functioning	Role Emotional	Mental Health	Vitality	General Health	Role Physical
Education									
No education	21	87.9(19.0)	81.8(30)	73.9(28.7)	80.9(40.2)	81.9(23.3)	75.2(21.0)	60.1(20.1)	70.2(45.8)
Primary 1-4	10	91.0(14.3)	98.4(5.1)	85.0(33.7)	70.0(48.3)	80.0(22.7)	83.5(18.0)	58.4(26.6)	85.0(33.8)
Primary 5-7	141	90.1(17.4)	93.6(15.3)	85.4(23.8)	68.9(44.3)	84.7(56.0)	78.7(22.1)	62.4(22.0)	73.8(41.4)
Secondary	28	92.9(13.3)	91.7(17.3)	77.8(35.6)	71.6(42.1)	77.2(26.8)	83.5(21.2)	64.2(18.1)	89.3(27.7)
F		0.38	3.14	1.57	0.46	0.19	0.75	0.25	1.43
P-value		**0.77**	**0.03**	**0.19**	**0.71**	**0.89**	**0.53**	**0.86**	**0.24**
Employment									
Peasant	19	86.8(20.8)	88.1(22.3)	77.6(27.5)	56.1(48.5)	84.4(15.6)	74.0(21.8)	65.3(16.5)	57.9(50.7)
Government Employee	3	75.0(18.0)	84.7(26.6)	71.0(50.2)	100.0(0.0)	77.3(20.5)	78.3(7.6)	60.3(14.3)	83.3(28.9)
Private sector Employee	38	95.2(15.6)	95.2(15.6)	88.5(24.4)	83.3(36.9)	95.3(103.4)	78.0(24.9)	59.5(25.1)	85.5(31.1)
Petty trader	76	91.4(14.3)	94.1(14.8)	85.2(26.2)	72.8(42.1)	82.9(20.2)	82.3(19.6)	65.2(20.4)	74.8(42.5)
Not employed	59	88.3(19.7)	91.2(20.0)	80.9(27.8)	63.3(47.0)	77.3(23.6)	79.3(21.3)	60.3(21.9)	78.4(37.9)
Others	5	85.0(20.6)	79.4(24.5)	65.0(22.4)	66.6(47.2)	64.0(33.4)	60.0(29.6)	48.6(19.4)	60.0(54.8)
F		1.44	1.26	1.22	1.75	0.79	1.35	1.01	1.43
P-value		**0.19**	**0.28**	**0.30**	**0.12**	**0.56**	**0.24**	**0.42**	**0.22**

All scales 0-100. A high score indicates better health.

4.6.2 Comparison of mean scores of eight SF-36 scales of study population by medical characteristics

Table 10 shows that at least one category of duration since first HIV positive test had a mean score that was significantly different from the other categories in the physical function, role limitation due to physical problem, general health, vitality and mental health scales. The general trend was that an increase in time since first HIV positive test was associated with improvement in health-related quality of life as evidenced by increase in means scores in the respective scales. However in multivariate analyses these differences were not significant in all SF-36 scales.

At least one category of duration of being on HAART had a mean score that showed statistical significant difference from the mean scores of other categories in physical function, role limitation due to physical problems, general health, vitality and social functioning scales. However in multivariate analyses the differences in mean scores were significant in general health and mental health scales only. The general trend again was an improvement in mean scores with an increase in duration of being on HAART.This indicated that HAART played a significant role in improving general health (that is people do no get sick easier) and mental health (Table 10).

Table 10: Comparison of mean scores of eight SF-36 scales of study population by duration since first HIV positive test and duration of taking HAART (n =200)

