

**“THE HEALTH RELATED QUALITY OF  
LIFE  
OF HIV/AIDS PATIENTS ON ANTI-  
RETROVIRAL THERAPY  
IN NAIROBI”**

**A THESIS SUBMITTED TO THE FACULTY OF MEDICINE  
DEPARTMENT OF COMMUNITY HEALTH  
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DEGREE OF MASTER OF PUBLIC HEALTH  
OF THE UNIVERSITY OF NAIROBI**

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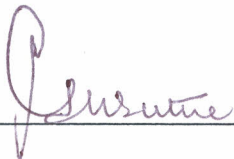


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## DECLARATION

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## APPROVAL

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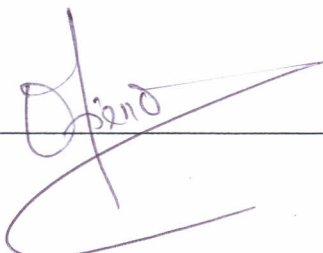
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## **DEDICATION**

To my parents Francis and Sylvania, my sisters Mbithe and Koki and my brother Mutemi for their love, support and encouragement. To all the people affected and infected by HIV/AIDS and particularly those who took the time to participate in this study.

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## ABBREVIATIONS

|         |   |
|---------|---|
| AAI     | Accelerated Access Initiative                       |
| ART     | Anti-retroviral Therapy                             |
| CD4     | Cluster Differentiation 4                           |
| HAART   | Highly Active Anti-retroviral Therapy               |
| HAT-QOL | HIV/AIDS Targeted Quality of Life                   |
| HIV     | Human Immunodeficiency Virus                        |
| HRQOL   | Health-related Quality of Life                      |
| MOH     | Ministry of Health                                  |
| MOS     | Medical Outcome Study                               |
| NACC    | National AIDS Control Council                       |
| NASCOP  | National AIDS and STD Control Program               |
| NCPD    | National Council for Population and Development     |
| NNRTI   | Non-nucleoside Reverse Transcriptase Inhibitor      |
| NRTI    | Nucleoside analogue Reverse Transcriptase inhibitor |
| PLWHA   | People living with HIV and AIDS                     |
| PI      | Protease Inhibitor                                  |
| QOL     | Quality of Life                                     |
| RNA     | Ribonucleic Acid                                    |
| WHO     | World Health Organisation                           |

## ABSTRACT

*Background:* It is estimated that less than 10% of PLWHA have access to anti-retroviral treatment in every region except the Americas. Until the year 2000, the cost of treatment was the single most significant factor influencing access. With the recent price reductions, wholesalers have reported a 30-50% increase in demand for these drugs. In just over one decade, anti-retroviral therapy has transformed the human immunodeficiency virus (HIV) infection from a fulminant and invariably fatal illness to a chronic albeit incurable disease. As in any other chronic illness, quality of life is emerging as a significant medical outcome and its enhancement is as important a treatment goal as viral suppression and immune reconstitution.

*Objective:* To determine the health-related quality of life (HRQOL) status of HIV positive patients on anti-retroviral therapy in Nairobi (Kenya).

*Design:* Cross-sectional survey to determine the HRQOL of HIV-infected individuals on anti-retroviral therapy.

*Setting and time frame:* Four hospitals in Nairobi city between January and April 2003.

*Subjects:* Non-pregnant HIV infected adults on Highly Active Anti-retroviral Therapy.

*Methods:* Self-administered semi-structured questionnaires for patients who were physically able to fill the questionnaires. Those that were too weak to do so were assisted in filling the questionnaires.

*Results:* Approximately 80% of all the respondents had above average HRQOL. Mental health was the most adversely affected domain of HRQOL. Female respondents scored better than their male counterparts ( $P < 0.001$ ). Those that were employed and working scored better than those that were unemployed or those that were employed but on sick leave ( $P < 0.001$ ). Respondents that were on protease inhibitor (PI) based regimens scored better than those that were on PI sparing regimens ( $P < 0.001$ ). Inpatients had worse scores than outpatients ( $P < 0.001$ ). Patients that were compliant to therapy had higher scores than those that reported non-compliance ( $P < 0.001$ ). Counseling did not have any impact on HRQOL as would have been expected ( $P = 0.995$ ). Patients that had disclosed their HIV status did not score differently from those that had not ( $P = 0.203$ ). Those that had CD4 counts of less than 200c/ml scored less than those that had CD4 counts of  $\geq 200$ c/ml

( $P < 0.01$ ). CD4 count was positively correlated to HRQOL and was found to predict 40% of the variance in HRQOL.

*Conclusion:* Poor mental health is highly prevalent among HIV-patients on anti-retroviral agents. Counseling programs do not provide the required psychological support. CD4 counts can be used to predict overall HRQOL as well as the mental and physical health domains of HRQOL.

*Recommendations:* Palliative care for HIV infected individuals is an important component of HIV management. QOL assessment instruments can be used to monitor progress for patients on anti-retroviral therapy as well as to screen for underlying mental distress. Counseling programs need to be evaluated to establish if any deficiencies exist in content, type or staff qualification. HRQOL instruments need to be harmonized to enable meaningful comparison across various populations.

## INTRODUCTION

In defining quality of life (QOL), health care providers must consider not only the physical responses to medical treatment, but also the psychological and social implication of illness and its treatment to the patient. In just over a decade, AIDS has evolved from a fulminant and invariably fatal illness to a possibly chronic albeit incurable disease. The overriding goal of any treatment should be to relieve the patient's suffering by seeking to improve the health-related QOL of the chronically ill patient.

Chapter one begins by providing statistics of the global and local HIV situation with some emphasis on its socio-economic impact as well as its public health significance. Costs remain prohibitive in many low-income countries even with the recent sharp price reductions. HIV infection often leads to stigmatization and discrimination and this can impact negatively on QOL. The causes, manifestation and consequences of HIV/AIDS related stigma are discussed briefly. In addition, the role of voluntary counseling and testing (VCT) in reducing this stigma is highlighted. Health-related quality of life (HRQOL) is a consequence of both the illness and its treatment. Anti-retroviral therapy (ART) reduces the viral load and improves the immune response leading to a decrease in the number of opportunistic infections (OIs) and the frequency of hospitalization. This leads to an increase in the level of productivity and an increase in the stability and longevity of families. The disadvantages of ART include the need for life long intake of the drugs, the onset of adverse drug reactions and the complex drug regimens that require near perfect adherence in order to achieve undetectable viral loads and to prevent the development of resistance. Often there is a need to modify one's lifestyle to accommodate *treatment requirements and this can result in conflicts in the home or work place*. At the same time, treatment is a constant reminder of the HIV status which in *many settings* remains a stigmatized disease. This study focuses on three main domains of the health-related QOL namely the physical status, the social interaction and the mental status.

Chapter two provides the literature review that forms the basis and the justification of this study. Quality of life is a multidimensional concept and its assessment is plagued by

difficulties in defining what constitutes QOL. This has been evidenced by the multiplicity of QOL assessment tools. Various studies have been conducted to assess QOL in people living with HIV/AIDS (PLWHA) especially in the era of ART. Limitations, results of these studies and the existing QOL assessment tools are discussed. Also discussed in this chapter are issues such as adherence, sexuality and gender in as far as they relate to QOL.

Chapter three defines the research problem and gives the justification for the research thesis. It also defines the objectives of this research. Chapter four gives the methods and materials that were used for the study. It defines the variables that were studied, the sampling methods and sampling criteria and the ethical issues that are relevant to the research.

There were 206 HIV infected patients who participated in this study and chapter five is devoted to presenting the study results. Chapter six is divided into three parts. The first part discusses the results of this study and how they compare to other studies. Study limitations are also outlined. The second part of the chapter deals with the conclusions that can be drawn from the findings while the final part of the chapter deals with recommendations for future research as well as recommendations to health-care providers.

All the references quoted in the body of the proposal are given in the reference section which is then followed by the appendices. The Appendix I section contains a sample of the questionnaire. Appendix II and III provide details of the individual domain scores discussed in chapter 5.



## CHAPTER 1

### BACKGROUND

#### 1.1 Global Situation

The first cases of AIDS were reported in five homosexual men in Los Angeles in the United States of America (USA) in 1981. In Kenya, however, the first case was reported in 1984 (MOH 1997). By the end of 2003, an estimated 34.6 million to 42.3 million people worldwide had the HIV infection and 20 million people had died of AIDS (UNAIDS 2004). In 2003 alone, about 4.8million people acquired the infection and 2.9million died of AIDS. Sub-Saharan Africa remains the epicenter of the epidemic where majority of the world's people living with HIV and AIDS (PLWHA) live. By 1990, HIV/AIDS was thought to rank 26<sup>th</sup> contributing 0.84% of the total world disease burden. By the year 2020, it is expected to move up the rank to the 10<sup>th</sup> position accounting for 2.61% of the total disease burden (Prescott 1997). It is estimated that less than 10% of the PLWHA in all regions except the Americas have access to anti-retroviral therapy (UNAIDS 2004). The current worldwide distribution of PLWHA is summarized in Table 1:

Table 1: The Global HIV-AIDS Epidemic at the end of 2003

| REGION                            | No. of PLWHA | Prevalence among adults (%) | New infections in 2003 | Deaths due to AIDS |
|-----------------------------------|--------------|-----------------------------|------------------------|--------------------|
| 1. Sub-Saharan Africa             | 25,000,000   | 7.5                         | 3,000,000              | 2,200,000          |
| 2. South and South-East Asia      | 6,500,000    | 0.6                         | 850,000                | 460,000            |
| 3. Latin America                  | 1,600,000    | 0.6                         | 200,000                | 84,000             |
| 4. Eastern Europe & Central Asia  | 1,300,000    | 0.6                         | 360,000                | 49,000             |
| 5. North America                  | 1,000,000    | 0.6                         | 44,000                 | 16,000             |
| 6. East Asia                      | 900,000      | 0.1                         | 200,000                | 44,000             |
| 7. Western Europe                 | 580,000      | 0.3                         | 20,000                 | 6,000              |
| 8. North Africa & the Middle East | 480,000      | 0.2                         | 75,000                 | 24,000             |
| 9. Caribbean                      | 430,000      | 2.3                         | 52,000                 | 35,000             |
| 10. Oceania                       | 32,000       | 0.2                         | 5,000                  | 700                |
| TOTAL                             | 37,800,000   | 1.1                         | 4,800,000              | 2,900,000          |

\*Source: UNAIDS 2004

Data is variable and discrepancies between reported and actual cases may be considerable largely due to:

1. Low capacities to undertake surveillance;
2. Poor diagnostic tools;
3. Stigmatization of HIV/AIDS leading to under-reporting of data.

However, from Table 1, it is clear that although Africa is home to only 11% of the world population, almost 70% of PLWHA live in sub-Saharan Africa and it is estimated that 75% of all estimated deaths due to HIV/AIDS have occurred in the same region. Of the nine countries with the most HIV-infected people, eight are in sub-Saharan Africa and Kenya is one of them. Botswana so far has the highest prevalence of 37.3% (Steinbrook 2004). In Eastern and Southern Africa, crude death rates are now 50-500% higher than expected with the increased mortality being experienced by young adults and children under five years. In some areas, life expectancy has already dropped by 15 years and an estimated 12million African children have lost their mothers or both their parents to HIV/AIDS (Quinn 2001). The scale and rate of spread of the pandemic with its wide-ranging and catastrophic effects has forced policy makers to view HIV as a global developmental problem. The fact that full access to ART will not be achieved immediately and universally does not preclude the progressive introduction of anti-retroviral treatment. *This must however be done cautiously if maximal benefit of treatment is to be realized. People living with HIV/AIDS need to play a central role in designing, implementing and monitoring anti-retroviral treatment programs* (Farmer et al 2001). Involving infected people in treatment-related activities helps to reduce stigma and makes the programs more effective.

## **1.2 The Kenyan Situation**

### **1.2.1 Public Health Impact**

An estimated 820,000 to 1.7million people are living with HIV/AIDS in Kenya (UNAIDS 2004) and at least 180,000 people die of AIDS each year. In an effort to control the scourge, the Kenyan government declared HIV/AIDS a national disaster and a public health emergency in 1999 and set up the National Aids Control Council to develop

strategies for controlling the spread. By then the prevalence had risen from 5.3% in 1990 to 13.1% in 1999, with higher rates of 16-17% in the urban centers than in the rural areas (11-12%) (NACC 2000). Current adult (15-49 years) prevalence of HIV/AIDS is estimated to be between 4.7-9.6% (UNAIDS 2004). Prevalence is higher in women and in urban dwellers (KDHS 2003). This has led to an increase in both the numbers of people seeking health care and the cost of health care to the government, employers, insurance and the individual families. Hospital bed utilization by HIV patients increased from 15% in 1992 to 51% in the year 2000 (NACC 2000). The length of hospital stay by HIV patients is on average longer due to the higher incidence of complications and comorbidity. As a result, up to 50% of public expenditure on health is spent on HIV/AIDS (MOH/NASCOP/NCPD 1999). Life expectancy dropped from 57.7 to 51 years among men and from 69.4 to 53 years among women between the years 1989 and 1997 (UN 2001) and by 2002 overall life expectancy had reached 50.9 years (WHO 2004).

The National AIDS Control Council (NACC) has developed a strategic plan for the Kenya National HIV/AIDS control programme which has identified treatment of PLWHA as one of the top five priorities as a means of mitigating the socio-economic impact of HIV/AIDS (NACC 2000).

### **1.2.2 Economic Impact**

It is becoming clear that socio-economic factors not only foster the spread of HIV/AIDS, but also add to the severity of its impact on individuals, communities and nations. The economy has been adversely affected by the AIDS epidemic due to the reduction of productivity occasioned by the fact that the majority (80-90%) of those afflicted are between the ages 15-49 years (NACC 2000). High death rates among the adults in the 20-40 year age group are depleting human capital and the skill base necessary for social development and economic growth. By killing the most productive members of society, it increases dependency ratios, reduces the tax base and impairs the inter-generational transfer of knowledge and skills (Haddad et al 2001). According to some surveys done in Kenya and presented in the African Development Forum 2000, the economic impact of AIDS in Kenya is predicted to lead to a reduction in the Gross Domestic Produce (GDP)

of 14.5% by the year 2005 (UNAIDS/ECA 2000). This is because HIV/AIDS in the workplace leads to:

1. Increased absenteeism;
2. High staff turnover with resultant loss of skills;
3. Increased demands for training and recruitment;
4. More money spent on insurance cover, medical assistance and funeral costs.

Industries are also affected because AIDS infection within the communities leads to declining markets, smaller labor pools and reduced supplies (Daly 2000). A study done on six firms in Kenya in 1994, showed that AIDS related losses in profit vary between 0-6% (average 1.7%) with an average annual cost per employee with AIDS being between US\$17-49 (UNAIDS/ECA 2000). This is projected to increase to US\$122 in the year 2005 (Adetunji 1999). The reduction of farm labor, will force farmers to switch agricultural production from cash crops to subsistence farming. There is also an increased demand for social services due to the growing numbers of widows and orphaned children. In Kenya alone more than 1.2 million children (3.7% of the total population) have been orphaned by the death of their mother (WHO 2004). At the household level it is estimated that families lose up to 49-78% of their income when one person dies of HIV depending on whether or not the deceased is the main bread winner in the family (UNAIDS/ECA 2000).

The most disturbing aspect of the pandemic is the fact that, as the pandemic intensifies with a parallel need for action, the actual capacity to act is decreasing. Individuals in the government and non-governmental organizations continue to die therefore the gap between what is needed and what can be delivered continues to widen (Haddad et al 2001).

### **1.3 Highly Active Anti-retroviral Therapy (HAART)**

#### **1.3.1 Anti-retroviral Therapy**

Most efforts to date have focused on reducing immediate risks by bringing about behavior change. However, behavior change has been frustratingly difficult to achieve and sustain because the risks related to HIV/AIDS exposure are not always easy to

control. In the past, it has been argued that in resource poor settings, either prevention or treatment must be prioritized. Prevention programs have been funded at the expense of treatment programs merely because prevention programs are generally cheaper (UNAIDS 2004). It is now clear that prevention, care, support and treatment of people affected by HIV/AIDS are mutually reinforcing elements of an effective response (Farmer et. al 2001, Piot et al 2001, UNAIDS 2004). Incorporating AIDS treatment into the established preventive measures, only serves to fortify them. It must be acknowledged that ART, though important, is only part of a comprehensive treatment programme for HIV disease that includes voluntary screening, the diagnosis, prevention and treatment of opportunistic infections. They are essential for the success of therapy because they prevent re-infection and reduce the transmission between discordant partners. This is because, even with ART, low levels of viral replication continue at concentrations of viral load that is below the limits of detection.

While the cure for HIV infection does seem distant at the present moment, the enormous potential of these drugs to delay disease progression is undoubted. Treatment and prognosis of HIV/AIDS improved dramatically between 1992 and 1995 with the development of protease inhibitors in 1992 and the subsequent introduction of the highly active anti-retroviral therapy (HAART). It is now agreed that optimal therapy for HIV/AIDS involves the combination of three or more anti-retroviral drugs (Sanford et.al 1997). Anti-retroviral drugs are broadly classified into the following groups:

1. Nucleoside analogue reverse transcriptase inhibitors (NRTI);
2. Non-nucleoside reverse transcriptase inhibitors (NNRTI);
3. Protease inhibitors (PI).

Stunning benefits of anti-retroviral therapy include dramatic delays in HIV progression, improved survival, decrease in the incidence of opportunistic infections and decreased hospitalization. There is a renewed sense of optimism that HIV could be transformed from a rapidly fatal disease to a manageable chronic illness. However, even among those on treatment, drug resistance, drug side effects, co-morbidity, complexity of regimens, life-long pill taking and the quality of life that results from ART use may significantly limit the outcome of anti-retroviral therapy.

The late 90s were characterized by enormous changes in the care of PLWHA. Extensive research led to the development of quantitative measures of viral RNA in serum. It also led to the development and approval of potent new anti-retroviral agents especially protease inhibitors. This enabled clinicians to monitor the therapeutic effects of the drugs and to reduce viral load to undetectable levels in most patients (Boucher et. al 2000). Although currently available anti-retroviral drugs are far from ideal, ongoing pharmacological research may, in the future, produce drugs that are less costly, easier to administer and fewer adverse effects and/or resistance. Access to anti-retroviral drugs can motivate individuals to be tested for HIV and help to break the barriers of isolation and despair (Piot et. al 2001). Over the last one year the issue of making AIDS drugs more readily available to people in poor countries has received heightened attention from treatment advocates, policy makers, heads of state and the media. Faced with growing pressure for expanded access and the threat of competition from generic manufacturers, several pharmaceutical companies have decreased the price of their brands of anti-retroviral drugs.