		Mean scale score (standard deviation)							
	n	**Physical Functioning**	**Role Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Social Functioning**	**Role Emotional**	**Mental Health**
Months since first HIV positive test									
1-37	37	80.7 (25.3)	51.6(47.2)	89.0(21.4)	52.2(23.5)	65.1(27.4)	79.7(24.7)	65.9(45.5)	75.7(21.0)
38-74	90	92.5 (12.2)	82.2 (36.6)	93.3(17.4)	65.2(20.8)	81.2(19.6)	85.4(26.1)	73.3(42.8)	79.9(21.7)
75-111	62	91.3 (15.8)	78.2 (39.3)	93.1(17.2)	62.1(19.8)	82.7(18.8)	81.3(28.3)	67.2(45.4)	81.68(23.4)
112-148	6	99.2 (2.0)	91.7(20.4)	97.3(6.5)	74.3(20.5)	91.7(9.3)	100(0.0)	83.3(40.8)	92.0(248)
149-185	5	99.0 (2.2)	100 (0.0)	85.6(14.0)	69.6(18.6)	88.0(13.5)	70.0(44.7)	86.6(30.0)	84.8(26.0)
F		4.51	4.97	0.71	3.21	5.69	1.29	0.58	8.96
P-value		**<0.01**	**<0.01**	**0.587**	**0.01**	**<0.01**	**0.28**	**0.67**	**<0.01**
Months on HAART									
1-14	58	84.6(22.6)	59.7(46.6)	92.4(17.9)	53.5(22.8)	71.9(26.0)	79.5(29.0)	68.9(44.1)	77.0(22.6)
15-28	82	92.5(12.6)	82.3(34.6)	94.5(16.1)	65.1(20.9)	81.3(18.8)	85.7(25.8)	70.7(44.6)	78.1(23.4)
29-42	57	92.5(14.4)	82.5(38.4)	89.4(20.1)	66.6(18.6)	83.3(19.5)	84.9(23.7)	71.9(43.1)	96.9(83.1)
43-56	1	100.0	100.0	100.0	55.0	90.0	0.0	33.0	40.0
57-70	2	97.5(3.5)	100.0(0.0)	86.0(19.8)	72.0(28.3)	82.5(24.8)	75.0(35.4)	100.0(0.0)	100.0(0.0)
F		2.54	3.68	0.79	3.69	2.49	3.08	0.44	1.85
P-value		**0.04**	**<0.01**	**0.53**	**<0.01**	**0.04**	**0.02**	**0.78**	**0.12**

All scales 0-100. A high score indicates better health

Table 11 shows that there were significant mean differences between those with and those without history of recent hospitalization in the physical function scale, role limitation due to physical problems scale, general health scale, vitality scale, social functioning scale and role limitation due to emotional problems. Generally those with history of being hospitalized within the previous three months had poorer health-related quality of life than those with no such history. . Multivariate analyses showed same findings.

At least one CD4+ cell count category had a mean score which was significantly different from the other categories in the physical function scale, role limitation due to physical problems scale, general health scale, vitality scale and social function scale. Nevertheless in multivariate analyses the differences in mean scores were significant in general health and vitality scales only. Multiple comparison test (Bonferroni t Test) showed that 0-200 cells/mm^3 and 201-499 cells/mm^3 categories had statistical significant differences in both general health and vitality scales. Generally respondents who had CD4+ count between 0-200 cells/mm^3 had lower mean score than those who had CD4+ count between 201-500 cell/mm^3. This indicated that an increase in CD4+ count was associated with improvements in vitality and general health scales (Table 11).

At least one HIV/AIDS clinical stage differ from the others by more than would be expected by sampling variation in the in all eight scales with the exception of body pain

and mental health scales. Similar results were obtained in multivariate analyses. The general trend was a decrease in mean score as the HIV/AIDS clinical stage advanced indicating that there is deterioration of HRQOL as the clinical stage advanced.

There was no significant difference in the mean scores of eight SF-36 scales between respondents who were on first line HAART and those who were on the second line HAART (Table 11).

Table 11: Comparison of mean scores of eight SF-36 scales of study population by history of recent hospitalization, CD4+ cell count, HIV clinical stage and type of HAART taken (n =200)

Mean scale score (standard deviation)

	n	Physical Functioning	Role Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role Emotional	Mental Health
Recent Hospitalization									
Yes	20	77.0(23.9)	47.5(47.9)	87.7(19.4)	50.5(21.8)	60.5(30.9)	67.5(31.5)	46.6(45.1)	73.4(28.4)
No	180	91.8(15.3)	79.2(38.4)	92.9(17.7)	63.5(21.1)	81.3(19.4)	84.9(25.8)	73.3(42.7)	84.3(50.7)
t		-3.85	-3.41	1.25	-2.60	-4.24	-2.90	-2.63	-0.95
P-value		**<0.01**	**<0.01**	**0.21**	**0.01**	**<0.01**	**<0.01**	**<0.01**	**0.35**
CD4 cell count (Cells/mm³)									
0-200	97	87.1(19.7)	67.3(44.9)	90.8(19.5)	57.0(22.1)	73.9(23.4)	78.6(27.7)	70.1(43.2)	76.8(23.4)
201-499	86	94.4(10.9)	85.0(33.4)	94.3(15.3)	67.5(20.0)	84.0(19.3)	88.5(23.1)	72.5(44.1)	85.5(18.1)
500 and above	17	87.3(20.2)	80.9(37.0)	91.6(20.1)	64.7(18.7)	85.0(15.8)	81.7(34.8)	64.5(46.4)	100(154.7)
F		4.70	4.68	0.93	5.85	5.88	3.21	0.25	3.13
P-value		**0.01**	**0.01**	**0.40**	**<0.01**	**<0.01**	**0.04**	**0.78**	**0.046**
HIV stage									
Stage 1	49	96.0(10.7)	91.3(28.2)	95.1(15.1)	69.0(19.0)	88.3(15.1)	87.8(24.5)	84.4(36.1)	81.5(22.1)
Stage 2	81	92.3(14.6)	78.4(38.1)	90.4(20.0)	61.2(21.7)	78.9(21.0)	85.1(24.8)	67.9(44.9)	90.6(71.1)
Stage 3	61	85.7(18.6)	65.3(45.9)	93.0(15.5)	60.0(20.8)	74.0(22.8)	79.1(27.7)	66.6(44.7)	76.2(23.5)
Stage 4	9	72.2(29.6)	44.4(46.4)	91.3(26.0)	49.3(29.2)	67.8(34.8)	68.1(42.9)	55.6(52.7)	72.9(33.4)
F		7.97	6.11	0.74	3.05	5.16	2.06	2.40	1.19
P-value		**<0.01**	**<0.01**	**0.53**	**0.03**	**<0.01**	**0.11**	**0.07**	**0.31**
Type of HAART									
First line	196	90.2(17.0)	75.9(40.6)	92.2(18.0)	62.4(21.4)	79.3(21.7)	82.8(27.0)	70.7(43.7)	83.3(49.4)
Second line	4	95.0(7.07)	81.3(37.5)	100(0.0)	52.3(26.7)	76.3(25.0)	100(0.0)	66.8(47.1)	75.0(29.7)
t		-0.56	-0.26	-0.86	0.94	0.27	-1.27	0.18	0.34
P-value		**0.57**	**0.80**	**0.39**	**0.35**	**0.78**	**0.20**	**0.86**	**0.74**

All scales 0-100. A high score indicates better health

4.7.1 Association between the mean scores of the two summary measures of SF-36 and the medical predictors of HRQOL in the study population (HIV/AIDS sample)

The association between the mean scores of the two summary measures of SF-36 controlling for age, sex and education status and quantitative medical predictors of HRQOL was examined for each predictor independently using multiple linear regression analyses.

Table 12 shows that last CD4+ cell count, duration since first HIV positive test and duration of being on HAART were positively associated with mean score of mental component summary measure. However the association between last CD4+ cell count and mean score mental component summary measure was not statistically significant. HIV/AIDS clinical stage was negatively associated with mean score of mental component summary measure and the association was statistically significant.

Table 12: Association between mean scores of mental component summary measure and the selected quantitative medical predictors of HRQOL in the study population (n =200)

Predictors	Beta coefficient	t	p-value	95% confidence interval
Last CD4+ cell count	3.71	1.92	0.57	-0.10 to 7.53
HIV/AIDS clinical stage	-6.11	-4.305	<0.01	-8.91 to -3.31
Duration of being on HAART	0.27	2.46	0.02	0.05 to 0.48
Duration since first HIV positive test	0.13	2.44	0.02	0.03 to 0.24

Table 13 shows that last CD4+ cell count, HIV/AIDS clinical stage, duration of being on HAART and duration since first HIV positive test had statistically significant association with the mean scores of physical component summary measure of SF-36. Duration of being on HAART, last CD4+ cell count and duration since first HIV positive test were positively associated with the mean scores of the physical component summary measure. This indicated that as the duration since first HIV positive test and duration of being on HAART increased, the health-related quality of life improved. HIV/AIDS clinical stage was negatively associated with mean scores of physical component summary measure indicating that as clinical stage advanced, the health-related quality of life deteriorated.