### **1.3.2 Adherence to anti-retroviral drugs**

The terms “adherence” and “compliance” have often been used inter-changeably. However, adherence is preferable because it denotes a negotiated treatment plan rather than a dictated course from the physician to the patient. The term “adherence” is therefore broader than compliance because it reflects a collaboration between the patient and the provider in devising a regimen (Miller, Hays 2000). This requires the formation of a relationship that fosters trust and respect between the two parties. Non-adherence is defined as not taking the medication at all, taking in reduced amounts, not taking at prescribed intervals or not matching medication to food requirements (Altice, Freidland 1998). At the same time, adherence could relate to the extent to which patients execute lifestyle changes in accordance to medical advice. For instance the use of condoms to prevent re-infection or to reduce transmission is an example of lifestyle changes required while on ART. Medical adherence is a complex behavioral pattern influenced by a variety of factors related to the patient, medical regimen, patient-physician relationship and the medical system through which the patient receives care. Ultimately it is related to

the QOL resulting from the illness and/or its management. In general, adherence tends to decrease as the number of medications, the doses per day or pill burden increases. Patients experiencing two or more side effects are less likely to adhere than patients who tolerate their medication well.

Adherence to HIV therapies present special issues that result from the biology of HIV and the magnitude of the desired therapeutic effect. However, some scientists feel that if any gain in survival or quality of life no matter how small is possible, then treatment should be made available to all infected with HIV. Others find this unacceptable from the viewpoint of development of resistance and the consequent reduction in effectiveness of therapy now and in the future. Insufficiently supervised treatment would not improve survival, but would enhance resistance, undermine prevention efforts and perhaps be a drain of resources.

### **1.3.3 Access to anti-retroviral therapy**

Without treatment it takes 9 to 11 years for *HIV infection to progress to full blown AIDS* (Steinbrook 2004). A total of 2.2million people died in sub-Saharan Africa in the year 2003 compared to only 6000 people in Western Europe where effective treatment is widely available (UNAIDS 2004). Equal access to ART is a fundamental principle that WHO promotes as a human right (WHO 1997). This means that anyone who meets the criteria for treatment should have access to it. However, universal coverage in sub-Saharan African countries implies expenditure 20 times the level of the entire budget on health (WHO 1997). Beside the issue of cost of therapy, the technical complexity of offering ART limits its widespread availability. Therefore existing programmes provide limited access determined through eligibility. Access is then determined by market forces which means the patients' ability to afford treatment. ART administration demands reliable and continuous funding. It also requires an efficient and operational drug procurement and distribution network. At one level, sustainability applies to the entire health system and addresses the capacity of the system to function effectively and independently over time with minimum external (donor) support. At the patient's level, it relates to the continued ability of the patient to afford treatment and additional care over

time. Considering that many patients may not be covered by health insurance and given the tendency for some employers to discriminate against and, to some extent, terminate the services of employees diagnosed to have HIV, this poses a significant challenge. Failure to address the issue of sustainable drug supply can lead to the haphazard use of drugs determined by the patient's ability to pay and the ability of the health care system to provide the drugs.

In May 2000, UNAIDS launched an initiative aimed at reducing the price of HIV drug. Accelerating Access Initiative (AAI), aims at accelerating sustained access to appropriate interventions for the prevention, care and treatment of PLWHA. AAI is a partnership with the pharmaceutical industry and five UN agencies that work with governments to ensure appropriate treatment of patients both in terms of their overall health care and use of drugs. It is borne out of a recognition that improving access to treatment is a shared responsibility. In Kenya, preliminary results of studies to evaluate access to ART, show that the practice of differential pricing on some of the branded products has led to dramatic price reduction and an increase in the demand for anti-retroviral drugs of between 30-50% (Kimani 2000). Figure 1 shows the effects of access to ART.

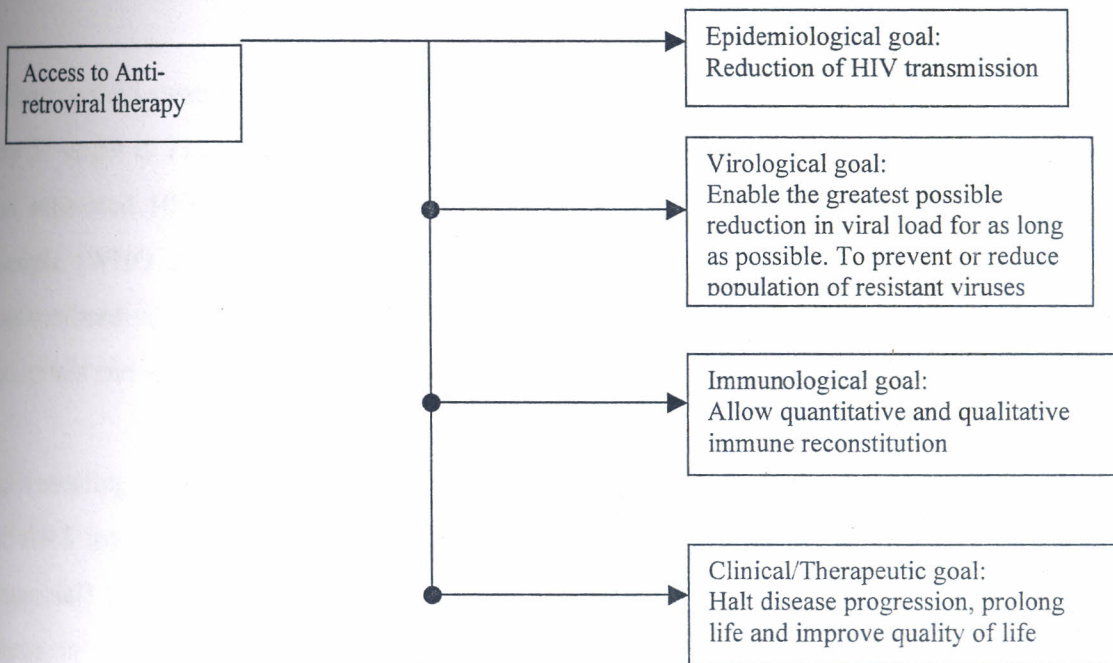


Figure 1: Goals of anti-retroviral therapy (Adapted NASCOP 2001)



On World AIDS day 2003, WHO announced its “3 by 5” initiative. This is an interim target of treating 3 million people in developing countries by the end of the year 2005 as part of a global movement to expand treatment access (UNAIDS 2004). This is an ambitious plan given the current treatment coverage rates as indicated in Table 2.

Table 2: Coverage and Need for Anti-retroviral Treatment as of June 2004

| REGION                                | ESTIMATED NEED | NO. PEOPLE ON TREATMENT | COVERAGE |
|---------------------------------------|----------------|-------------------------|----------|
| Africa                                | 3,840,000      | 150,000                 | 4%       |
| South-East Asia                       | 860,000        | 40,000                  | 5%       |
| Americas                              | 410,000        | 220,000                 | 54%      |
| Western Pacific                       | 170,000        | 15,000                  | 9%       |
| Europe (Eastern Europe, central Asia) | 120,000        | 11,000                  | 9%       |
| Eastern Mediterranean                 | 100,000        | 4,000                   | 4%       |
| TOTAL                                 | 5,500,000      | 440,000                 | 8%       |

\*Source: WHO 2004

Kenya’s total treatment need in 2005 is estimated to be 220,000 people and the WHO “3 by 5” target is 110,000 (based on 50% of need). During 2003, the government provided an estimated 1000 people with ART while other sectors covered an additional 10,000 people (WHO 2004). The Kenyan government is currently making plans to open 30 comprehensive care centers including all provincial hospitals, 15 high volume district hospitals and support to six mission hospitals as part of the scaling up process.

In a meeting held in Dakar in October 2000 (APTAA 2000), it was felt that introduction of ART into Africa requires the mobilization of all the resources (human, material and financial) necessary for their prescription and use. Participants called for research to focus on:

1. Operational aspects e.g. assessment of ARV requirement on the basis of epidemiological data, funding mechanisms, ART distribution mechanisms, factors that contribute to non-adherence and studies on cost-effectiveness;
2. Clinical aspects like drug side effects and drug interactions;
3. Virological aspects including the profiling of sensitivity patterns;
4. Public health and economical aspects e.g. studying ARV accessibility according to the patients' socio-economic level and
5. Psychological and social dimensions like the effect on the quality of life.

#### **1.4 Definition of the Quality of life Concept**

In defining the QOL, health care providers must consider not only the physical responses to medical treatment, but also the psychological and social implications of the illness both to the patient and to his/her family. QOL has been defined as the congruence between one's dreams, ambitions, aspirations for the future with one's present lifestyle and experiences (Douaily, Singh 2001). In a clinical setting it includes those dimensions of life directly affected by the overall state of health. The term "health-related quality of life" (HRQOL) is therefore more appropriate. It is a multidimensional concept that includes global health perceptions, symptom status, functional status, biological and physiological variables (Douaily Singh 2001). Although frequently related, the physical and psychosocial domains of HRQOL are seen as distinct areas of the patient's life. This is because the effect of an illness or its treatment may affect the two domains to varying extents. In summary health-related QOL refers to how well people are able to perform daily activities (functioning) and how they feel about their lives (well-being) (Lorenz et al 2001). WHO defines health as a state of complete physical, mental and social well-being and states that the promotion and protection of the health of people contributes to better quality of life (WHO 1978). For this reason, the domains evaluated in this study are the physical, mental and social domains and this is outlined in Figure 2.

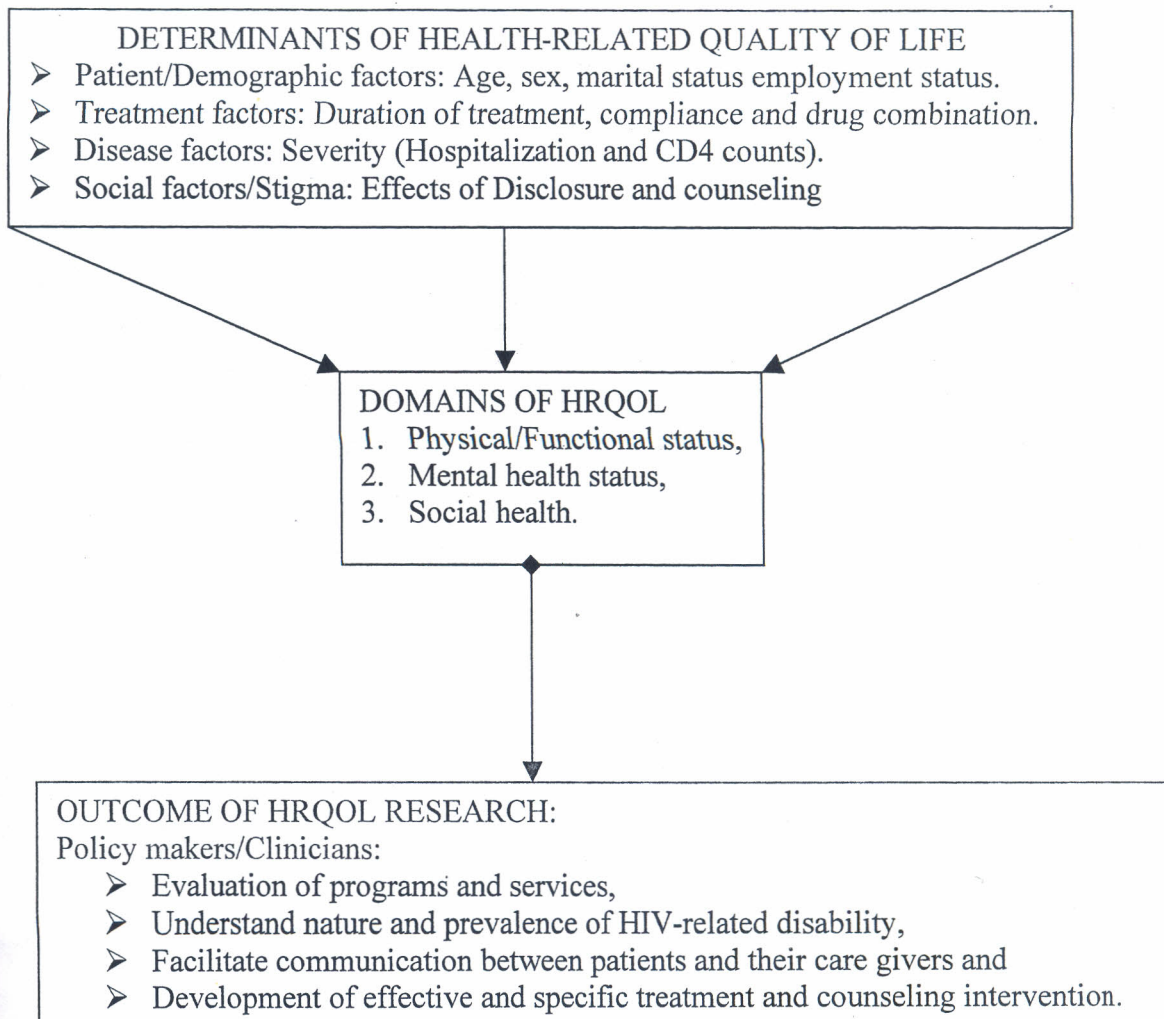


Figure 2: Conceptual Framework - HRQOL research:

### 1.5 The Gender dimension

Women are biologically, culturally and economically more susceptible to HIV infection than men. Biologically, the risk of infection due to unprotected vaginal sex is two to four times higher than in men (Haddad et al 2001). They are more susceptible to sexually transmitted diseases (STDs) and are less likely to seek treatment. If untreated, STDs multiply the risk of transmission by 300-400% (Haddad et al 2001). Consequently, susceptibility threatens reproductive health status by making pregnancy and child-bearing potentially life-threatening both to the mother and the offspring. By December 2003, women accounted for nearly 50% of all people living with HIV worldwide and 57% in

sub-Saharan Africa (UNAIDS 2004). In Kenya, women between 15-24 years of age are twice as likely to be infected as men this age. Prevalence of HIV among urban pregnant women is above the national average and is above 30% in certain areas (WHO 2004). Women suffer the same complications of AIDS that afflict men and exhibit similar characteristics to men due to some of the drug complications. However, they also suffer sex-specific manifestations of HIV such as vaginal and cervical diseases.

Negative cultural practices such as violence against women and sexual exploitation also contribute to women's increased risk of HIV infection. Rules governing sexual relationships differ for women and men with men holding most of the power (UNAIDS 2004). In Kenya 44% of married, divorced or separated women reported having been either physically or sexually violated by their husbands or partners at some point in time (KDHS 2003). These social and economic power imbalances raise fears that women may be denied equitable and timely access to treatment options (UNAIDS 2004). Gender also defines much of the division of labor hence the burden of care is disproportionately distributed between the sexes. Women perform nearly all primary roles of food production and preparation, child care, energy production and use, house-hold management, health care and community organization. They provide home-based care for the disabled, convalescent and chronically sick. When they are sick, society still demands that they continue their role of providing care for their families. They therefore tend to bear the bulk of the psychological and emotional burden of HIV/AIDS (KANCO 2000). Men on the other hand tend to bear the bulk of the financial and medical expense burden. As a result, when a man falls sick, there is a significant drop in the disposable household income. When a woman falls sick, the social network is threatened as is the household food security (KANCO 2000).

### **1.6 HIV/AIDS-related Stigma and Discrimination**

HIV/AIDS-related stigma results in HIV/AIDS-related discrimination and this is recognized as a driving force in fueling the HIV/AIDS epidemic. Stigma and discrimination also results in negative outcomes in the mental and physical health of PLWHA. It occurs in care settings whether at home or in health institutions and it results

from a complex mixture of factors. There is a need to recognize, understand and deal with the causes, manifestations and consequences of HIV/AIDS-related stigma. Often stigma is based on moral judgment of the sexual behavior through which HIV is acquired. Inadequate depth of knowledge about HIV can also lead to exaggerated fears of infection and the belief that PLWHA can no longer make positive contribution to society. *In the terminal stages of illness where patients require intensive support to perform even basic human functions and when financial resources continue to dwindle, care-giver burn-out can lead to stigmatization. The realities of poverty dictate how and on whom to spend scarce resources. Stigma can take the form of verbal abuse, physical isolation, social distancing and the dissolution of relationships. This can result in differential treatment at home and in health-care facilities. It can also lead to loss of employment. This limits disclosure and voluntary counseling and testing (VCT) uptake. It also violates the rights of PLWHA. On a personal level, PLWHA are left feeling angry and hopeless. Many respond by retreating from society as they are often unable to confront those who stigmatize them. Some may develop desires for revenge and this results in inappropriate sexual behavior aimed at maliciously spreading the disease.*

### **1.7 Protection from Stigma and Discrimination**

The government of Kenya has drafted a bill that seeks to outlaw all forms of discrimination of HIV infected individuals (Otieno 2003). The *HIV and AIDS Prevention and Control Bill (2003)* would outlaw denial of employment, promotion, and educational opportunities on the basis of one's HIV status. It bars compulsory HIV testing as well as discrimination in the granting of bank loans or life and/or health insurance. It guarantees access to essential health-care to all HIV-infected individuals. It also requires that health care workers observe confidentiality of test results. The Bill is yet to be tabled and debated in the Kenyan Parliament before being made into a law and this is expected to go a long way in mitigating the stigma and discrimination that is occasioned upon HIV-infected individuals.

### **1.8 Role of Voluntary Counseling and Testing (VCT)**

The establishment of VCT was meant to encourage people to know their sero-status. For those who test HIV-negative, post-test counseling can encourage them to maintain behavior that ensures that they stay HIV-negative. However, for those that test HIV-positive, VCT can be an entry point for future clinical and social support. Support groups for them can help reduce HIV/AIDS-related stigma, fear and anxiety by increasing openness. It empowers them to make informed decisions about marriage, pregnancy and responsible sexual behavior. It should also help them deal with issues of disclosure.

## LITERATURE REVIEW

### 2.1 Introduction – Scope of Literature review

In conducting a literature search on the topic of HRQOL, one of the key areas is the review of the strengths and the limitations of the existing QOL assessment tools. Numerous tools emphasizing various domains of HRQOL exist. They range from dimension specific tools that address particular domains of HRQOL, to disease specific tools that address several HRQOL domains within the limited context of individual diseases. There is limited data on generic instruments that can be used to evaluate HRQOL across different patient populations. Additionally, review of the use of utility-based measures was not undertaken as the cost of treatment vis-à-vis QOL was not evaluated in this study. Research has identified various factors that influence HRQOL and this too was reviewed to determine the extent to which these factors applied to the HIV-infected population in Nairobi.