Table 13: Association between physical component summary measure and the selected quantitative medical predictors of HRQOL in the study population (n =200)

Predictors	**Beta coefficient**	**t**	**p-value**	**95% confidence interval**
Last CD4+ cell count	5.85	3.20	<0.01	2.25 to 9.46
HIV/AIDS clinical stage	-6.48	-4.8	<0.01	-9.14 to -3.82
Duration of being on HAART	0.354	3.39	<0.01	0.15 to 0.56
Duration since first HIV positive test	0.12	2.26	0.03	0.015 to 0.22

CHAPTER 5

5.0 Discussion

The main finding in the current study was that the group of people living with HIV/AIDS reported poor health than the general population. On one hand, PLWHA reported poorer health than the general population in five out of eight scales although the difference was significant in four scales only. The scales were physical function, role limitation due to physical health problems, role limitation due to emotional health problems and social functioning scales. On the other hand, PLWHA reported significant higher health than the general population in vitality and bodily pain scales. The poor self reported health in patients with HIV/AIDS was in congruence with earlier studies (O'Keefe et al., 1996, Eriksson et al., 2000 and Meng et al., (2007). The somewhat surprising perceived higher HRQOL among PLWHA than the general population in bodily pain and vitality scales was not in keeping with the previous studies although the association was statistically significant. This could be explained by improved health-related quality of life among PLWHA as a result of increased access to HAART and other treatments for opportunistic infections. The alternative explanation could be the poor health-related quality of life in the general population as about 27% of these people reported history of disabilities, 34% reported an illness in the previous two weeks and 11% reported that they had a chronic health condition. Nonetheless, introduction of HAART has complicated interpretation of HRQOL in PLWHA.

In the current study, there was no significant difference in health-related quality of life by sex except in the role limitation due to emotional problems scale where women reported significant poorer health. This finding concurs with the study done by Grimsley et al., (2006) who concluded that there were no significant difference between men and women on QOL on the lives of HIV positive persons but is in contrast to the study done by Rao et al., (2007) who showed that women had poorer health than men especially in physical health domain and the study done by Hays et al., (2000) where it was shown that being a female was associated with poor health. Lack of significant differences between men and women in other scales in the current study could be explained by the small representation of men in the sample size.

Regarding age and HRQOL respondents who were in the age group 15-24 years had a better health in the social functioning scale than those in the age group 55-64 years. This was the only significant difference as far as age groups and HRQOL were concerned. This finding suggested that old age was associated with poor health among PLWHA.These findings correlate with those of Meng et al., (2007) and Hays et al., (2000). However, the study by Johnson et al., (2000) had contradictory findings by concluding that there were no significant differences in HRQOL when stratified according to age groups. These inconsistent results could be due to different psychometric properties of the various HRQOL assessment tools utilized in different cultural settings.

The findings in this study showed that marital status had an influence in the social functioning scale whereby divorced respondents had the poorest health indicating that there is limitation in the participation of social activities when one is HIV positive and is divorced. Since seventy percent of the divorced respondents were females the negative influence of HIV positive status and being divorced on the social functioning could be attributed to stigma, among other factors.

In the assessment of relation between religion and HRQOL, the study showed that Protestants had higher health-related quality of life compared to Catholics or Muslims although the differences were not significant. This can be explained by high spirituality of these Protestants as majority of them were born again Christians. The current study also shows that respondents who attend religious activities frequently had better health in the physical functioning scale than the respondents who never attend. This is corroborate findings of the study conducted by Grimsley et al., (2006) which showed a positive and significant relationship between spirituality as measured by the spirituality perspective scale and HRQOL.The current study was not able to explore well the role spirituality on HRQOL because spirituality was not assessed using a standardized scale.

Regarding education status and HRQOL, respondents who had primary school education scored higher than those with no education in the bodily pain scale. The implication of this finding is that higher education enabled respondents to tolerate their bodily pain and continue with their daily activities. However, the study done by Wig et al., (2006) in

India showed that there was a significant difference in HRQOL scores in the psychological domain with respect to education status among PLWHA as opposed to bodily pain domain as found in the current study. Such contradictory findings could be due to different roles played by education in different cultural setups as far as HRQOL is concerned. Generally, education is known to have a positive effect on patient perceptions of QOL (Grimsley et al., 2006).