Studies have shown that in most chronic illnesses, symptom control, restoration of functional status and the cultivation of positive health perceptions are key to the enhancement of good QOL (Douaily, Singh 2001). HRQOL may be influenced by factors that are neither constant nor universal. They may vary from person to person, from setting to setting and from time to time. This is because the course of HIV/AIDS is highly variable and unpredictable. This results in a wide range of potential complications and in varied rates of survival. In general, these factors may be classified as follows:

1. Quality of care: Patients may have inadequate knowledge about the disease, the effectiveness of treatment, the importance of adherence to treatment and the importance of healthy living. This may result from communication difficulties that may arise when the patients' attitude towards his illness and its treatment differs from that of the provider. An open and non-judgmental relationship between health providers and patients is very important for effective communication. Additionally, in areas of high prevalence, the burden on health-care providers coupled with limited resources can impact negatively on the quality of health-care provided.

2. Unstable living and/or working conditions with limited or lack of social support. This is compounded by the presence of other immediate life needs that are considered more important than taking medication such as housing, food and child-care.
3. Stigma and discrimination resulting in the onset of conflicts within the work and home environments. This arises from the potential disclosure of their HIV condition when treatment is started and the need to adjust their daily routines to fit their regimens;
4. Type of drug regimen and stage of HIV infection especially when side effects develop or the complexity of drug regimens affect the quality of life.

As ART provides the opportunity for patients to live longer, QOL is emerging as a significant medical outcome measure and its enhancement is becoming an important goal. Less well-known are the formidable challenges that anti-retroviral therapy presents. Current data describe the ability of HIV to hide and remain dormant in sanctuary sites of the body, reactivate later and cause disease. As a result, research from John Hopkins University suggests that complete eradication of the dormant viruses in the body of an infected person could take more than 60 years (Siff 2001). Patients seeking HAART need to assess their commitment to lifelong therapy. Quality of life remains a concern in the management of HIV patients especially in the light of increasing emergence of long-term toxicities, rapidly evolving treatment regimens and the indeterminate longevity of therapeutic effectiveness of currently available regimens.

## **2.2 Quality of life assessment**

HIV infection gives rise to an incurable debilitating disease and its treatment, which prolongs survival, is often associated with toxicity. QOL assessment is therefore important in evaluating clinical interventions in HIV-infected persons. Ultimately, this information is important in identifying the needs of these people as well as directing health-care resources. The assessment of QOL in relation to other chronic and debilitating illnesses dates back to the 1930s and the 1940s with the development of the New York heart association classification and the Karnofsky performance status (Badia



et al 2000). Since then a wide range of other QOL instruments has been developed. Some of the challenges of designing a QOL instrument relate to:

1. The difficulties in delineating the impact of the disease from the effects of treatment and instruments used in clinical trials should be responsive even to small treatment effects (Shumaker et al 1997).
2. The designing of an instrument that is both culturally appropriate and suitable to the literacy level of the population. This is especially so because clinical research in a wide range of illnesses including HIV/AIDS is becoming increasingly global and QOL instruments should be applicable across national boundaries (Shumaker et al 1997).
3. The multiplicity of domains within the concept of quality of life. The inclusion of more domains makes the instrument more comprehensive and exhaustive in evaluating QOL. However this also makes it more time consuming to administer and produces additional difficulties in data analysis and interpretation. Even with the increasing enthusiasm to incorporate QOL measures in clinical trials, there is no consensus on the best way to deal statistically with the multiplicity of HRQOL endpoints. The alternatives that have been suggested include the separate evaluation of few primary HRQOL endpoints or the use of summary measures that combine the results of the chosen domains (Sprangers et al 2002). Difficulties also exist in determining whether statistically significant differences are also clinically significant (Symonds et al 2002).
4. Designing an instrument that is appropriate to the time and energy of the patient and with sufficient range and breadth in each health domain. When the instrument is too long, missing data becomes a problem. This is more likely to happen among patients with advanced disease, patients with rapidly deteriorating health status and patients experiencing drug induced toxicity. In the analysis stage missing data presents a special problem. It reduces the number of participants for analysis, introduces bias and leads to overestimation of HRQOL scores. It has been found that if the rate of missing data is kept at <10-15%, the results are not compromised (Lin et al 2002).

Various studies have been done to compare the existing instruments and the results of these studies are often as varied as the studies. The Medical Outcome Study-HIV (MOS-HIV) consists of 35 questions covering eleven dimensions of QOL. It is by far the most widely used and has been translated into various languages. Several studies have been conducted and have determined its validity as compared to other instruments (O'Leary et al 1998, Badia et al 2000). This validity has been established even among some of the translated versions (Badia et al 1999). In a separate study comparing MOS-HIV with the more detailed instrument HIV Overview of Problems-Evaluation System (HOPES), scores obtained from the former were found to be more representative of the patients functional status (O'Leary et al 1998). Wu et al (1997), suggests that it is possible to choose from within the sub-scales contained within MOS-HIV depending on the objectives of the intended study, the available resources (including time) and the logistical concerns of the study. Besides MOS-HIV several other QOL instruments have been evaluated and recommended. These include:

1. The HIV/AIDS targeted quality of life instrument (HAT-QOL) (Holmes, Shea 1998, 1999);
2. The Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) QOL instrument (Peterman et al 1997);
3. The AIDS Health Assessment Questionnaire (AIDS-HAQ) (Lubeck, Fries 1997);
4. The Quality of well-being scale (QWB) (Anderson et al 1998).

The multiplicity of instruments underscores both the lack of a gold standard of QOL assessment and the difficulties of defining QOL and hence the difficulties in designing or choosing a QOL instrument. Some experts have recommended that the design of a QOL instrument should involve the patients in order to more comprehensively include the patients' perspectives (Leplege et al 1997, Holmes, Shea 1998). For instance the development of the HAT-QOL instrument involved 243 HIV-Infected individuals. These participants were divided into two groups. One group comprising 42 individuals was used to develop item content for the instrument while the remaining group was cross-sectionally studied using the items generated (Holmes, Shea 1998). However it is of interest to note that of the 42 individuals 76% were male, 66% were white and 55% were

either gay or bisexual. This clearly raises doubts as to its applicability to Kenyan populations. In Kenya, as in most of sub-Saharan Africa, majority of the inhabitants are black, women make up at least half of those infected with HIV and the predominant mode of transmission is through unprotected heterosexual contact (Steinbrook 2004).

### **2.3 QOL in people living with HIV/AIDS**

Non-specific constitutional symptoms such as fatigue, night sweats, anorexia, intermittent diarrhoea and weight loss are frequently encountered in the course of HIV infection. These may occur even in the absence of a complicating opportunistic infection. They are thought to be due to a primary effect of the HIV infection (Katz Hollander 2000). In a study conducted on 205 patients with symptomatic HIV, it was found that, except for weight loss, the presence, number and duration of other constitutional symptoms was strongly related to HRQOL (Cunningham et al 1998). Six constitutional symptoms were considered namely weight loss, fever, night sweats, anorexia/nausea/vomiting, exhaustion and myalgia. On 0 (worst) to 100 (best) point scales, mean scores ranged from 34 (for individuals with all five symptoms other than weight loss) to 78 (for patients with none). Another study conducted on a sample of 2267 patients with HIV found that the presence of white patches in the mouth (oral thrush), nausea/loss of appetite, persistent cough, difficulty in breathing and weight loss was associated with poorer overall scores in QOL (Lorenz et al 2001). Headache, pain in the mouth/lips/gums, fever/chills and diarrhoea were also associated with worse perceived QOL. The presence of these disease-related symptoms often signify advancing clinical stage of the disease. Some studies done to compare HIV with other chronic illnesses have found that the impact of advanced HIV infection on HRQOL was more significant than that of diseases such as cancer or depression (Douaily, Singh 2001).

However even in the absence of symptoms, HIV infected patients generally have poorer QOL than the general population. A study conducted in Italy to compare 214 asymptomatic patients with 2031 normal uninfected people found that on average the former reported lower scores than the latter (Arpinelli et al 2000). These findings were also demonstrated in another study conducted in the USA involving 154 individuals

(Miners et al 2001). This is because psychological dysfunction is evident from as early as the time of HIV diagnosis (O'Keefe, Wood 1996).

Co-morbidity adds layers of complexity to HIV management by increasing treatment requirements, increasing drug side effects and drug interactions and by creating competing health priorities. They also significantly compromise the patients' QOL. To get an accurate picture of how demanding the typical AIDS patient's regimen actually is, one has to take into consideration the fact that most of these people are also taking medication to:

1. Prevent or treat AIDS related opportunistic infections;
2. Stimulate appetite and/or libido;
3. Alleviate pain;
4. Supplement suspected or actual nutritional insufficiencies;
5. Combat depression, fatigue and insomnia and
6. Drugs to counter side effects such as nausea and neuropathies.

Co-morbid psychiatric conditions are fairly common in HIV-infected people. Some studies have reported an average prevalence rate of 40% which is 2-3 times higher than in the general population (Sherbourne et al 2000). The same study demonstrated that after controlling for the stage of disease, HIV-infected patients with any mood disorder had significantly worse physical functioning and general wellbeing than similarly infected patients without mood disorders (Sherbourne et al 2000). Those with mood disorders reported more days of disability, reduced social functioning, greater pain, more fatigue and other non-specific symptoms. More specifically, the presence of depression is associated with diminished scores in multiple areas of functioning and well-being independent of disease progression (Holmes et al 1997). Pneumocystis carinii pneumonia (PCP), an infection that frequently affects HIV-infected patients, has been found to adversely affect the patients ability to maintain good physical functioning (Douaihy Singh 2001).

Other studies have explored the impact of demographic variables on QOL. Eller (2001) found that work status along with depression and fatigue predicted 58% of the variance in

QOL among HIV patients. Another study done on 72 HIV-infected men in Sweden found that low income, low basic education, sick leave or disability pension were all associated with worse HRQOL (Eriksson et al 2000).

The social impact of HIV is related to the stigma associated with the illness. The stigma associated with HIV is largely attributed to the notion that HIV is a sign of sexual promiscuity (KANCO 2000). The diagnosis of AIDS brings with it the feelings of guilt, shame, depression, fear of disclosure and self-imposed isolation. In a case study of an African HIV positive patient conducted to determine the reasons of treatment failure, fear of disclosure and stigmatization were found to be the key reasons for non-compliance (Barfod 2000). Another study conducted on 75 HIV-positive public speakers found that Africans were more likely to be discriminated than their Asian and Australian counterparts (Braxton 2000). The same study found that in all instances women were more likely to be discriminated than men. Zierler and colleagues (2000), in a study on violence and victimization after HIV infection, discovered that revealing a positive HIV status triggered assault on about 45% of HIV infected people. Majority of these patients were assaulted by people close to them. This underscores the social disruption brought about by this disease.

#### **2.4 Quality of life in the era of HAART**

Greer (2001) reports a study done by Brechtel in which researchers questioned the ability of HAART to improve the quality of life for HIV patients. The study found that even when HAART was effective at improving the physical wellbeing of patients and was thus considered clinically successful, regimens had little effect on the quality of their extended life. This was based on information collected about pain, symptom severity, depression and psycho-social function. Comparing HIV-infected individuals on ART with those not on ART, one study found that being on treatment was associated with poorer QOL (Eriksson et al 2000). ATHENA, a project commissioned by the government of The Netherlands to study the effects of treatment on HIV infected individuals, used self administered questionnaires at six month intervals and used pain, vitality, mental health, general quality of life, general health and social function as parameters to assess impact.

It was found that quality of life improved in symptomatic but not asymptomatic patients (Govt. Netherlands 2002). In asymptomatic patients, the appearance of such side effects as lipodystrophy, a condition characterized by disordered fat metabolism and fat distribution can be quite distressing and has been associated with the use of PI. In some cases this leads to the deposition of fat at the base of the neck ("buffalo hump"), or the abdomen or the emergence of a "moon face" similar but unrelated to the Cushings' syndrome. This can occur even in the absence of overall weight gain and can be aesthetically unacceptable to the patient (Serra 2000). A study conducted at St. Vincent's hospital in the USA found that 64% of 116 HIV infected patients taking PIs had a loss of fat from the face and limbs and accumulation of abdominal fat after an average duration of ten months of treatment (Stephenson 1998).

### **2.5 Clinical benefits of treatment**

The aim of ART is to keep PLWHA alive and productive in their families, communities and workplaces for as long as possible. ART does this by reducing the rate at which the virus multiplies and reducing the chances of an individual picking up opportunistic infections that need hospitalization. It also aims at strengthening the immune system and slowing the onset of AIDS hence prolonging life. The ultimate goal of treatment is not just to prolong life but to improve the quality of life. The advent of HAART has reduced AIDS mortality and morbidity by up to 90% in the USA (Farmer et. al 2001). In Brazil, where a presidential directive made in 1996 guaranteed treatment to all those that qualified for it, AIDS related mortality dropped by at least 50%. The estimated savings from the avoidance of hospitalization is estimated at US\$350 million in addition to the added benefit flowing from healthy productive life years gained (Piot et. al 2001). In a study conducted in Sao Paulo between 1995-97, the average length of hospital stay declined by 13 days and opportunistic infections that necessitate daily hospital care fell dramatically from a total of 198 cases in 1995 to 75 in 1997 (Casseb et. al 1999). These findings were reproduced in studies done in Taiwan in a 5-year prospective study. The positive impact on health was demonstrated even in patients with advanced stages of HIV infection (Hung et. al 2000). By reducing the viral load, ART also reduces the risk of transmission of the virus to non-infected people. One study was conducted in Italy on 436

couples in which the men were HIV-positive and the women were initially HIV-negative. It was found that the probability of the women becoming infected by their partners was reduced by up to 50% when the men were using the drug AZT (Musicco et al 1994). In these men the use of ART was associated with significant reductions in the levels of HIV in semen (Vernazza et al 1997). ART can therefore serve both as a curative and a preventive measure. It is expected that these positive effects will be reproduced in Kenya because clinical trials done to evaluate efficacy of the drugs on HIV infected African patients concluded that country of origin or viral subtypes had no impact on the outcome of HAART (Frater et. al 2001). It is therefore expected that the reduction in hospitalization as well as the reduction in AIDS related morbidity will be associated with improvement in the social, physical and psychological dimensions of HRQOL.

## 2.6 Cost

For many Kenyans the triple therapy remains largely out of reach even with the recent sharp price drops announced by some of the leading drug companies that resulted in a price reduction of between 80-90% of the previous prices. Where the average course of therapy was costing US\$1000-1500 per patient per month (WHO 1997), the current cost ranges from US\$100-150 per patient per month, depending on the combination. It was assumed that as drugs become more available, employers, insurers and health management organizations would assume a bigger role in the treatment of people living with HIV/AIDS. Local studies have shown this to be untrue and 76% of people on anti-retroviral therapy pay for it from their savings (Kimani 2000). This may lead to patients taking sub-optimal doses in order to minimize cost and therefore minimizing the efficacy of the therapy.

Theoretically, part of the cost may be offset by savings made due to the improved health status that results from the decrease in opportunistic infections and hospitalization and the return to work with its resultant increase in productivity as demonstrated in the studies done in Mexico (Daly 2000). Another study found ART to be more cost-effective than treatment for various other chronic illnesses such as radiation therapy for early stage breast cancer and dialysis in patients with chronic renal failure (Freedberg et al 2001).

However, these findings have not been consistently demonstrated. One study showed that the mean monthly hospitalization and associated in-patient costs decreased and remained low two years after the introduction of protease inhibitors. The same study also concluded that the cost savings were transitory and were primarily due to reduction on admission rates. Overall health care costs continued to rise over time due to the introduction of more intensive regimens resulting from the development of drug resistance or the onset of drug side effects. Any savings made from lack of hospitalization were therefore transferred to out-patient pharmacies and ambulatory care (Hyland et al 1999, Keisser et al 2001). DeGroot (1997) reports a study done by Bozzette and colleagues to evaluate the impact of HAART on total HIV care costs. That study showed that while emergency room visits decreased among HIV patients on HAART, drug expenditure and clinic visits increased. Total costs of caring for HIV/AIDS patients on ART were no different from those not on ART. In a study involving 196 HIV-infected patients, it was found that financial losses as a result of the illness, constituted a major concern and reflected negatively on the QOL (Demmer 2001).

## **2.7 Role of counseling**

It is rare that a physician is able to address all the concerns of a patient during the standard clinic visits. Optimal care should be capable of meeting both the medical and psychosocial needs of a patient. However, in reality, studies have shown that care that meets all medical needs may fail to meet a client's emotional or social needs and vice versa (Aldana et al 2001). It is therefore important that adequate time is set aside for counseling so that appropriate and informed decisions on therapy and its implications are made by the patient (WHO 2000). All the positive messages initiated during the pre- and post-test counseling should be reinforced during counseling for ART. The issues that can be discussed during counseling sessions include financial considerations, drug information, emotional support, disclosure and drug adherence. Counselors should also help patients to make decisions on prevention of transmission especially among discordant partners, decisions about getting pregnant or entering marriage and decisions about appropriate sexual behavior. All these are important in overall outcome of treatment since they outline the expectations of both the caregivers and the patients.



Studies indicate that individuals who confront the stress occasioned by their illness with positive problem -solving and behavior-modifying activities have significantly better quality of life than those displaying passive acceptance of their illness (Douaihy, Singh 2001). The social network is an important source of support for all HIV patients regardless of whether or not they are on treatment. Cultural attitudes towards sex tend to lead to silence, denial, stigma and discriminations at all levels. In general, there are at least three dimensions of social support. These are emotional support, tangible support (e.g. financial assistance) and informational support. Counselors can help clients to explore their social support resources and select those relatives and friends who will accept and support them emotionally and even financially. In a study involving a sample of 118 HIV-infected Venezuelan patients, it was found that social support was associated with significantly better QOL scores in all domains except social functioning (Bastardo, Kimberlin 2000). Studies have shown that informational and/or tangible support is a stronger predictor of better HRQOL than emotional support (Douailly, Singh 2001). Informational support is important because many people with HIV know about the anti-retroviral drugs and may have unrealistic expectations about their effects. Studies done in Kenya found that women and men infected with AIDS expressed the following needs for information (KANCO 2000). Women were concerned with information about prenatal transmission and how to minimize transmission risk to their babies. They were also concerned with family related needs such as counseling for their families. Men on the other hand were concerned with how to continue having a pleasurable sex life while at the same time avoiding transmission and re-infection (KANCO 2000). Numerous prevention and intervention programmes have focused on women with less attention to the information needs of men (KANCO 2000). This leaves men more vulnerable to misinformation and myths.

ART is a lifelong undertaking and the disruption of lifestyle brought about by this should not be underestimated. A relationship must be established between the patient and the care team. Depression and despair are common when CD4 counts do not rise and weight is not gained as expected. This is aggravated when the patient is aware that he/she is draining the limited family resources on treatment that may ultimately be deemed futile.

Support groups can also help to break the sense of isolation and provides a good entry point for peer educators who can have a powerful impact on patients trying treatment for the first time. In a study conducted on 46 HIV-infected Chinese patients, it was found that behavioral group therapy was associated with improvement in the mood of participants particularly in the areas of anger, tension-anxiety, depression and confusion (Molassiotis et al 2002). Overall QOL scores were higher in this group than in a control group that did not receive any therapy or counseling. It is therefore intriguing that among the challenges that were identified in a study done on Kenyan HIV patients on anti-retroviral therapy was that few counseling services or support groups were available especially among the elite (Kimani 2000). This phenomenon was first described in a survey done to evaluate counseling services in Nairobi in 1999. The survey further revealed that while many slums and underprivileged communities had access to counseling, hardly any services targeted well-to-do individuals. Private health facilities were found not to provide psycho-social support such as on-going counseling (Pop. Council 1999). This is a significant omission in the provision of therapy that is likely to have an effect on the impact or outcome of treatment.

## 2.8 Adherence

In a study done on a cohort of 84 HIV patients taking ART, among those with more than 95% adherence, 81% had undetectable viral loads compared to 50% among those who had adherence levels between 80-90%. Majority (81%) had missed at least one dose since starting the regimen, 21% had missed a dose the day before the interview and 34% had missed a dose within the last three days before the interview. The reasons given for missing doses were

1. Forgetting (47%);
2. Feeling too sick (17%);
3. Being too busy (8%) and
4. Not having the medication at the dosing time (6%) (Stone 2000).

These findings were supported by another study done on 203 HIV patients among whom 57.4% reported taking their medication incorrectly most days. Seventeen percent of the patients missed a dose more than once a week while 83% misses a dose at most once a

week (Wolf et al 2001). Studies have also shown that adherence is slightly lower among patients taking PIs compared to patients taking NNRTIs (Wu 2001). This has been attributed to the higher frequency of side effects, more incidences of drug interactions and the more lifestyle disruption resulting from PI use. Individuals especially those who are asymptomatic or mildly symptomatic are likely to skip doses if they develop drug side effects. A study in Mexico conducted to evaluate factors that are associated with poor adherence established cost and adverse drug reactions as the most common factors in patients attending private institutions accounting for 44% and 28% of the cases respectively (Rodriguez et al 2000). Other factors identified were the complexity of treatment regimens, lack of knowledge/education and various psychological aspects of the patients. Clearly factors that affect QOL such as adverse drug reactions are important considerations when evaluating the reasons for non-adherence. The use of family members and peers to enhance compliance has emphasized the importance of social support in the treatment of HIV patients (Altice et al 1998). In one study conducted to assess compliance, the belief that taking more anti-retroviral medication would result in better life was found to be positively co-related with better compliance (Williams et al 2000).

## 2.9 Sexuality

It is feasible that the use of ART will increase the spread of the epidemic. This is because ART increases the length of the individual's life therefore increasing the period during which he/she can spread the disease to others. The availability of ART can also reduce the effectiveness of prevention messages. A survey done on 54 homosexual men in San Francisco found that some had already started taking risks due in part to the availability of ART (Dilley et al 1997). Forsythe (1998) quotes another study conducted at John Hopkins that found that a significant portion, (39%), of homosexual men had engaged in unprotected sex over the 6 months preceding the study. This was attributed to a false perception that ART represented a cure for the disease. Even among heterosexual individuals, one study showed that the respondents were more likely to believe that AIDS was less severe with the advent of ART and that safer sex practices were less important (Demmer 2001). The consistent and correct use of the male latex condoms greatly

reduces the risk of becoming infected with HIV. In studies of heterosexual couples in which one individual was HIV positive while the other was not, regular condom use was associated with extremely low rates of HIV transmission (NIAID 2001). However, according to the Kenya Demographic and Health Survey of 2003, 17% of men and 5% of women reported having used a condom in their most recent sexual encounter. In both men and women, condom use was found to be much more limited between spouses and cohabiting partners (3% and 2% respectively) than with premarital and extramarital sexual partners (46% and 23% respectively) (KDHS 2003).

### **2.10 Choice of regimen**

Maximal suppression of viral replication occurs only when combinations of anti-retroviral agents are used. No currently available agent is sufficiently potent to provide sustained suppression. Mono-therapy yields incomplete viral suppression for a very limited duration of time and is only indicated for the prevention of mother to child transmission (WHO 2000). Except in pregnant women where mono-therapy has been found to reduce mother-to-child transmission (MTCT) by up to 70% (WHO 1997), studies have shown that the use of only one drug results in the rapid development of drug resistance and treatment failure (WHO 2000). Using two drugs provides a more durable effect but the most effective combination involves the use of at least three drugs. Combination therapies that include protease inhibitors are associated with more significant and sustained reduction in viral load (Volberding 1997). However, PIs have had several problems related to frequency of dosing, the intake of large numbers of drugs, food restrictions and the multiple drug interactions that ultimately affect their tolerability.

### **2.11 Women and HIV therapy**

Recent data indicates that women are almost twice as likely as men to be HIV positive (9% Vs. 5%) (KDHS 2003). According to the 1998 Kenya Demographic and Health Survey (KDHS), 48% of all women are not currently employed (with employment being defined as receiving payment in cash or kind for work). Thirty-nine percent are employed all year round, 10% are employed seasonally and 35% are employed once in a while (NCPD/CBS/MIC 1999). Only 12% of all women work in professional, technical or

clerical capacities. This situation is likely to have remained the same given that currently only 12% of women have complete secondary level education and only 6% have college or university level education (KDHS 2003). It is also estimated that 13% of women have never attended formal schooling. Women living with HIV/AIDS are therefore more likely to be poorer, uninsured or under insured as compared to their male counterparts. Social and economic pressures leave women with fewer options and little influence on decisions that ultimately determine their health like the use of contraceptive including condoms that prevent pregnancy and re-infection while using anti-retroviral drugs. Gender norms often determine what men and women are supposed to know about sex and sexuality. This limits their ability to determine their risk level and to acquire information and means of protecting themselves. Stein et al (2000) showed that many women who are HIV positive, put the needs of the children or their infected partners ahead of their own and are more likely to be pre-occupied with immediate practical concerns such as housing, food and child care. They are therefore more likely to forego the benefits of treatment. It was found that 14% of women and 6% of men with HIV had delayed seeking care for themselves in the previous six months as a result of caring for someone else. Women were found to be nearly twice as likely as men to put off needed care especially in households that had children or another infected person. These social gender roles are thought to influence QOL differently in HIV infected women (Douaihy Singh 2001). Lenderking et al (1997) reported poor physical functioning in HIV infected women than in similarly infected men even after controlling for stage of disease. Even among those started on ART, the choice of treatment given to women has consistently been found to differ from their male counterparts. In 1996, a survey conducted on 3000 HIV-infected individuals showed that women were significantly less likely to be on HAART (defined as taking 3 anti-retroviral drugs consecutively), than men (49% Vs 87%). This was despite having the same indications for treatment (Stone 2000) and the same immunological and virological responses to treatment. However, the study did not determine what proportion of these access differentials was due to provider decisions and what was due to individual patient's preferences. This finding has been reproduced in other studies and the disparities appeared to be independent of financial considerations (Mocroft et al 2000).

STATEMENT OF THE PROBLEM

3.1 Research problem

Widespread access to ART is likely to transform HIV/AIDS into a manageable, albeit incurable, chronic illness. ART in HIV is now an established integral part of HIV/AIDS care that has evolved greatly in the past decade. Since the year 2000, the cost of ART has declined by up to 90% leading to a 30-50% increase in demand. Improved treatments and longer survival times have made functioning and QOL important treatment goals for people infected with HIV. The drug regimens, especially those involving three or more drug regimens, are complex and the duration of treatment is lifelong. In order to maximize the benefits of treatment immense personal discipline and commitment are required of the patient.

Studies conducted in the developed countries are of limited application in Kenya given that in these countries HIV has largely been limited to certain specific groups such as intravenous drug users (IDUs), homosexuals and marginalized ethnic groups. In all these groups, other factors that are independent of the HIV infection or treatment status influence QOL. HIV in Kenya cuts across the whole spectrum of the population and transmission is largely through heterosexual contact. In addition, scarcity of resources and epidemic HIV levels in Kenya creates constraints that can impact negatively on the use of anti-retroviral agents. For instance poverty, stigma with the attendant lack of social support and loss of employment may not allow one to sustain ARV therapy. Maximum benefit cannot be realized when one is not full adherent to treatment. The study was used to generate information on what deficiencies exist in the provision of anti-retroviral therapy. This study was also used to answer the following questions:

1. What factors influenced HRQOL among HIV-infected patients using ART in Nairobi?
2. Which of the three dimensions of HRQOL (namely physical, mental and social dimensions) is most affected?

3. How did the findings compare with similar studies conducted elsewhere?

By identifying the variables that influence HRQOL among HIV-infected patients, specific and effective treatment and counseling interventions can be designed.

### **3.2 Rationale**

HIV is affecting 2million Kenyans and accounts for up to 50% of the public expenditure on health (MOH/NASCOP/NCPD 1999). Access to anti-retroviral drugs can mitigate the socio-economic effects of HIV by reducing the rate and length of hospitalization, reducing opportunistic infections and increasing the productivity of those infected and affected. HIV infected persons must be persuaded to view the use of anti-retroviral therapy as a worthwhile investment rather than a hopeless waste of their limited resources. Showing a positive outcome on HRQOL becomes a useful tool for monitoring treatment outcome. It is also useful to the policy makers and advocates for increased access to treatment.

### **3.3 Justification**

The WHO defines health as a state of complete physical, emotional and social well-being (WHO 1978). In line with the recommendations of the Dakar meeting of 2000, this study focuses on the physical, mental and social impacts of ART. HRQOL is an outcome of healthcare as well as a consequence of illness or injury. Most healthcare services in the past have focused on the treatment of the patients' pathology with less attention to the whole person in terms of emotional and social aspects. In the current climate of growing concern about the effectiveness and efficiency of treatment, evidence based medicine is becoming more important. Healthcare is shifting from a disease-oriented approach to a patient-oriented approach. HRQOL is an important outcome measure for evaluating healthcare. QOL of life data, though subjective, is important because patients describe their functional status, their level of satisfaction with life and their experiences with treatment. It can therefore facilitate communication between health-care providers and their patients leading to improvement in the quality of care delivered. Information collected from this study can be used to assist in drug therapy selection and also help identify the domains of QOL that require specific attention especially through counseling.

Treatment plans can then be made that address the patients' medical needs within the social context of their lives.

The study is set within the context of dramatic price reductions of between 70-90% of some of the branded drugs in a move expected to lead to a higher demand of the drugs. With Kenya's industrial property rights bill of June 2001, there is hope for more widespread coverage. The bill addresses among other issues patent rights and compulsory licensing thereby allowing the government to import or manufacture cheaper generic brands. There are companies such as Cipla based in India willing to supply 3-drug combinations at a cost of between US\$350-600 per patient per year (Redfern 2001). Governments are struggling to develop treatment policies for developing countries where needs are greatest but resource constraints are most pressing.

### 3.4 Objectives

#### 3.4.1 Broad Objectives

To determine the health-related quality of life of HIV infected patients on anti-retroviral therapy.

#### 3.4.2 Specific Objectives

1. To determine the relationship between demographic characteristics (age, sex, marital status, employment status and family size) of HIV-infected patients on ART and HRQOL;
2. To determine the relationship between duration of ART and HRQOL;
3. To determine the relationship between regimen choice and HRQOL;
4. To determine the relationship between hospitalization and HRQOL;
5. To determine how adherence to treatment is related to HRQOL;
6. To determine how counseling is related to HRQOL;
7. To determine how disclosure of HIV status is related to HRQOL;
8. To determine the relationship between CD4 count and HRQOL.



### 3.5 Hypotheses

1. Treatment factors (regimen choice and treatment duration) have no relationship with HRQOL.
2. Patient factors (demographic characteristics, drug adherence and disclosure status) have no relationship with HRQOL.
3. Disease stage (hospitalization and CD4 counts) has no relationship with HRQOL.
4. Counseling has no relationship with HRQOL.

## CHAPTER 4

### METHODOLOGY AND MATERIALS

#### 4.1 Study design

The study was a cross-sectional survey in which both quantitative and qualitative methods of data collection were used.

#### 4.2 Study area

Health capacity to provide services is much greater in urban than in rural areas (Kimani 2000). This is because provision of ART must be supported by a functioning health system that ensures sustainability of drug supplies and trained health providers. It also requires basic laboratory facilities for monitoring both drug toxicity and treatment response. For these reasons, this study was conducted in Nairobi city. The population of Nairobi was estimated to be approximately 2 million people according to the 1998 census and is expected to reach 2.38million by the year 2003. The estimated HIV prevalence rate in Nairobi is 9.1% (KDHS 2003) and among these an estimated 5% have access to anti-retroviral therapy (WHO 2004). Nairobi has a total of 475 health institutions out of which 52 are registered as hospitals (GOK 2001). Participant were HIV positive adults on anti-retroviral therapy for at least three months attending treatment in the following four hospitals in the city:

1. Kenyatta National hospital,
2. M.P.Shah Hospital,
3. Aga Khan Hospital and
4. Mater Hospital.

All hospitals chosen for this study are part of the accelerated access initiative that provides branded anti-retroviral drugs at reduced prices. They therefore receive prescriptions from external health-care providers hence their catchment area extends beyond the patients seeking treatment from hospital based health-care providers. They have established 'best-practice' policies by specifically training their pharmacists to honor only prescriptions that conform to internationally set guidelines in the use of ART. This has been in an effort to reduce the use of inappropriate drug

combinations or incorrect dosages that lead to the development of drug resistance. They also provide the laboratory and clinical facilities required for ART provision in-house without the need to out-source these services. The specific hospitals represent different socio-economic cadres as well as the different health care institutions. Kenyatta hospital is chosen because it is a public hospital serving patients of low socio-economic status (SES). It is also a tertiary level and a teaching hospital and is therefore equipped with the technical resources to provide ART. Mater Hospital, MP Shah Hospital and Aga Khan Hospital are all private religious based hospitals sponsored by three different religious groups serving middle and high income patients. Nairobi hospital was chosen, though did not participate, because it is a private hospital that serves patients of the high socio-economic categories. Initially all the sites were to provide equal numbers of participants but this was not achievable due to higher levels of non-response in some of the sites.

#### **4.3 Inclusion criteria**

Non-pregnant HIV infected individuals on HAART aged more than 18 years and who had been on treatment for at least 3 months.

#### **4.4 Exclusion Criteria**

HIV positive patients aged below 18 years on HAART;

HIV positive pregnant women on HAART;

HIV positive individuals who have been on HAART for less than three months;

HIV positive individuals not on HAART.

Pregnant women are excluded because factors related to the pregnancy that are independent of the HIV status are likely to influence HRQOL. In addition, most pregnant women are only maintained on therapy for a very limited period. After onset of therapy, the recommendation is that the first formal laboratory evaluation be done after three months to assess effectiveness of the regimen. This therefore, represents the minimum time required to register any impact of treatment. This is why the three month cut off period is required of the sample population. Patients who are minors (aged less than 18 years) are exempted because obtaining a verbal consent from them may not cover the

legal requirements. Additionally, HIV in children differs from disease in adults in its clinical presentation and disease progression (NASCO 2001). The rapid disease progression is due to the immature immune system in children which results in poor control of HIV replication. This in turn leads to high susceptibility to infectious diseases.

#### 4.5 Sample size

Calculation of the sample size is made by using the equation:

$$n = \frac{Z^2_{(1-\alpha/2)} P(1-P)}{d^2}$$

where n= sample size

a= level of significance set at 0.05

P= estimated proportion of patients on ART reporting a positive QOL

d= degree of precision set at  $\pm 5\%$

Z= critical value corresponding to 95% Confidence Interval (CI) obtained from the standard normal distribution. (1.96) (Daniel 1991)

Badia et al (2000) demonstrated that 86.4% of patients starting or switching ART reported significant improvement of HRQOL. Based on this study P is set at 0.864.

In choosing this formula to calculate the sample size, consideration is given to the fact that the data collected will largely be qualitative and therefore the parameters being sought are population proportions and percentages.

Substituting for the equation:

$$n = \frac{(1.96)^2 (0.864)(0.136)}{(0.05)^2} = 180.6$$

n= 181 people

To cater for missing data which is inevitable in self administered questionnaires, a 10% increase (Lin et al 2002) in the sample size is added.

$$n = (181 + 18) = 199 \text{ people.}$$

#### 4.5.1 Sampling procedure

Consecutive HIV patients on ART who qualify for inclusion and are willing to participate.

#### 4.6 Variables

##### 4.6.1 Dependent Variables

Quality of life of patients on anti-retroviral therapy defined in terms of:

1. Physical health;
2. Mental health;
3. Social interaction and functioning.

A scoring system was used to quantify HRQOL. Since the questions required predominantly Yes/No answers a score of "0" was awarded for a negative outcome while a score of "1" was for a positive outcome. In the interpretation of the results therefore, a higher score represents a better HRQOL and vice versa. There was an overall HRQOL score representing the three domains being assessed as well as three individual domain scores.

Using the scoring system applied in the MQOL-HIV instrument (Badia 2000), physical health was weighted against social and mental health. Weighting was done for the physical health domain because physical and functional health status has been found to be the most important component of a patient's QOL. Its improvement has been found to prevent or at least delay institutionalization (Resnick 2000). A QOL index was therefore generated using the formula:

$$\begin{aligned} & \text{Mental health score} + \text{Social functioning Score} + (2 \times \text{Physical health score}) \\ & = \text{Overall QOL score} \end{aligned}$$

#### 4.6.2 Independent Variables:

Regimen type

Hospitalization

Compliance

Duration of treatment (in months)

Demographic characteristics (Age, sex, marital status, employment status and family size)

CD4 count

HIV status disclosure

Counseling

#### 4.7 Ethical considerations

Informed verbal consent was obtained from the participants before filling of the questionnaire to ensure that participation was purely on a voluntary basis. Assurance of the confidentiality of their responses and identities was made. Clearance for the study was sought from the ethical committees and the advisory/ethical committees of the respective hospitals.