Results from the current study showed that there were no significant differences in HRQOL with respect to employment status. Other studies have shown that unemployment and low income were associated with worst HRQOL and health status (Eriksson et al., 2000 and Hays et al., 2000). The lack of relation between employment status and HRQOL in the current study could be due to the fact that majority of the respondents had primary school education (75%) and therefore the differences in their income were not significant regardless of their employment status.

With respect to duration since the first HIV positive test, the results showed that there were significant mean differences in five out of eight scales. The general trend was that increase in duration since the first HIV positive test was related to better HRQOL. In multivariate analysis these differences were not significant. This lack of significance in multivariate analysis could be due to high correlation of this variable with other variables apart from being due to confounding factors. In multiple linear regression controlling for age, sex and education status, duration since first HIV positive test had a

positive association with both physical component summary measure and mental component summary measure and the associations were significant. This improvement in HRQOL as duration since first HIV positive test increased could be attributed to the overall good care PLWHA get in HIV/AIDS care and treatments centers which mitigate the negative long term impact of HIV/AIDS on HRQOL.

Exploration of the results on the relationship between duration of taking HAART and HRQOL showed that there were significant mean differences in physical function scale, role limitation due to physical problems, general health, vitality and social functioning scales. However, in multivariate analysis the mean differences were significant in general health and mental health scales only. The general trend was an increase in mean scores correlated with increase in duration of being on HAART. Multiple linear regression adjusting for age, sex and education status resulted in significant positive association between duration of being on HAART and both the physical component and mental component summary measures. Similar findings were observed by the study done by Patrizia et al., (2003). The implication of these findings is that in the long run, the beneficial effects of HAART outweigh the side effects of these drugs and allow patients to resume the activities that improve their HRQOL.

Generally, PLWHA with history of being hospitalized within the previous three months had poorer health-related quality of life than those with no such history. Multivariate analysis resulted in the same findings. Similar findings were observed by Murri et al.,

(2003) who showed that hospitalization during the three months prior to enrollment in the cohort study was independently associated with poor physical and mental component summary measures. This ability of the SF-36 to discriminate different categories as far as health is concerned provides more evidence of its construct validity.

Results from this study also indicate that there was significant difference in the mean scale scores with respect to CD4+ cell count in the physical function scale, role limitation by physical problems scale, general health scale, vitality scale and social function scale. However, in multivariate analysis these differences in mean scores were significant general health and vitality scales only. In multiple linear regression, recent CD4+ cell count was independently related to physical component summary measure and not with the mental component summary measure. These results concur with those of the studies done by Murri et al., (2002) and Campsmith et al., (2003) who showed CD4+ cell count was the best predictor of physical health and poor predictor of mental health. The study done by Gill et al., (2002) also showed that CD4+ cell count was positively associated with HRQOL. However, other studies had discrepant findings. Johnson et al., (2000) concluded that there was no significant difference in QOL when stratified according to CD4+ cell count. The reason cited for this discrepancy was that the respondents were Americans who have been on HAART for some time and consequently their CD4+ cell counts were generally high and viral loads were very low allowing the respondents to return to those activities that improve their HRQOL. In another study by Murri et al., (1997) it was shown that HRQOL was not related to CD4+

cell count. This study was among patients with non-advanced disease and therefore CD4+ cell count could not interfere with activities that determine their HRQOL.

Univariate and multivariate analyses of the data in the current study showed that there were significant differences of the mean scores when HRQOL was stratified according to HIV/AIDS clinical stages. The general trend was deterioration of HRQOL as the clinical stage advances. Multiple linear regression analysis showed that HIV/AIDS clinical stage was negatively and independently associated with both physical and mental component summary measures and the associations were statistically significant. Similar findings were observed by O'Keefe., (1996), Wig et al., (2006) and Murri et al., (2003).This is an additional evidence of capacity of SF-36 to discriminate different disease stages as far as its construct validity is concerned.

Exploration of the HRQOL in relation to type of HAART taken showed that the mean scores did not differ significantly. This could be attributed to the small percentage of the respondents who were on second line HAART (4%) as compared to those who were on first line HAART (96%). Further studies are needed to explore the influence of type of HAART on HRQOL.