#### 4.8 Data collection instrument

In developing the instrument, the contents of 3 other existing QOL instruments were adopted. The MOS-HIV instrument has 35 questions covering the following domains General health perception (GHP), Pain, Physical functioning (PF), Role functioning, Social functioning (SF), Mental health (MH), Energy/fatigue, Health distress, Cognitive function (CF), Health transition and overall QOL (Badia 2000). The MQOL-HIV has 40 questions covering 10 dimensions namely MH, PF, Physical health, SF, Social support, CF, Financial status, Partner intimacy, Sexual function and medical care (Badia 2000). The HAT-QOL covers nine dimensions namely overall function, health worries, SF, disclosure worries, financial worries, life satisfaction, medication concerns provider trust and HIV mastery (Holmes W, Shea J 1998). Several considerations were made in choosing the HRQOL instrument. All

three instruments are disease specific. MOS-HIV was chosen because it is one of the most widely used HRQOL instrument. It has also been widely reviewed and has been found to be particularly useful in patients on ART in capturing outcomes of treatment in the social and physical domains ( Wu et al 1997, Holmes 1999, Badia et al 1999, Badia et al 2000, Davis 2001). However, in some studies, MQOL has outperformed MOS-HIV (Badia 2000). HAT-QOL was chosen only in as far as it addressed the issue of disclosure. The tool used in this study was composed of questions derived from these three tools but simplified into dichotomous YES/NO responses with language modification.

The data were collected over a period of four months. This was an extension of one month from the originally set period and was necessitated by the need to get the sample size set. Outpatients who were willing to participate collected questionnaires from the pharmacies and completed them unassisted. Inpatients from Mater and MP Shah Hospitals were assisted in filling the questionnaire if they were physically incapable of doing so themselves. Data collection was achieved using self-administered questionnaires formatted in the English language (Appendix I). *Translation* was not required since current studies showed that 81% of patients on anti-retroviral therapy have thirteen or more years of education (Kimani 2000). The self-administered questionnaire was chosen for this study because it is free from interviewer bias, it gives respondents adequate time to give well thought out answers and it gives respondents the privacy of answering delicate questions especially related to sexuality.

#### **4.9 Minimizing biases and errors**

Bias and error was minimized by:

1. *Providing for missing data by increasing the sample size;*
2. Use of a standard questionnaire for all respondents;
3. Pre -testing of the questionnaire which was conducted by the principle investigator at KAM health services Ltd. and the questions were modified accordingly prior to collection of data.

#### **4.10 Data processing and analysis**

The filled questionnaires were edited and pre-coded when all questionnaires were completed and collected. Classification and tabulation of data according to common characteristics was then done after which data analysis was conducted using Statistical Package for Social Sciences on personal computer (SPSS-PC) package. Chi square statistical tests of significance were applied to identify relationships between HRQOL and the independent variables in patients on ART. Linear regression analysis was done to determine the correlation between CD4 count and HRQOL scores. Qualitative data from open-ended questions was transcribed, synthesized, and categorized into relevant themes.

#### **4.11 Data Presentation**

Data were then presented in tabular and graphic forms.



## STUDY RESULTS

In the study design, questionnaires for the outpatients were left at the respective hospital pharmacies for patients to collect. It was anticipated that some patients would take the questionnaires and fail to return them. Therefore, even though a sample size of 199 was deemed adequate for the study, more than 199 questionnaires were distributed. All completed questionnaires were analyzed and the results are presented in this chapter. This chapter is broadly divided into three parts. The first part gives a profile of the respondents in terms of their demographic and treatment properties. The second part gives the results of the three domain scores. The last part of the chapter presents the analyses of the relationship between the various characteristics and the overall HRQOL. The results of the open ended question were summarized into related themes. These were also included in the chapter to support the other findings of the HRQOL analyses.

### 5.1 DISTRIBUTION OF PARTICIPANTS

There were 206 HIV infected patients using ART who participated in this study. They were drawn from four out of the five hospitals in Nairobi which were initially chosen to participate in the study. Patients from the casualty departments, consultant clinics, patients referred from private practitioners and inpatients were all included as long as they were willing to participate in the study. Many in-patients were excluded because they were confused, comatose or too weak to talk. Those that could talk but were either too weak to write or were paralyzed were assisted in filling the questionnaire. Access to inpatients was granted in two of these hospitals namely Mater and MP Shah hospitals which is why more patients were derived from these two hospitals. Table 3 demonstrates the distribution of the study participants.

Table 3: Participant Distribution Among Study Health Facilities in Nairobi. (n=206).

| HOSPITAL | RESPONDENTS |      | PERCENTAGE |
|----------|-------------|------|------------|
|          | FEMALE      | MALE |            |
| MP SHAH  | 31          | 23   | 26.2       |
| KNH      | 15          | 7    | 10.7       |
| AGA KHAN | 27          | 17   | 21.4       |
| MATER    | 54          | 32   | 41.7       |
| TOTAL    | 206         |      | 100        |

Majority of the patients who participated were out-patients. Out of 206 participants, 47 (22.8%) were inpatients while 159 (77.2%) were out-patients as shown in Figure 3.

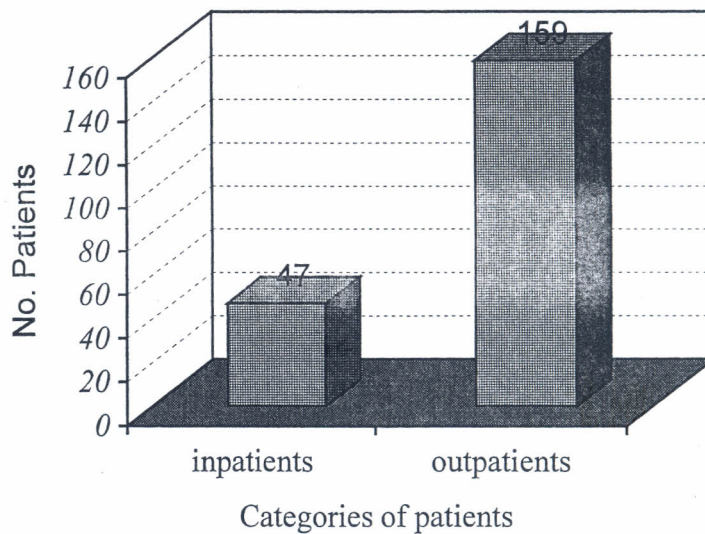


Figure 3: Proportion of Inpatients and Outpatients (n=206).

## 5.2 SOCIO-DEMOGRAPHIC CHARACTERISTICS

Respondents were categorized according to the following socio-demographic characteristics; sex, age, level of education, marital status, employment status and family size. Out of the 206 participants majority (61.7%) were female. Those that had only primary level education accounted for only 5.8% of the total number. Those that had at least secondary school education accounted for 55.8% of the total number while the rest (38.3%) had post-secondary school training.

### **5.2.1 Age Distribution**

The age ranged from 18 years to 68 years with a mean age of 37.6 years and a standard deviation of 7.2 years. Three people did not indicate their ages. Eight (3.8%) people were aged below 25 years while those aged 45 years and above were 17% of the total. Majority (51.5%) were between 35-44 years while the rest (26.2%) were between 25-34 years.

### **5.2.2 Marital Status**

There were 104 (50.5%) participants who reported that they were married at the time of filling the questionnaire. The rest were either single (27.7%), widowed (12.1%) or separated/divorced (8.7%). Two people did not disclose their marital status.

### **5.2.3 Number of Children**

Majority (53.4%) of the participants reported they had between 1 and 3 children. Forty nine (23.8%) people had no children while forty three (20.9%) people had between 4 and six children. Only 3 people reported they had more than six children. One person did not respond to this question.

### **5.2.4 Employment Status**

Those participants who reported that they were formally employed and working both part-time and full-time, accounted for 47.1% of the total number. The rest were either employed but on sick leave (13.1%), self-employed (14.1%), unemployed (21.4%) or *retired* (4.4%).

## **5.3 TREATMENT PROFILE**

In trying to establish the treatment profile of the patients, information on the duration of therapy, payment modality and the anti-retroviral combination was sought. Additionally the co-morbidity profile as indicated by the use of additional medication was established. The level of adherence to treatment and the side-effect profile was also established.

### 5.3.1 Duration of therapy

Duration of therapy ranged from 6 months to 61.92 months (5.16 years) with a mean of 16 months and a standard deviation of 13.4 months. Three people did not indicate when they started treatment.

### 5.3.2 Payment Modality

The burden of paying for treatment is borne largely by patients (62.1%) and their relatives (18.5%). In 22.6% financial difficulties due to the cost of treatment was described. Insurance payment accounted for only 1% of the patients while employers catered for 6.8% of the patients. Those that were sponsored by an NGO or a project accounted for 11.7% of the total. Among the respondents, 40.4% wanted a reduction in the cost of treatment including the availability of generic drugs.

### 5.3.3 Anti-retroviral Combinations

All but one participant responded to this question. Twelve different drug combinations were used as shown in Table 4. These combinations can be summarized as PI sparing regimens, standard PI and boosted PI regimens. Standard PI regimens are those in which a single PI is used in combination with drugs from the other two drug groups (NNRTI and NRTI). Only 6 (2.9%) participants were in this category. There were 37 (18%) participants using the boosted PI regimens. In this type of treatment, two PIs are used in combination with drugs from the other two groups. A low dose of one PI (Ritonavir) is used to improve the drug levels of the second PI which is then used at a lower dose. The rest (79%) were using combinations that did not include a PI. Boosted PI regimens were used at the Aga-Khan and Kenyatta Hospitals. None of the participants from Kenyatta hospital were on standard PI regimens.

Table 4: Specific Anti-retroviral Combinations (n=206).

|   | DRUG COMBINATION                              | Frequency | Percentage |
|---|---|-----------|------------|
| 1 | Stavudine; Didanosine; Efavirenz              | 94        | 45.6       |
| 2 | Lamivudine, Zidovudine; Efavirenz             | 50        | 24.3       |
| 3 | Saquinavir; Ritonavir; Lamivudine, Zidovudine | 23        | 11.2       |
| 4 | Lamivudine, Zidovudine ; Nevirapine           | 7         | 3.4        |

|    |   |     |     |
|----|---|-----|-----|
| 5  | Lamivudine, Zidovudine ; Invirase ; Ritonavir | 7   | 3.4 |
| 6  | Stavudine; Didanosine; Nevirapine             | 6   | 2.9 |
| 7  | Lamivudine; Efavirenz ; Stavudine             | 5   | 2.4 |
| 8  | Lamivudine, Zidovudine; Ritonavir; Indinavir  | 4   | 1.9 |
| 9  | Lopinavir, Ritonavir; Didanosine; Stavudine   | 3   | 1.5 |
| 10 | Lamivudine, Zidovudine ; Indinavir            | 3   | 1.5 |
| 11 | Indinavir ; Stavudine; Didanosine             | 2   | 1.0 |
| 12 | Indinavir ; Efavirenz; Didanosine             | 1   | 0.5 |
|    | MISSING DATA                                  | 1   | 0.5 |
|    | TOTAL   | 206 | 100 |

### 5.3.4 Self-Reported Adherence

In this section, patients were required to state whether they had missed any doses in the preceding 24hrs and 72hrs. A 10% increase in the non-adherence rate was noted between 24-72 hours as indicated in Table 5.

Table 5: Distribution of Participants According to Self-Reported Adherence (n=206).

| ADHERENCE                 | FREQUENCY  |             | MISSING DATA | TOTAL      |
|---------------------------|------------|-------------|--------------|------------|
|                           | YES        | NO          |              |            |
| Missed =>1 dose in 24 hrs | 37 (18.0%) | 168 (81.6%) | 1 (0.4%)     | 206 (100%) |
| Missed =>1 dose in 72 hrs | 59 (28.6%) | 147 (71.4%) | 0 (0%)       | 206 (100%) |

The most common reason for not taking drugs as instructed was lack of medication due to financial constraints. This accounted for 14.1% of the cases of non-adherence. Additionally, some people had more than one reason for missing doses. Ten people said that severe side-effects were responsible for non-adherence. Other reasons for non-adherence included “feeling too sick”, “feeling like the drugs were not working” and “traveling out of town”. These reasons accounted for 8.7% of cases.

### 5.3.5 Co-morbidity Profile

In this section patients were asked to state what additional drugs they were taking. This was useful in assessing co-morbid illnesses. In addition this was used in the overall physical health score as it was a reflection of symptomatic illness. As shown in Table 6, more than half (58%) of the respondents indicated that they were on additional

medication. Patients were also required to specify which additional drugs they were using. Pain treatment was reported by 59 (28.6%) patients while 50 (24.3%) patients were on treatment for bacterial infections and 13 (6.3%) patients were on anti-histamines. Notably, 48.5% of patients reported that they were experiencing pain at the time of the study.

Table 6: Types of Additional Medicines (n=206).

| TYPE                     | FREQUENCY | %    |
|--------------------------|-----------|------|
| Pain killers /Analgesics | 59        | 28.6 |
| Antibiotics              | 50        | 24.3 |
| Anti-fungals             | 39        | 20.9 |
| Vitamins/Appetizers      | 37        | 18.0 |
| Antihistamines           | 13        | 6.3  |

In addition, there were patients with other co-morbid chronic illnesses. Six patients were on treatment for hypertension, one person had sickle-cell anemia and one person was on treatment for tuberculosis.

### 5.3.6 Side effect profile

The presence of common distressing but not necessarily life-threatening side-effects were investigated and the results are summarized in Figure 4. In all cases, less than half the respondents reported any of these side effects. Nausea and/or vomiting experienced immediately after taking drugs were the most common side effects and this was reported by 40.3% of patients. Only 16% of the respondents reported that they had had to change their medication due to side-effects.

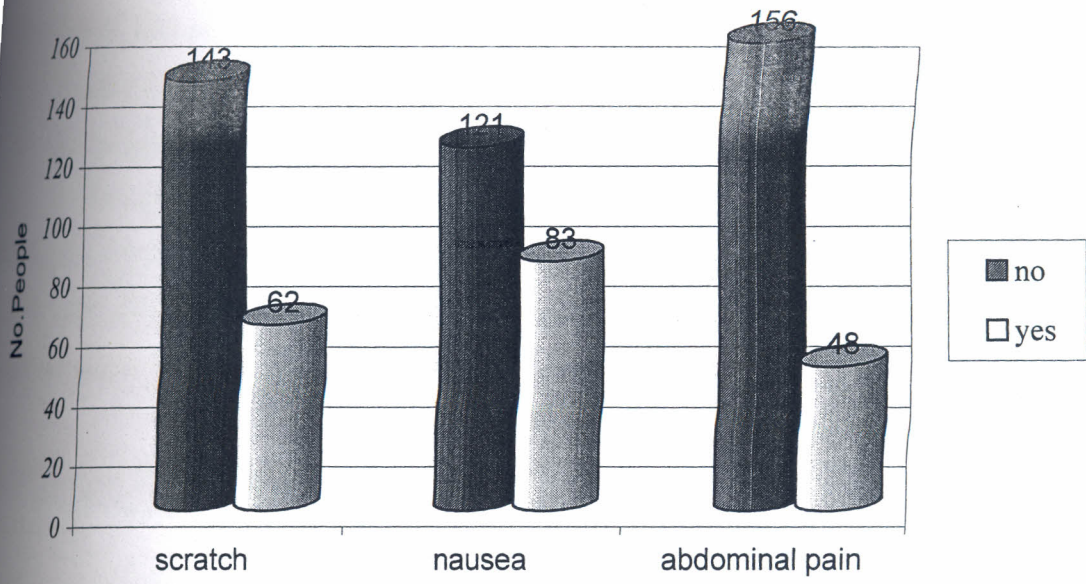


Figure 4: Self-reported Side effect Profile (n=206).

#### 5.4 SYMPTOM STATUS

Among respondents, 53.9% reported that treatment had been beneficial and had led to overall improvement in health status. The presence of common constitutional symptoms associated with HIV/AIDS infection was sought. Patients were also required to state if they had oral sores, cough and whether or not they had gained weight in the course of treatment. More than half the respondents reported that they had skin rashes. Somatic pain was the second most common symptom. Majority (65%) of the patients reported weight gain since starting treatment. These results are summarized in Table 7.

Table 7: Proportion of Symptomatic Patients (n=206).

| SYMPTOMS          | YES   |
|-------------------|-------|
| Skin rashes       | 62.1% |
| Somatic Pain      | 48.5% |
| Fever             | 44.2% |
| Night sweats      | 38.3% |
| Mouth ulcers      | 31.6% |
| Coughing          | 26.7% |
| Diarrhea/Vomiting | 23.8% |

## 5.5 MENTAL HEALTH STATUS

There were 205 respondents analyzed to give their mental health status at the time of the study. One person did not respond to the questions in this section. In evaluating the mental health status, features common in depressive illness such as mood disorders, fatigue, low appetite and poor sleep were inquired about. The results indicate that mood disorders and fatigue were the most common features. Slightly more than a quarter of the patients experienced poor sleep as indicated in Table 8.

Table 8: Mental Health Status (n=205).

| SYMPTOM             | YES   | NO    |
|---------------------|-------|-------|
| Sad/guilty/hopeless | 45.6% | 53.9% |
| Fatigue             | 43.7% | 55.8% |
| Poor concentration  | 41.7% | 57.8% |
| Poor appetite       | 32%   | 67.5% |
| Poor sleep          | 26.7% | 72.8% |

In order to assess adjustment mechanisms, patients were further categorized into three groups according to whom they blamed for their illness. The "GUILT" group consisted of those people who felt responsible for their illness. This group had the most people and accounted for 47.1% of the total. The "BLAME" group consisted of those who held someone else responsible for their HIV status. This group consisted of 33.0% of the total number of respondents. The last group consisted of those who felt no-one was to blame for their HIV status. These were regarded to have accepted and come to terms with their HIV status and they made up only 19.4% of the total number of respondents.

These data were further analyzed according to sex. It was established that among those that experienced guilt, 36 (37.1%) were women while 61(62.9%) were men. Among those that blamed someone else for their illness, 62 (91.2%) were female while 6(8.8%) were male. Among those that had accepted their health status, 28(70%) were female while 12(30%) were male. The 127 female respondents can further be divided into those who blamed someone else (49.8%), those who experienced guilt (28.2%) and those who had accepted their health status (22.0%) as shown in figure 3. The 79 male respondents



however had a higher tendency to experience guilt with 77.2% falling in this category. Only 7.6% had accepted their status while 15.2% blamed someone else for their illness.

### 5.6 SOCIAL SUPPORT

To assess the level of social support, the four components that were considered were disclosure pattern, counseling, sexuality and emotional support.

#### 5.6.1 Disclosure Pattern

Majority (81.4%) of the respondents had disclosed their HIV status to at least one person. Two respondents did not declare their disclosure status. Men were more likely not to disclose their HIV status than women and this difference was statistically significant ( $p=0.017$ ) as indicated in Table 9.