In this study, the internal consistent coefficient (cronbach's alpha) of seven out eight SF-36 scales ranged from 0.72 to 0.95 indicating high internal consistency reliability. Only one scale (GH) showed low internal consistency (Cronbach's alpha= 0.52). Similar

findings were observed by the study done by Smide et al., (1999) which reported low internal consistency (cronbach's alpha=0.59) when the validated Swahili SF-36 version was used to assess HRQOL among diabetic patients in Dar es salaam. A Study done by Allen et al., (1997) also supported this finding when the same questionnaire was used in Kenya. The reasons given for this discrepancy were problems in translating the English terms relating to the concept of GH to Swahili. However, in an article by Hobart et al., (2002) it was concluded that GH and SF scales generated low reliability scores regardless of the language employed emphasing the need to improve the wording of the items in these scales to improve the internal consistency.

Results of this study also indicated that the floor effects were low, but on five of the eight SF-36 scales (PF, RP, RE, BP and SF) ceiling effects were high. For a scale to be responsive to changes it must it must not have floor or ceiling effects. The scale range must extend beyond the range of function of the patients for whom it will be used, or it will be incapable to demonstrating further improvement (ceiling) or deterioration (floor). The study done by Wyss et al., (1999) to validate the Swahili version of SF-36 also showed similar finding of the high ceiling effects in the same respective scales. The authors raised questions whether this was related to translational issues or cultural norms. In the study done by Rob et al., (2002) it was also shown that a number of scales of the SF-36 exhibit floor and/or ceiling effects. However, it was noted the psychometric properties of an instrument are sample dependent. This means that the resulting scales may exhibit considerable ceiling and floor effects in score distribution when they are

used with groups of patients with a lower or higher average level (such as PLWHA) of functional health.

Several limitations should be considered in the interpretation of the findings from this study. A few of the health scales exhibited ceiling effects. The SF-36 is a generic questionnaire used to measure HRQOL in diverse populations and may not have been able to detect small differences in HRQOL in patients with HIV/AIDS. Accordingly, the generalizability of our findings is uncertain. Patients with more severe disease may have participated in the study at disproportionately low rates when compared with healthier counterparts. Number of males in the sample selected was considerably smaller than that of the female counterparts. Furthermore critical predictors of disease progression like CD4+ cell count were not confirmed through clinical testing. Meaningful comparison between respondents who were on first line HAART and those who were on second line HAART could not be made because of very small number of respondents in the selected sample who were on second line HAART. Comparison of the SF-36 mean scores between the study population and the general population data set using adjusted mean scores to address the issue confounding factors was not possible because of unavailability of general population raw data set.Lastly,not all the selected participants agreed to participate in the study.

CHAPTER 6

6.0 Conclusion

1. Individuals with HIV generally have significantly lower health-related quality of life compared with the general population despite availability of HAART.

2. Some socio-demographic characteristics such as female gender, old age, and low education status, being divorced and low religiosity are significantly related to poor health-related quality of life while employment status and type of religion is not related at all to health-related quality of life.

3. Results indicate that absence of recent hospitalization history, long duration since first HIV positive test, long duration of being on HAART, higher CD4+ cell counts are significantly associated with high health-related quality of life.

4. The Swahili version of SF-36 is a highly reliable HRQOL assessment tool with the exception of general health scale and it has high construct validity as shown in the current study by its ability of discriminating disease stages.

6.1 Recommendations

1. As PLWHA have lower HRQOL compared to the general population, multisectoral efforts to prevent further transmissions of HIV virus is still likely to prevent significant morbidity losses, despite availability of HAART.

2. In addition to the use of conventional disease specific parameters for on going follow up of care of PLWHA, the use of HRQOL by Ministry of Health and Social Welfare, Higher Learning Institutions and other research institutions can provide a focused approach to monitoring associated problems and targeting interventions over time.

3. Care of PLWHA has to be individualized because the disruption in health-related quality of life fluctuated within the HIV/AIDS sample.

4. Scaling up of multisectoral efforts to encourage people to go for voluntary counseling and testing will be beneficial because the current study has shown that earlier knowledge of ones HIV positive status has been associated with better health in the future possibly due to availability of care.

4. This study could be seen as a base for further studies to explore health-related quality of life in other groups of people.

References

Ammassari, A., Murri, R., Pezzotti, P., Trotta, M.P., Ravasio, L., De Longis P, L., Caputo, S., Narciso, P., Pauluzzi, S., Carosi, G., Nappa, S., Piano, P., Izzo, C.M., Lichtner, M., Rezza, G., Monforte, A., Ippolito, G., d'Arminio Moroni, M., Wu, A.W., Antinori, A.; AdICONA Study Group.(2001). Self-reported symptoms and medication side effects influence adherence to highly active antiretroviral therapy in persons with HIV infection Acquir Immune Defic Syndr. 28(5): 445-9.

Allen, T., Parker, M., Amuyunzu, A., Johnson, K., Mwenzo, I., Mwenesi, H., Fox-Rushby, J. (1997). Conception of health in quality of life research. Quality of Life Research.6, 614

Campsmith, M.L., Nakashima ,A.K., and Arthur J Davidson ,A.J. (2003) Self-reported health-related quality of life in persons with HIV infection: results from a multi-site interview project. Health and Quality of Life Outcomes. 24; 1(1):12.

Cleary, P.D., Fowler, F.J., Jr., Weissman, J., Massagli, M.P., Wilson, I., Seage, G.R., et al. (993). Health-related quality of life in persons with acquired immune deficiency syndrome. Med Care; 31(7):569-80.

Detmar, S.B., Muller, M.J., Schornage, l.J.H., Wever, L.D., Aaronson, N.K. (2002). Health-related quality-of-life assessments and patient-physician communication: a randomized controlled trial. JAMA. 288(23): 3027-34.

de Boer, J.B., van Dam, F.S., Sprangers, M.A. (1995). Health-related quality-of-life evaluation in HIV-infected patients. A review of the literature. Pharmacoeconomics ; 8(4):291-304.

Douaihy, A., Singh, N. (2001). Factors affecting quality of life in patients with HIV Infection. AIDS 11(9): 450-4, 460-1, 475

Fayers, P.M., Machin, D. (2000). Quality of Life Assessment, Analysis and Interpretation, Chichester, John Wiley and Son Ltd.p 3-345

Gill, C.J., Griffith, J.L., Jacobson, D., Skinner, S., Gorbach, S.L., Wilson, I.B. (2002). Relationship of HIV viral loads, CD4 counts, and HAART use to health-related quality of life. J Immune Defic Syndr Acquir. 30(5): 485-92.

Grimsley, L.P. (2006) Spirituality and quality of life in HIV-positive persons. J Cult Divers.13 (2): 113-8.

Gelber, R.D., Lenderking, W.R., Cotton, D.J., Cole, B.F., Fischl, M.A., Goldhirsch, A., et al. (1992). Quality-of-life evaluation in a clinical trial of zidovudine therapy in patients with mildly symptomatic HIV infection. The AIDS Clinical Trials Group. AnnIntern Med ; 116(12 Pt 1):961-6.

Hays, R.D., Cunningham, W.E., Sherbourne, C.D., Wilson, I.B., Wu, A.W., Cleary, P.D., McCaffrey, D.F., Fleishman, J.A., Crystal, S., Collins, R., Eggan, F., Shapiro, M.F., Bozzette, S.A., (2000) 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. 108(9): 714-22.

Hobart, J.C., Williams, L.S., Moran, K., Thompson, A.J. Quality of life measurement after stroke: uses and abuses of the SF-36. Stroke. 2002; 1349–1356.

Johnson, D., Ramer, L. (2000). Quality of life in HIV disease in the post HAART era. Int Conf AIDS. 13: abstract no. WePpD1325

Kaplan RM. Profile versus utility based measures of outcome for clinical trials. In: Staquet MJ, Hays RD, Fayers PM, editors. Quality of Life Assessment in Clinical Trials: Method and Practice. Oxford: Oxford University Press; 1998. p. 69-90.

Kerlinger, F. (1973). Foundations of behavioral research. 2nd ed. New York: Holt, Rinehart and Winston.

Miners, A.H., Sabin, C.A., Mocroft, A., Youle, M., Fisher, M., Johnson, M. (2001). Health-related quality of life in individuals infected with HIV in the era of HAART. HIV Clin Trials. 2(6): 484-92

Meng ,Y..J, Li, N.X., Chen, J.H., Song,Y.C., Qian,Z.S.(2007). Using the SF-36 to assess the quality of life of people living with HIV in Sichuan. Sichuan Da Xue Xue Bao Yi Xue Ban. 2007 Jun; 38(3):471-4

Murdaugh, C. (1998). Health-related quality of life in HIV disease: achieving a balance. J Assoc Nurses AIDS Care. 9(6): 59-71.