Table 9: Sex and Self-Disclosure Status (n=204).

| GENDER                                | SELF DISCLOSURE |           | TOTAL |
|---------------------------------------|-----------------|-----------|-------|
|                                       | Not Disclosed   | Disclosed |       |
| MALE                                  |                 |           |       |
| ▪ Count                               | 21              | 57        | 78    |
| ▪ % within sex                        | 26.9%           | 73.1%     | 100%  |
| ▪ % within disclosure status category | 55.3%           | 34.3%     | 38.2% |
| FEMALE                                |                 |           |       |
| ▪ Count                               | 17              | 109       | 126   |
| ▪ % within sex                        | 13.5%           | 86.5%     | 100%  |
| ▪ %within disclosure status category  | 44.7%           | 65.7%     | 61.8% |
| TOTAL                                 |                 |           |       |
| ▪ Count                               | 38              | 166       | 204   |
| ▪ % of respondents                    | 18.6%           | 81.4%     | 100%  |

Chi-square 5.734

df=1

p=0.017

Among immediate family members, spouses were the most likely and children were the least likely to be told about the HIV-status of the respondents. Out of 156 respondents who were reported to have children, only 17 (four male and 13 females) had disclosed their status to their children. This is shown in Table 10.

Table 10: Frequency Table for Disclosure Pattern (n=205).

| PERSON DISCLOSED TO | FREQUENCY | PERCENTAGE   |
|---------------------|-----------|--------------|
| Spouse              | 96        | 46.6%        |
| Brothers /sisters   | 82        | 39.8%        |
| Parents             | 40        | 19.4%        |
| Friends             | 19        | 9.2%         |
| Children            | 17        | 8.3%         |
| Others              | 7         | 3.4%         |
| <b>No one</b>       | <b>38</b> | <b>18.4%</b> |

Out of 104 married respondents, 96 had disclosed to their spouses. Spousal disclosure was therefore 92.3%. Out of the eight that did not disclose to their spouses, two were female and six were male. Concern about doctor-patient confidentiality was expressed by 16.1% of respondents. Even at the pharmacy level, a need for more discretion when dispensing drugs was raised to prevent accidental disclosure of HIV status.

### 5.6.2 Counseling

There were 172 (83.5%) respondents who had received counseling before they were started on treatment compared to 33 (16%) who had not. This trend was reversed once treatment was started with only 82 (39.8%) of respondents receiving counseling during treatment compared to 123 (59.7%) who did not. There were 135 (65.5%) respondents who believed that they needed counseling. Seventy (34%) respondents did not think counseling was needed. This is presented in Figure 5.

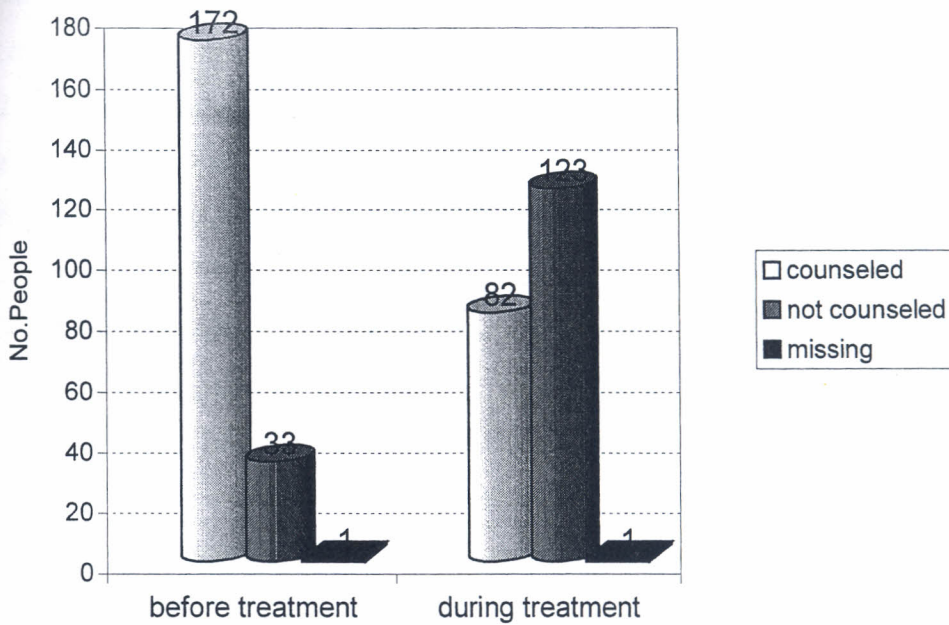


Figure 5: Counseling Status Among Study Subjects (n=206).

### 5.6.3 Sexuality

There were 156 (75.7%) respondents that felt that their sex drive was reduced compared to 47 (22.8%) who felt their sex drive was normal. Out of these 47, eight were female and 39 were male. Three female participants did not answer the question. Additionally, 104 (50.5%) respondents reported they currently had one sexual partner compared to 97 (47.1%) who did not have any current sexual partner. Only 4 males (1.9%) reported that they had more than one sexual partner at the time of the interview. One person did not respond. There were 128 (62.1%) respondents that reported that they had used a condom during their last sexual encounter prior to the interview compared to 74 (35.9%) who did not. Fifty four among those that had used a condom were married.

### 5.6.4 Emotional Support

Patients were asked to state their source of hope, encouragement and strength. Only 24 (11.7%) patients identified health care providers as such. Thirty (14.6%) patients out of

which two were female and 28 were male had no source of hope or encouragement. Forty male and ninety-one female patients said religion was their source of encouragement. Family members and friends provided emotional support to 35.9% of the patients. There were 32.8% who said they needed more emotional support from their families. Conflict, desertion or stigma within families related to HIV status was reported by 5.4% of respondents. Two people did not respond to this question.

## 5.7 ACTIVITIES OF DAILY LIVING

To gauge the level of physical incapacitation, patients were evaluated on their ability to perform activities of daily living. These include bathing, walking, dressing, feeding, getting out of bed and going to the toilet without assistance. On average 85.5% of the patients were able to perform these tasks without assistance as shown in Table 11.

Table 11: Proportion of People Performing Activities of Daily Living (n=206).

| ACTIVITY                              | YES   |
|---------------------------------------|-------|
| Feeding without assistance            | 86.4% |
| Walking without assistance            | 85.4% |
| Dressing without assistance           | 85.4% |
| Go to the toilet without assistance   | 85.4% |
| Bathe without assistance              | 85.4% |
| Getting out of bed without assistance | 85%   |

## 5.8 HRQOL SCORES

### 5.8.1 Physical Health Score

In determining the physical health score, 4 parameters were considered. These were the ability to perform activities of daily living (section 5.7), the use of additional medication (section 5.3.5), the side-effect profile (section 5.3.6) and the symptom status (section 5.4). One mark was awarded to all positive responses while 0 was given to negative responses. Physical health score was weighted against the other dimension scores by multiplying it by a factor of 2. The maximum attainable score was 36. Two people scored 0 representing severe physical incapacity while 32 (15.5%) scored 36 points. Eighteen

percent of the patients scored  $\leq 18$  points as shown in Figure 6. (Detailed tables for the individual domain scores are in Appendix II)

**5.8.2 Mental Health Score**

In determining the general mental health status, six questions in part 5 of the questionnaire were scored. Seventy six people (36.9%) scored 6/6 while forty people scored '0' as shown in Figure 6. This category was answered by all patients and it had the highest number of people who scored less than half the overall dimension score.

**5.8.3 Social Functioning and Interaction**

Social functioning and interaction was determined by scoring the questions that dealt with disclosure, sexuality and counseling to get a maximum score of 8. No-one scored 0, fifty-nine (28.9%) people scored 6/8. Only 6.4% attained the maximum score which was 8 while 33.8% scored between 0-4 as shown in Figure 6. Two people did not respond to all the questions in this section.

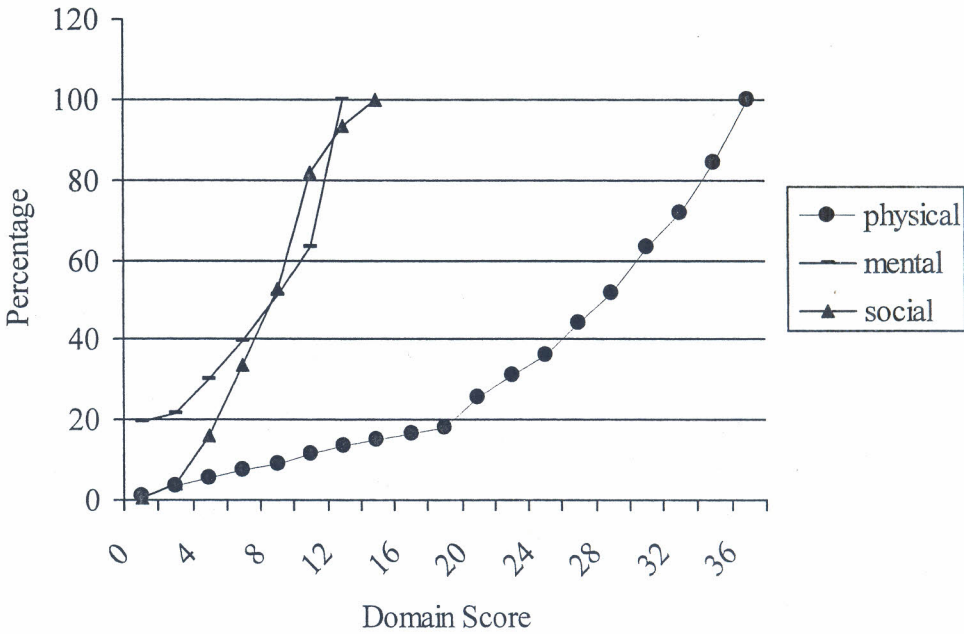


Figure 6: Cumulative Frequencies of Individual Domains

#### **5.8.4 Categorized overall HRQOL Score**

The highest possible score achievable after adding the three dimensions was 50. The overall score was therefore categorized into three. There were those that scored  $\leq 25$  representing below average and poor overall HRQOL. These accounted for 19.6% of the total while the rest had above average overall HRQOL. In total, 80.4% of the respondents had above average HRQOL scores. This later category was further subdivided into those that scored between 26-44 representing good overall HRQOL. These were the majority and accounted for 56.4% of the total number. The remaining 24.0% scored  $\geq 45$  representing excellent HRQOL. Two people were excluded from the overall score because they did not complete all the questions in the social functioning section. One person scored the lowest score which was 5/50 while two people scored 50/50.

### **5.9 RELATIONSHIP BETWEEN HRQOL AND SOME SELECTED CHARACTERISTICS**

#### **5.9.1 Relationship between Socio-Demographic characteristics and Overall HRQOL**

Using cross-tabulation, an analysis was done to determine the relationship between the respondents socio-demographic characteristics and the overall HRQOL. Out of the 206 respondents, two did not complete the social functioning and interaction domain and they were excluded in the analyses.

##### **5.9.1.1 Gender and HRQOL**

More males than females scored less than 25/50 and they accounted for 70% of the people in this category. More females scored  $\geq 45/50$  and accounted for 75.5% of the people in this category. This difference was statistically significant ( $p < 0.001$ ) as shown in Table 12.

Table 12: Relationship Between Sex and HRQOL (n = 204\*).

| GENDER                         | Category of HRQOL score |       |       | TOTAL |
|--------------------------------|-------------------------|-------|-------|-------|
|                                | <=25                    | 26-44 | =>45  |       |
| Male                           |                         |       |       |       |
| ▪ count                        | 28                      | 38    | 12    | 78    |
| ▪ % within sex                 | 35.5%                   | 48.7% | 15.4% |       |
| ▪ %within HRQOL score category | 70.0%                   | 33.0% | 24.5% |       |
| Female                         |                         |       |       |       |
| ▪ count                        | 12                      | 77    | 37    | 126   |
| ▪ %within sex                  | 9.5%                    | 61.1% | 29.4% |       |
| ▪ %within HRQOL score category | 30.0%                   | 67.0% | 75.5% |       |
| TOTAL                          | 40                      | 115   | 49    | 204   |

Chi-square 22.323      df=2      p<0.001

(\*Two people did not fill the social functioning and interaction category.)

### 5.9.1.2 Age and HRQOL

Patients were divided into three age clusters namely <35 years, 35-44 years and >44 years. These were tabulated against the three categories of HRQOL scores. In addition to the two people that did not complete the questions the questions in the social interaction and functioning section, there were three people who did not indicate their ages. Therefore, only 201 participants were analyzed. There was no relationship between age and the overall HRQOL score ( $X^2=4.412$ ,  $df=4$ ,  $p>0.1$ ).

### 5.9.1.3 Level of Education and HRQOL

Patients with only primary level education were under represented in the study. In the analysis, they were grouped together with those that had received both primary and secondary level school education. This group was then compared to those that had post-secondary level training. There was no statistically significant difference between those that had post-secondary education and those who had primary or secondary level education ( $X^2=4.539$ ,  $df=2$ ,  $p>0.05$ ).

### 5.9.1.4 Marital Status and HRQOL

In analyzing the relationship between marital status and overall HRQOL, patients who declared that they were single, widowed or separated/widowed were all classified as being without spouse. They were then compared to those who declared that they were married and the results are shown in Table 13.

Table 13: Relationship Between Marital Status and HRQOL (n=203\*).

| MARITAL STATUS       | Category of HRQOL score |       |       | TOTAL |
|----------------------|-------------------------|-------|-------|-------|
|                      | ≤25                     | 26-44 | >44   |       |
| Married              |                         |       |       |       |
| ▪ count              | 23                      | 61    | 20    | 104   |
| ▪ %of married        | 22.1%                   | 58.7% | 19.2% |       |
| ▪ %in HRQOL category | 57.5%                   | 53.5% | 40.8% |       |
| Without Spouse       |                         |       |       |       |
| ▪ count              | 17                      | 53    | 29    | 99    |
| ▪ %of without spouse | 17.2%                   | 53.5% | 29.3% |       |
| ▪ %in HRQOL category | 42.5%                   | 46.5% | 59.2% |       |
| TOTAL                | 40                      | 114   | 49    | 203   |

*Chi-square 2.993*

*df=2*

*p=0.224*

(\*Out of the 204 that were eligible for analysis, one person had not declared his marital status. Refer to section 5.2.2)

There was no statistically significant difference between those who were married and those who were *unmarried* ( $p=0.224$ ).

### 5.9.1.5 Employment Status and HRQOL

In determining the relationship between employment status and overall HRQOL, respondents were classified into three groups. Those in formal employment were classified as being employed. Those on sick leave were classified alone while the rest were classified as being unemployed/informal employment. People who were in formal employment scored better than those that were either unemployed, self employed or employed but on sick leave. Employed patients accounted for 63.3% of those that scored >44/50. This difference was statistically significant ( $X^2=81.983$ ,  $df=4$ ,  $p<0.001$ ).



### 5.9.1.6 Family size and HRQOL

Respondents who had no children were compared to those that had between 1-3 children and those that had >3 children. Out of the 204 respondents, one participant had not declared the number of children she had. There was no relationship between the number of children a patient had and the overall HRQOL score ( $X^2=7.501$ ,  $df=4$ ,  $p>0.1$ ).

### 5.9.2 Duration of ART and Overall HRQOL Score

In this analysis, patients were divided into two groups. Those that had been on treatment for less than a year were compared to those that had used anti-retroviral agents for a year or more. The analysis is presented in Table 14.

Table 14: Relationship Between Duration of Therapy and HRQOL (n=202\*).

| TREATMENT DURATION     | Category of HRQOL score |       |       | TOTAL |
|------------------------|-------------------------|-------|-------|-------|
|                        | <=25                    | 26-44 | >44   |       |
| Therapy duration <1yr  |                         |       |       |       |
| ▪ count                | 22                      | 53    | 20    | 95    |
| ▪ %of <1yr             | 23.2%                   | 55.8% | 21.1% |       |
| ▪ %in HRQOL category   | 55%                     | 46.5% | 41.7% |       |
| Therapy duration =>1yr |                         |       |       |       |
| ▪ count                | 18                      | 61    | 28    | 107   |
| ▪ %of =>1yr            | 16.8%                   | 57%   | 26.2% |       |
| ▪ %in HRQOL category   | 45%                     | 53.5% | 58.3% |       |
| TOTAL                  | 40                      | 114   | 48    | 202   |

(Two out of the 204 patients did not declare how long they had been on treatment. Refer to section 5.3.1)

There was no relationship between the duration of anti-retroviral therapy and the overall HRQOL score ( $X^2=1.587$   $df=2$ ,  $p=0.452$ ).

### 5.9.3 Regimen choice and Overall HRQOL score

Participants were broadly classified into two groups depending on whether or not their drug therapy included a Protease inhibitor and the results were cross-tabulated as shown in Table 15.

Table 15: Relationship Between Regimen Choice and HRQOL (n=203\*)

| REGIMEN CHOICE       | Category of HRQOL score |       |       | TOTAL |
|----------------------|-------------------------|-------|-------|-------|
|                      | ≤25                     | 26-44 | >44   |       |
| PI sparing           |                         |       |       |       |
| ▪ count              | 40                      | 79    | 41    | 160   |
| ▪ %of PI sparing     | 25%                     | 49.4% | 25.6% |       |
| ▪ %in HRQOL category | 100%                    | 69.3% | 83.7% |       |
| PI based regimen     |                         |       |       |       |
| ▪ count              |                         | 35    | 8     | 43    |
| ▪ %of PI based       |                         | 81.4% | 18.6% |       |
| ▪ %in HRQOL category |                         | 30.7% | 16.3% |       |
| TOTAL                | 40                      | 114   | 49    | 203   |

Chi-square 17.588

df= 2

p<0.001

(One person did not declare the type of treatment she was using. Refer to section 5.3.3)

Patients who were using PI based regimens scored better than those that had PI sparing regimens and this difference was statistically significant (p<0.001).

#### 5.9.4 Hospitalization and Overall HRQOL score

Inpatients were found to have lower scores than outpatients even though they had 100% compliance rates. They were found to comprise 72.3% of all the patients that scored ≤25/50. No inpatient scored more than 44/50. This difference was found to be statistically significant (p<0.001).

#### 5.9.5 Drug adherence and Overall HRQOL score

Patients who were adherent to their medication scored better than those who had missed at least one dose in the three days preceding the interview. This difference was found to be statistically significant (p<0.001). Only two out of the 58 in the non-adherent group of patients scored >44/50 as indicated in Table 16.