Msoka, A., Lugina, H., Smide, B. (2006). Assessment of health-related quality of life in people with diabetes and people without diabetes in Tanzania. European Diabetes Nursing.3 (1): 34 - 39

Murray, J.L., Lopez, A.D., Eds. (1994). Global Comparative Assessment in The Health Sector. Disease Burden, Expenditures and Intervention Packages. Geneva: World Health Organization.

Morgan, D., Mahe, C., Mayanja, B., Whitworth, J.A. (2002). Progression to symptomatic disease in people infected with HIV-1 in rural Uganda: prospective cohort study. BMJ 324 (7331): 193-196.

National AIDS Control Programme (NACP), Ministry of Health (Tanzania). 2004 HIV/AIDS/STI Surveillance Report Number 18: January-December 2003.Dar es salaam: Ministry of Health.

Nunnally, J. (1978). Psychometric theory. 2nd ed. New York: McGraw-Hill.

Protopopescu, C., Marcellin ,F., Spire, B., Preau, M.,Verdon, R., Peyramond, D., Raffi, F.,Chene, G., Leport, C., Carrieri,M.P. (2007). Health-related quality of life in HIV-1-infected patients on HAART: a five-year longitudinal analysis accounting for dropout in The APROCO-COPILOTE cohort (ANRS CO-8). Qual Life Res. 16(4): 577-91.

Patrick, D.L., Deyo, R.A. (1989). Generic and disease-specific measures in assessing health status and quality of life. Med Care; 27(3 Suppl):S217-32.

Reed, P.G. (1986). Religiousness among terminally ill and healthy adults. Research in Nursing & Health. 9: 35-39.

Reed, P. G. (1987). Spirituality and well being in terminally ill hospitalized adults. Research in Nursing & Health. 10: 335-344.

Rob, J. de Haan. (2002). Measuring Quality of Life After Stroke Using the SF-36. Stroke. 33:1176

Stasis, P. (2000). Health-related quality-of-life measurements in HIV/AIDS care. AIDS Patient Care STDS. 14(8): 427-38.

Smide, B., Whiting, D., Mugusi, F., Felten, L., Wikblad, K. (1999). Self perceived health in urban diabetic patients in Tanzania. East African Medical Journal.76, 67-70

Testa, M.A., Lenderking, W.R. (1995). Quality of life considerations in AIDS clinical trials. In: Finkelstein, D.M., Schoenfeld, D.A., editor. AIDS clinical trials. New York: Wiley-Liss, Inc.

Van Sighem, A.I., van de Wiel, M.A., Ghani, A.C., Jambroes, M., Reiss, P., Gyssens, I.C., Brinkman, K., Lange, J.M., de Wolf, F.; ATHENA Cohort Study Group. (2003). Mortality and Progression to AIDS after starting highly active antiretroviral therapy. AIDS. 17(15): 2227-36

Wagner,A.K.,Wyss, K., AK, Whiting, D., Mtasiwa, D.M., Tanner, M., Gandek, B., Gandek, B., Kilima, P.M. (1999). Validation of the Kiswahili version of the SF-36 Health Survey in a representative sample of an urban population in Tanzania. Qual Life Res. 8(1-2): 111-20.

Ware, J.E., Sherbourne, C.D. (1992). The MOS 36-Item Short-Form Health Survey (SF-36). Conceptual framework and item selection. Med Care. 30(6): 473-48328.

Ware JE, Kosinski M, Gandek B. (1993). SF-36 Health Survey. Manual and Interpretation Guide. Boston, MA: The Health Institute, New England Medical Center.

Ware JE, Kosinski M, Keller SD. (1994) SF-36 Physical and Mental Health Summary Scales. Boston MA: The Health Institute, New England Medical Center.

World Health Organization. Definition of Health.(1946). Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York; signed on 22nd July,1946 by representatives of 61 states (Official Records of the World Health Organization,no.2 ,p.100) and entered on to force on 7th April,1948.

World Bank. World Development Report 1993: Investing In Health. Washington DC: World Bank, 1993.

Wu, A.W., Rubin, H.R. (1992). Measuring health status and quality of life in HIV and AIDS. Psychology and Health *6, 251 264.*

WHOQOL Group (1993). Study protocol for the World Health Organization project to develop a quality of life assessment instrument (WHOQOL). Quality of Life Research. 2:153-159.

Appendices

Appendix 1: SF-36 Measurement Model