Table 16: Relationship Between Adherence and HRQOL (n=204).

| ADHERENCE CATEGORY        | Category of HRQOL score |       |       | TOTAL |
|---------------------------|-------------------------|-------|-------|-------|
|                           | <=25                    | 26-44 | =>45  |       |
| Adherent                  |                         |       |       |       |
| ▪ count                   | 20                      | 79    | 47    | 146   |
| ▪ % within adherent group | 13.7%                   | 54.1% | 32.2% |       |
| ▪ % within HRQOL category | 50%                     | 68.7% | 95.9% |       |
| Non-compliant             |                         |       |       |       |
| ▪ count                   | 20                      | 36    | 2     | 58    |
| ▪ % within non-adherent   | 34.5%                   | 62.1% | 3.4%  |       |
| ▪ %within HRQOL category  | 50%                     | 31.3% | 4.1%  |       |
| TOTAL COUNT               | 40                      | 115   | 49    | 204   |

Chi-square 23.889

df= 2

p<0.001

### 5.9.6 Counseling and Overall HRQOL score

To determine the relationship between counseling and HRQOL, patients who reported that they had received counseling during the course of their treatment were compared to those who had not. The findings were that there was no difference in the scores of the two groups (n=204,  $X^2 = 0.010$ , df=2, p=0.995). In both groups approximately 56% scored 26-44/50, approximately 19.5% scored <26/50 and approximately 24% scored >44/50. The pattern was strikingly similar.

### 5.9.7 Disclosure status and Overall HRQOL score

To establish the relationship between HIV disclosure status and overall HRQOL, patients were classified into two groups depending on whether or not they had disclosed their status to anyone. There was no statistically significant difference in the HRQOL of those who had disclosed their HIV status compared to those who had not (n=204,  $X^2 = 3.190$ , df =2, p=0.203).

### 5.9.8 CD4 counts and Overall HRQOL score

The determination of CD4 counts is an essential part of the follow-up of HIV infected patients on ART and they are used to evaluate the effectiveness of treatment. Normal CD4 values range from 359-1725c/ml (Katz 2000). CD4 counts were only available for 73 out of the 206 participants. This is because CD4 counts are done, on average, every

six months for patients. However this is subject to the availability of funds on the part of the patient. In the group studied the mean CD4 count was 168c/ml with a range of 3-840. Patients with CD4 counts of less than 200c/ml scored worse than those with CD4 counts equal to or more than 200c/ml. The former constituted 97.2% of those that scored  $\leq 25/50$  while 95.2% of those with CD4 counts  $\geq 200$ c/ml scored more than 25/50. This difference was found to be statistically significant ( $p < 0.01$ ) and it is demonstrated in Table 17.

Table 17: Relationship Between CD4 Count and HRQOL (n=73\*).

| CD4 CATEGORY              | Category of HRQOL score |        | TOTAL |
|---------------------------|-------------------------|--------|-------|
|                           | $\leq 25$               | $> 25$ |       |
| CD <200                   |                         |        |       |
| ▪ count                   | 36                      | 16     | 52    |
| ▪ % within CD <200        | 69.2%                   | 30.8%  |       |
| ▪ % within HRQOL category | 97.2%                   | 44.4%  |       |
| CD $\geq 200$             |                         |        |       |
| ▪ count                   | 1                       | 20     | 21    |
| ▪ % within CD $\geq 200$  | 4.8%                    | 95.2%  |       |
| ▪ % within HRQOL category | 2.8%                    | 55.6%  |       |
| TOTAL COUNT               | 37                      | 36     | 73    |

Chi-square 25      df = 1       $p < 0.01$

(\*CD4 counts were only available for 73 out of the 206 participants.)

Linear regression analysis showed that CD4 count was positively correlated to HRQOL and was found to predict 40% of the variance in overall HRQOL ( $r^2 = 0.40$ ). When the different HRQOL domains were evaluated separately, CD4 count was found to predict 44% and 42% of the variance in mental and physical health respectively. However the correlation between CD4 count and social health was weak ( $r^2 = 0.15$ ). (Refer Appendix

III)

## CHAPTER SIX

### DISCUSSION CONCLUSION AND RECOMMENDATIONS

#### 6.1 DISCUSSION

##### 6.1.1 Demographics and quality of life

In this study, the demographic characteristics that were found to be associated with poor HRQOL were male sex, sick leave, lack of formal employment or unemployment. However it is worth noting that it was beyond the scope of this study to establish whether those that were unemployed had any job qualifications. Eriksson et. al. (2000) found that sick leave and being on disability pension, resulting in low income, were all associated with worse HRQOL and health status. The reasons for the poor HRQOL scores among unemployed people include the fact that many may be physically able to work but they are denied this opportunity by virtue of their HIV status. In addition, unemployed HIV positive individuals often cannot apply for jobs because potential employers usually have an HIV screening policy. In 1988 WHO and the International Labor Organization (ILO), developed policies that precluded compulsory pre-employment and pre-insurance testing for HIV. Additionally, it was proposed that HIV infected individuals would enjoy the same rights as HIV negative people meaning there would be no termination of employment due to HIV status (WHO/ILO 1988). A study conducted in 1994 on 16 Kenyan companies showed that few private sector companies had adopted these policies and many managers felt that pre-employment HIV testing was justified (Roberts et al 1996). Only one company was found to comply with the WHO/ILO recommendations. The lack of income just as treatment costs escalate can further compound the distress experienced by these people. The role of income and higher socio-economic status (SES) was demonstrated in a study by Rapiti et al (2000) in which patients were stratified into four groups according to neighborhood SES. It was found that even in countries with universal health coverage providing treatment at no cost, there were differences in the outcome of treatment which could be attributed to SES. Patients of low SES had higher rates of poor treatment outcomes. However, he also found that low basic education were similarly associated. No relationship was demonstrated between level of education and

overall HRQOL in this study largely because people of low education level were not adequately represented in the study. Patients who had received primary school education only accounted for 5.8% of the respondents. The reason for this under-representation may be due to the fact that this population of people has limited access to ART as well as the fact that only one public hospital was selected to participate in the study. This is because education level determines employment and income which in turn facilitates access to treatment. The vast majority of Kenyans can only access drugs through out-of-pocket financing as shown in this study whereby 80.6% of the respondents relied on themselves and their relatives to pay for treatment. Faced with declining income and increasing health care costs, household can opt for certain measures such as withdrawing children from schools, purchasing drugs only when they have the money to do so or foregoing treatment in the long run.

Lenderking et al (1997) showed that in all scales women showed lower HRQOL scores than men. Various factors have been found to influence treatment outcome in women. In a study that was conducted to assess QOL in women living with HIV infection, it was found that social support and level of physical ability were the key determinants of QOL (Cowdery, Pesa 2002). The importance of social support was further demonstrated by Bastardo et al (2000) when he found that better social support was associated with better HRQOL score in a sample of 118 HIV-infected people living in Venezuela. Rosenfeld et al (1996) found that perceived adequacy of social support was significantly associated with lower levels of psychological distress and depression and overall better QOL. In an article outlining some of the determinants of outcome of care for HIV-infected women in Puerto-Rico, factors such as economic income, social and personal freedoms and the burden of family responsibilities were found to be important (Zorrilla, Santiago 1999). Social support has broadly been categorized into three aspects namely financial support, emotional support and psychological support in the form of counseling (Douaily, Singh 2001). As already alluded to earlier, the KDHS survey of 1998 indicated that women with HIV were more likely to be poorer and less likely to be in formal education than their male counterparts. It would therefore be expected that women would score worse in HRQOL. However it is also worth noting that women suffer from women-specific

symptoms of HIV. HIV-related gynecological problems vaginal yeast infections, pelvic inflammatory disease, genital ulcer disease and gynecological tumors occur more frequently and are more severe in HIV-positive women than in their HIV-negative counterparts. Menstrual irregularities are also common especially in those with severe immuno-suppression (Katz, Hollander 2000, NIAD 2001). This can cause both emotional and physical distress. Women who are HIV positive are discouraged from breastfeeding their infants or from conceiving and this can cause tremendous social distress. Part of Kenya's national reproductive health strategy for 1997-2010 includes the prevention of pregnancy in HIV infected women because HIV is associated with higher incidence of abortion, still births and premature deliveries. It also raises maternal morbidity and mortality and hastens progression of the disease (MOH 1996). For women who do get pregnant, it is estimated that overall transmission of HIV is 30-45% for those who breastfeed compared to 15-30% for those that do not (MOH 2001). In Burkina Faso HIV-positive women felt that they needed to continue fulfilling gender expectations by having children but instead they felt that the local professionals opposed this desire (pop. Council 2002). All these sex-specific HIV-related physical and social situations were not factored into the questionnaire. It is conceivable that these factors would have influenced the outcome had they been inquired about. Another factor that was not investigated was the role of alcohol intake and abuse. Sherbourne (2000) found that alcohol abuse was associated with negative HRQOL scores especially in the presence of other co-morbid psychiatric illness. This study demonstrated that men have a statistically significant lower tendency to disclose their HIV status. They also had a higher tendency to experience guilt for their HIV status. This might suggest that they are less inclined to discuss aspects of their lives affected by AIDS. As a result, most issues affecting men living with HIV/AIDS have not been clearly identified, articulated and prioritized (KANCO 2003).

Marital status was not related to HRQOL. This could be because all the participants who were single for reasons of being widowed, being divorced/separated or never having been married were all lumped together in the evaluation. Putting them all together masks the different social situations that determine the level of social support and acceptance available to each of these individual groups. In addition, being married can only have a

positive impact on HRQOL if there is partner intimacy and support that is both material and emotional. This implies that if married people do not score better than the unmarried, it may be a reflection of disharmony within the union. In a study involving 84 families, couple and family counseling was conducted in addition to one-on-one counseling with the individual patients. Out of these, 52 families reported that they had acquired conflict resolving skills that had led to a reduction of the stress level in the home (Sewayana 2003).

### **6.1.2 Duration of therapy and HRQOL**

In this study there was no relationship between the duration of therapy and HRQOL. This is in contrast to several studies which show that in all stages of HIV infection, the onset of ART use is associated with significant short-term decline in HRQOL (Douaihy Singh 2001). This has been attributed to the onset of new symptoms due to drug side-effects. As tolerance to drugs improves and as the drugs begin to take effect this trend is reversed. Over time, improved survival, delayed disease progression and effective viral suppression leads to improved QOL especially if side effects are managed or the offending drugs are withdrawn (Zinkernagel et al 1999, Revicki et al 2000). Theoretically, in the long term, the combination of disease progression, cumulative long-term drug side effects and development of drug resistance could lead to decline in the HRQOL. Unfortunately there are very few clinical studies that include patients with advanced HIV because of the higher chance of drug toxicity and the lower chance of durable anti-retroviral response (Hirsh et al 1999, Pulido et al 2003). Hirsh et al (1999) found that as disease advances, patients continue to respond to HAART. Piketty et al (1999) and Pulido et al (2003) also demonstrated that as long as potent anti-retroviral agents were used in previously treated patients with advanced HIV, benefit could still be realized. However, the proportion of patients with optimal response appeared to decline as the disease advances. There are two probable reasons why no relationship was demonstrated between the duration of treatment and HRQOL. The first reason for this is that the initial difficulties in tolerance experienced at the start of HAART are short lived. With time, a combination of disease progression and long term drug side effects set in with the overall result of balancing out the benefits with the negative outcomes. Finally, almost 30% of



the respondents indicated that they had missed their medication in the 72 hours preceding the interview. It is plausible that repeated treatment interruptions have the cumulative effect of poor virological and immunological response which is then manifest in reduced QOL scores over time.

### **6.1.3 Regimen choice and HRQOL**

Protease inhibitors are highly potent anti-retroviral agents. However the standard PI based regimens have been plagued by problems of not being easy to adhere to due to the fact that they are associated with more frequent short-term and long-term side effects. They are also associated with multiple drug to drug interactions. They tend to have higher pill burden and more frequent dosing and they are available at higher cost relative to other available alternatives.

Some studies done over the last five years have demonstrated significant success in a new trend in the use of PIs that involves the use of one PI (Ritonavir) at a low dose to inhibit the metabolism of the principle PI in the HAART regimen (Piketty et al 1999, Tebas et al 1999). This is the principle of the *“boosted”* PI regimens. It is expected that this will allow more drug to get into the blood stream leading to more convenient, less frequent dosing and a reduction of the pill burden. It will possibly reduce the cost of treatment and free the regimen from dietary restrictions.

In this study, patients that were using PI-based regimens scored better than those that were using PI-sparing regimens. This could suggest that the use of PI-based regimens may lead to better overall HRQOL. When protease inhibitors were first introduced into the market during the initial years of the HAART era, there was a dramatic decline in clinical progression and HIV-related mortality (Pulido et al 2003). This led to a widespread belief in the superior efficacy of PI based regimens. However, there is growing evidence that those benefits were not just due to the use of the PIs but also because of the strategy of using triple therapy to manage HIV/AIDS. Some current studies have demonstrated that some PI sparing regimens, especially those containing Efavirenz may have superior anti-viral efficacy (Pulido et al 2003). However boosted PI

regimens have been proven to be potent combinations that are effective even in previously treated patients with advanced HIV infection (Piketty et al 1999, Pulido et al 2003). *For this reason they have been used in "salvage" therapy in patients who have failed in several standard HAART regimens and who demonstrate multi-drug resistance.* The results of this study, though not unexpected, must be interpreted cautiously. This is in view of the fact that very few patients using the standard PI regimens participated in this study. In terms of frequency, the top three most commonly prescribed combinations of ART in Kenya are non-PI based. This is based on the perception by prescribers that compliance is better, cost is less and drug interactions are fewer when using non-PI based regimens (Kimani 2000). This means that there are fewer patients on PI based regimens than non PI based ones. Therefore in the evaluation all patients that were on at least one PI were grouped together. This masks the advantages and disadvantages between the standard and the boosted PI regimens.

#### **6.1.4 Hospitalization and HRQOL**

The availability of ART has shifted treatment more towards ambulatory care and less towards inpatient treatment. However, in the course of the illness hospitalization is sometimes inevitable. Indeed it often signals disease advancement, cumulative long-term drug toxicity, development of drug resistance and treatment failure. In a study done to investigate the determinants of hospital admission among HIV-infected individuals, it was found that high viral load, low CD4 counts, poor health status and previous admission were all key determinants (Weber et al 2000). The number, severity and frequency of symptoms necessitating admission have all been found to have a negative impact on the physical and emotional well-being aspects of QOL (Cunningham et al 1998, Burgoyne, Saunders 2001). Roubenoff (2000) found that factors associated with poor QOL include the reduction in lean body mass, reduced muscle strength and the increased dependence on assistance with activities of daily living that occurs in advanced HIV infection. Lenderking et al (1997) found that history of recent hospitalization was associated with poor HRQOL. Another study also showed that the longer the duration of hospitalization the worse the overall HRQOL. This was attributed to the fact that admission increased the number of disability days and reduced emotional well-being

(Wilson, Cleary 1996). It is therefore not surprising that in this study inpatients achieved worse scores than outpatients.

### **6.1.5 Drug adherence and HRQOL**

Non-adherence to therapy is a significant problem in chronic illnesses requiring long-term treatment. In this study 18% of respondents had missed at least one dose in the preceding 24 hours while 28.6% had missed at least a dose in the preceding 72 hours. These figures indicate levels of adherence are comparable to other studies. In a survey by Stone (2000), 21% had missed a dose in 24 hours while 34% had missed a dose in 3 days. In another study, 24% had missed a dose in 24 hours while 32% had skipped a dose in three days (Stone et al 2001). The reasons for non-adherence are however significantly different. While forgetfulness accounted 47% of the cases in the studies by Stone, this was true in only 3.5% of the respondents of this study. Lack of medication due to financial constraints were the most common reasons for missing drugs and accounted for 14.1% of the cases.

This study has demonstrated that those that were adherent to medication scored better in HRQOL than those that were not. This was also demonstrated in study conducted on 46 patients by Singh et al (1996). Adherent patients were found to have significantly better adaptive coping to their illness and experienced less psychological disturbance. At 12 months they had better Karnofsky scores than non-compliant patients. These findings are not surprising since the ability of a patient to adhere to a treatment program is essential for the success of that treatment. Adherence increases the likelihood of sustained virologic control hence reducing the HIV-related morbidity and mortality. It also prevents the emergence of drug resistance which would limit the effectiveness of treatment. In one study reported by Wu (2001) in which viral suppression after 12 months of treatment was compared to adherence levels, it was found that 66% of those that reported 100% adherence had viral loads of <50c/ml, 48% of those that had 80-90% adherence and 18% of those that reported <80% adherence achieved the same level of viral suppression. When treatment is interrupted, strong viral rebound may occur resulting in failure to

significantly increase CD4 counts and ultimately leading to rapid clinical deterioration (NASCO 2001).

The second most common reason for missing drugs in this study was “drug side-effects”. In one study, poor adherence was found to be more frequent in CDC classification group C patients (Knobel et al 1997). This group represents patients with advanced disease. It was found that besides being more symptomatic due to disease progression, this group of patients appeared more susceptible to drug side effects. This suggests that those that are non-adherent are more likely to have severer disease or to experience more side effects leading to poor overall HRQOL.

#### **6.1.6 Counseling and HRQOL**

This study did not demonstrate any relationship between counseling during therapy and the overall HRQOL score. In addition, 47.1% of the respondents still experienced guilt for their HIV status and 33% still blamed someone else for their illness. Only 19.4% had accepted their HIV status as indicated by the fact that they did not blame anyone for their status. Guilt reduces self-esteem and can lead to depression while blame is more likely to lead to bitterness, self pity and anger. Male respondents were more likely to experience guilt while female patients were more likely to blame someone else. This implies that in the majority of patients counseling had not had a positive impact on their lives. It also implies that counseling needs are different for men compared to women. This was the most unexpected result given the implied benefits of counseling in helping patients come to terms with their HIV status, helping patients that experience difficulties with their medication, reinforcing positive health practices and attitudes and providing emotional support to reduce the sense of isolation. However the scope of this study did not include an in-depth analysis of the type, frequency or content and content of the counseling sessions.

Molassiotis et al (2002) determined that patients that received counseling during treatment scored better than those that did not receive any psychological interventions. However, the study went further and compared different types of counseling. It compared

the effect of cognitive-behavior group therapy (CBT) and peer support/counseling (PSC) on HRQOL. It was found that the CBT group experienced greater reduction in psychologic distress and greater improvement in HRQOL compared to the PSC group. The CBT group improved in overall mood and experienced less confusion, tension, anxiety, anger and depression. Significantly, both these forms of counseling involve group therapy as opposed to one-on-one counseling. The advantages of group counseling are that it brings together people with similar experiences therefore forging relationships that are more comfortable and candid, it creates role models out of those with long term experience in ART and it reduces the feelings of loneliness and isolation. Even in advanced HIV/AIDS, counseling has been demonstrated to benefit patients. Bunch (1998) discussed strategies of helping patients deal with impending death in a sample of patients who had terminal HIV. Benefits to the patients were demonstrated in helping them talk and reminisce about the past while helping them let go of the future. This way, they were able to plan and prepare for death. In some of these incidences, the involvement of significant others was found to be beneficial.

*Besides the type of counseling, the content of counseling appears to be important. In one study individuals who confronted stressful situations with problem-solving and behavior-modifying approaches had better HRQOL compared to those that received emotionally supportive interventions that encouraged passive acceptance of the illness (Douaihy Singh 2001).*

### **6.1.7 Disclosure and HRQOL**

Spousal disclosure was 92.3% while only 17 people had disclosed their HIV status to their children. It is therefore evident that the person most likely to be disclosed to is the spouse. However, children are the least likely immediate family members to be aware of the HIV status of their parents. Some of the benefits of disclosure of HIV status are the reduction of the stress related to coping with the illness alone and the increased social support (both material and emotional). Disclosure is thought to facilitate responsible sexual behavior and the acceptance of the HIV status. The importance of social support has already been alluded to in reference to the studies conducted by Bastardo et al (2000)

and Rosefeld et al (1996). However disclosure does not always confer the above benefits. Sometimes disclosure of HIV status leads to stigmatization, rejection, hostility and violence. Braxton (2000) demonstrated in his study some of *these negative consequences* of disclosure. Discrimination by friends and relatives occurred in 76% of the Africans, 57% of the Asians and 13% of the Australians that participated in the study. This discrimination was worse for female HIV infected patients compared to their male counterparts. Zierler (2000) demonstrated in his study that revealing one's HIV status triggered physical violence on 45% of patients. Most of the time the perpetrators of this violence were close relatives. It is therefore not entirely surprising that this study has not demonstrated any association between the disclosure of HIV status and the overall HRQOL score implying that those that disclosed their status had scores that were similar to those that had not. In the open ended questions only 31.2% of the respondents stated that their families were happy and supportive of their treatment. Approximately a quarter of the respondents (22.6%) stated that their families found the treatment burdensome while 5.4% stated that treatment had led to outright conflict, desertion and/or stigmatization.

#### **6.1.8 CD4 and HRQOL**

In his study, Lenderking et al (1997) showed that there was no relationship between QOL and CD4 counts. However, Lubeck and Fries (1997) found that individuals who had decreasing CD4 counts also had significant declines in overall QOL and especially in the domains of physical functioning, general health and social functioning. These findings were supported by Wilson and Cleary (1996). This study has demonstrated that patients that had lower CD4 counts scored less than those that had CD4 count of more than 200c/ml. Patients with advanced HIV have lower chances of durable anti-viral responses and higher chances of drug toxicity (Hirsch et al 1999). Severe immunosuppression at the time of initiating HAART has also been shown to be associated with treatment failure (Piketty et al 1999). The obvious limitation of this study is the small number of participants that had current CD4 counts and this may preclude comprehensive evaluation of the relationship between CD4 counts and HRQOL. However since higher CD4 counts

signify better immune reserve, it makes sense to conclude that those that have higher CD4 counts should have better overall HRQOL.

### **6.1.9 Domains of HRQOL**

This study established that 80.4% of all the HIV positive patients on anti-retroviral therapy have above average HRQOL scores. It is in the mental health status domain that patients scored the poorest while questions on physical health elicited the most positive result. This reflects the high toll HIV/AIDS takes on the mental and social lives of patients and these findings are consistent with findings from other studies. In one study it was demonstrated that although becoming symptomatic had a significant negative impact on a majority of dimensions of QOL, HIV *diagnosis* resulted in significant disruption in the sense of well-being (Burgoyne, Saunders 2001). Another study also confirmed that psychological dysfunction occurred at the time of diagnosis long before the onset of symptoms (O'Keefe, Wood 1996). Sherbourne (2000), was able to demonstrate that depression occurred in 40% of all HIV-infected patients. The impact of this was that those that had symptoms of depression reported more days of disability, reduced social functioning, greater pain, fatigue and the risk of suicide. In addition, CD4 count was positively correlated to overall HRQOL. It was also positively correlated to the physical and mental dimension of HRQOL but is not useful in predicting social health status.

### **6.2 STUDY LIMITATIONS**

Only those patients who were willing to participate in the study were included. This kind of study can therefore introduce a selection bias because it is always difficult to determine whether willing respondents are truly representative of the entire eligible population. It is therefore difficult to tell whether or not the responses given are typical of those that would be received from all persons who did not participate but were eligible. This limits the extend to which the results can be generalized.

The contemporary clinical state of the patient at the time of filling the questionnaire was used to relate to HRQOL. Changes in HRQOL occasioned by the treatment were not

determined. In addition comparison with similar patients not on anti-retroviral therapy was not made.

As alluded to earlier, HRQOL is a multi-dimensional concept. This study only addresses three aspects of HRQOL. Therefore it did not exhaustively explore all domains of QOL. However it would be difficult to do so as this would make the questionnaire too long, too complex and too time-consuming to administer.

Out of the four hospitals that participated, only one was a government sponsored public hospital. Public hospitals cater for the lower socio-economic cadres. The results of this study would therefore be more indicative of patients in the higher socio-economic groups.

One of the consequences of using self-administered questionnaires is that respondents can often fail to respond to certain questions. Missing data makes interpretation difficult and it can lead to analysis bias by reducing the number of participants for analysis. The effect of this is to overestimate HRQOL scores. There are no universally accepted methods of handling missing data (Lin et al 2002). This study attempted to address this problem by providing for a larger sample size than was required but by so doing increased the potential margin of error.

Some studies have demonstrated that spirituality and various individual co-morbidities have independent effects on overall HRQOL. Spirituality has been described as bridge between hopelessness and meaningfulness in life (Douailly, Singh 2001) and this has a profound effect on the psychological, mental and social health of patients with terminal diseases. In addition, specific co-morbid illness such as PCP and anemia affect mainly the physical domain of HRQOL. These independent variables were not evaluated.



## 6.3 CONCLUSIONS

Factors that have no relationship with HRQOL are age, level of education, marital status and disclosure status. Additionally, exposure to counseling and duration of anti-retroviral therapy *has no relationship with HRQOL*.

Factors that are associated with good overall HRQOL are the use of PI-based regimens, adherence to treatment and the female sex. Disease severity characterized by reduced CD4 count and hospitalization are related to poor overall HRQOL. Lack of formal employment is also related to poor HRQOL.

It is in the mental health status domain that patients scored the poorest while questions on physical health elicited the most positive result of the three domains evaluated. Overall HRQOL was good with 80.4% of all the HIV-infected patients on anti-retroviral therapy having above average HRQOL scores.

CD4 count was positively correlated to overall HRQOL as well as the physical and mental health domains of HRQOL. However, CD4 count was not a good predictor of social health.

## 6.4 RECOMMENDATIONS

### 6.4.1 Research recommendations

The challenge to researchers to harmonize existing QOL instruments *remains in order to facilitate meaningful comparisons across different populations*. Alternatively, locally generated QOL tools that address local QOL concerns can be developed. There is a need to *develop domain specific instruments that evaluate the specific domains that are adversely affected by an illness and its treatment*. In the case of HIV/AIDS the mental health domain requires more comprehensive evaluation.

In order to quantify the improved QOL directly attributable to the use of anti-retroviral agents, studies need to be done that compare patients on ARVs with similarly infected patients not on ARVs.

#### 6.4.2 Recommendations to health-care providers

In the management of HIV, one of the most neglected areas is palliative care (UNAIDS 2004). Palliative care aims to achieve the best quality of life for patients suffering from life-threatening and incurable illnesses. A wide range of palliative care is needed for HIV-infected individuals on anti-retroviral agents. Central to this is the relief of all types of pain (physical, social and psychological) as well as the treatment of common distressing symptoms such as nausea, vomiting, skin problems and fatigue. A simple questionnaire should be used by health-care workers to screen for these symptoms as well as for underlying mental distress. Health care providers need to recognize that the mental and psychological domains of QOL are often adversely affected even as the physical domains of QOL improve with treatment. This dysfunction should therefore be anticipated and prevented even as the patient is started on treatment. When present, appropriate referral to psychiatric evaluation should be undertaken. The effects of mental distress on compliance or on the perception of counseling should also be anticipated. A comprehensive treatment program should pay as much attention to the physical effects of illness as to the social and mental effects. This involves a multidisciplinary approach in HIV/AIDS management where clinicians and counselors have equally important roles to play and health services delivered to PLWHA extend to involve home-based care givers.

HRQOL assessment instruments compare favorably with objective measures of monitoring treatment such as CD4 counts and health-care workers should use them in combination to form a more comprehensive form of monitoring progress of patients on anti-retroviral therapy.

Health-care workers need to scrutinize counseling programs in order to determine why no benefit is realized by those who have been counseled. One area that needs scrutiny is the content and type of counseling programs available. Additionally, the qualification of counselors needs to be evaluated. Exploring the potential for couple counseling to reduce marital conflict could enhance HRQOL for patients with spouses. Existing monitoring systems for counseling programs mainly depend on reports of attendance, coverage and return rates of clients. Although client attendance is important, it is also important to

ensure effective counseling that provides psychological support. Guidelines already exist for the voluntary counseling and testing (VCT) program for HIV (MOH, NASCOP 2001). Incorporated within these guidelines are recommendations for quality assurance. These include developing tools to assess the quality of counseling such as client exit interviews to assess client satisfaction, counselor self-assessment tools and supervisory sessions for the counselors. These recommendations should apply not just to VCT, but to all counseling programs. Within the VCT program, there is need to shift counseling emphasis to post-test counseling where the bulk of emotional and social support is required.

Patient-Doctor confidentiality is a concern to the patients in order to prevent deliberate and accidental disclosure of the HIV status. Disclosure of HIV status is a decision that should be taken after due consideration of the possible negative effects. Legal, medical and ethical concerns have led to pressure on health-care providers to disclose HIV status of patients to their spouses. The impact of this disclosure must be factored into the legal framework that will ultimately authorize such disclosure.

PI-based regimens are potent anti-retroviral agents. In spite of concerns about frequent dosing and drug to drug interactions, they are associated with better QOL than non-PI based regimens. Clinicians opting to use them should however balance the higher cost and higher risk of development of resistance in non-adherent patients to their effect on QOL. Adherence counseling before starting PI-based regimens is especially important.

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## APPENDIX I

This questionnaire forms part of a Masters of Public Health (MPH) project on Anti-retroviral drug therapy. The information collected will be treated with confidentiality and at no time will you be required to identify yourself by name. To participate, you must have used anti-retroviral drugs for at least **three** months.

Please answer the questions as completely and as clearly as possible by ticking or writing your responses (as the case may be) in the spaces provided.

### PATIENT QUESTIONNAIRE

#### PART ONE

SERIAL NUMBER: \_\_\_\_\_

DATE: \_\_\_/\_\_\_/\_\_\_

#### PART TWO: SOCIO-DEMOGRAPHIC PROFILE

2.1 Date of Birth: \_\_\_/\_\_\_/\_\_\_

2.2 Sex: Male [ ] Female [ ]

2.3 Education level [ ] None  
[ ] Primary  
[ ] Secondary  
[ ] Post-secondary

2.4 Marital Status [ ] Married  
[ ] Single  
[ ] widowed  
[ ] separated  
[ ] other (specify) \_\_\_\_\_

2.5 Number of children \_\_\_\_\_

2.5.1 Age of last born. \_\_\_\_\_

2.6 Employment status

[ ] employed full time  
[ ] employed part time  
[ ] Sick leave  
[ ] Voluntary retirement  
[ ] Involuntary retirement  
[ ] Unemployed  
[ ] Other (specify) \_\_\_\_\_

**PART THREE: MORBIDITY AND CO-MORBIDITY PROFILE**

3.1 When were you diagnosed to be HIV positive? \_\_\_\_\_

3.2 When were you started on anti-retroviral treatment? \_\_\_\_\_ / \_\_\_\_\_  
(mth) (yr)

3.3 Which anti-retroviral drug combination are you currently on?

| DRUG | HOW OFTEN DO YOU TAKE IT?<br>(Tick the appropriate response)                                 |
|------|--|
| 1.   | <input type="checkbox"/> Once <input type="checkbox"/> Twice <input type="checkbox"/> Thrice |
| 2.   | <input type="checkbox"/> Once <input type="checkbox"/> Twice <input type="checkbox"/> Thrice |
| 3.   | <input type="checkbox"/> Once <input type="checkbox"/> Twice <input type="checkbox"/> Thrice |
| 4.   | <input type="checkbox"/> Once <input type="checkbox"/> Twice <input type="checkbox"/> Thrice |

3.4 Have you missed any dose(s) in the last 24 hours?

- yes
- no

3.4.1 If yes, How many? \_\_\_\_\_

3.5 Have you missed any dose(s) in the last three days?

- yes
- No

3.5.1 If yes, how many? \_\_\_\_\_

If you answered yes to 3.4 and/or 3.5

3.6 Which of the following best describes your reason(s) for missing drugs?

- Drug side effects
- Forgetfulness
- Inconvenience/ too frequent dosing/too many drugs
- financial constraints
- others (specify)

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3.7 What other drugs (besides anti-retrovirals) are you currently on? (tick as appropriate)

| TICK | DRUG                            | HOW MANY TABLETS PER DAY |
|------|---------------------------------|--------------------------|
|      | Pain killers                    |                          |
|      | Appetite stimulants/vitamins    |                          |
|      | Sleeping pills                  |                          |
|      | TB treatment                    |                          |
|      | Antibiotics (other than for TB) |                          |
|      | Fungal infection treatment      |                          |
|      | Others (specify)                |                          |

3.8 Side effects profile

Tick the appropriate answer

| QUESTION   | YES | NO |
|--|-----|----|
| 3.8.1 Do you scratch yourself after taking your drugs?                       |     |    |
| 3.8.2 Do you vomit or feel like vomiting after taking your drugs?            |     |    |
| 3.8.3 Do you experience stomach pains after taking your drugs?               |     |    |
| 3.8.4 Has your doctor ever changed your treatment because you reacted to it? |     |    |

#### PART FOUR: SYMPTOM STATUS

Please tick the appropriate response.

|     | QUESTION  | YES | NO |
|-----|---|-----|----|
| 4.1 | Have you gained weight since starting treatment?          |     |    |
| 4.2 | Do you currently sweat at night?                          |     |    |
| 4.3 | Are you currently experiencing diarrhoea and/or vomiting? |     |    |
| 4.4 | Are you currently experiencing fever?                     |     |    |
| 4.5 | Do you currently have mouth ulcers (wounds)?              |     |    |
| 4.6 | Do you currently have skin rashes?                        |     |    |
| 4.7 | Are you currently coughing?                               |     |    |
| 4.8 | Are you currently having any pain?                        |     |    |

4.9 Who pays for you treatment?

- insurance (specify which insurance company) \_\_\_\_\_
- self
- other (specify) \_\_\_\_\_

4.10 How do you intend to sustain payments for your treatment?

- Salary
- Savings
- Sell property/assets

- [       ] Assistance from relatives  
 [       ] Other (specify) \_\_\_\_\_

**PART FIVE: MENTAL STATUS**

Please tick the appropriate response

|     | QUESTION  | YES | NO |
|-----|---|-----|----|
| 5.1 | Are you currently able to sleep well?                 |     |    |
| 5.2 | Do you feel relaxed after sleeping?                   |     |    |
| 5.3 | Do you currently have a good appetite for food?       |     |    |
| 5.4 | Do you constantly feel tired?                         |     |    |
| 5.5 | Do you feel sad or hopeless?                          |     |    |
| 5.6 | Do you find it difficult to concentrate on your work? |     |    |

5.7 Who do you blame for your illness?

- [       ] myself  
 [       ] my wife/husband  
 [       ] No one  
 [       ] others (specify) \_\_\_\_\_

**PART SIX: SOCIAL INTERACTION**

6.1 Who have you told about your HIV status?

- [       ] Spouse  
 [       ] Children  
 [       ] Parents  
 [       ] Brother(s)/Sister(s)  
 [       ] Friend(s)  
 [       ] Other (specify) \_\_\_\_\_

Please tick the appropriate response

|     | QUESTION   | YES | NO |
|-----|--|-----|----|
| 6.2 | Did you receive any counselling before you started your treatment? |     |    |
| 6.3 | Have you received any counseling during you treatment?             |     |    |
| 6.4 | Do you avoid your friends or relatives because of your illness?    |     |    |
| 6.5 | Do your friends or relatives avoid you because of your illness?    |     |    |
| 6.6 | Is your sex drive reduced?   |     |    |
| 6.7 | Did you use a condom during your last sexual encounter?            |     |    |
| 6.8 | Do you think counseling is useful for HIV patients on treatment?   |     |    |

6.9 How many sexual partners do you currently have?

- [       ] none  
 [       ] one (1)  
 [       ] more than one

6.10 what is your source of hope strength and encouragement?

- [        ] religion
- [        ] family/friends
- [        ] health workers
- [        ] others (specify) \_\_\_\_\_

**PART SEVEN: PHYSICAL FUNCTIONING**

Please tick the appropriate response

| STATEMENT  | YES | NO |
|--|-----|----|
| 7.1 I can get out of bed without assistance                |     |    |
| 7.2 I can walk without any assistance                      |     |    |
| 7.3 I can dress myself without assistance                  |     |    |
| 7.4 I can feed myself without any assistance               |     |    |
| 7.5 I can take myself to the toilet without any assistance |     |    |
| 7.6 I can take a bath without any assistance               |     |    |

8.1 In your opinion, in what way can the Hospital(s) and health workers improve the care given to HIV positive patients on anti-retroviral treatment?

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8.2 How has this anti-retroviral treatment affected you?

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8.3 How has your family been affected by your being on treatment?

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Thank you for taking the time to answer this questionnaire.

## APPENDIX II

**Table I: Frequency distribution of Physical health Score (n=206).**

| SCORE | Frequency | Percentage | Cumulative % |
|-------|-----------|------------|--------------|
| 0     | 2         | 1%         | 1%           |
| 2     | 5         | 2.4%       | 3.4%         |
| 4     | 4         | 1.9%       | 5.3%         |
| 6     | 4         | 1.9%       | 7.3%         |
| 8     | 4         | 1.9%       | 9.2%         |
| 10    | 5         | 2.4%       | 11.7%        |
| 12    | 4         | 1.9%       | 13.6%        |
| 14    | 3         | 1.5%       | 15.0%        |
| 16    | 3         | 1.5%       | 16.5%        |
| 18    | 3         | 1.5%       | 18.0%        |
| 20    | 16        | 7.8%       | 25.7%        |
| 22    | 11        | 5.3%       | 31.1%        |
| 24    | 11        | 5.3%       | 36.4%        |
| 26    | 16        | 7.8%       | 44.2%        |
| 28    | 15        | 7.3%       | 51.5%        |
| 30    | 24        | 11.7%      | 63.1%        |
| 32    | 18        | 8.7%       | 71.8%        |
| 34    | 26        | 12.6%      | 84.5%        |
| 36    | 32        | 15.5%      | 100%         |
| TOTAL | 206       | 100%       |              |

**Table II: Frequency distribution of Mental Health Score (n=206).**

| SCORE | Frequency | Percentage | Cumulative % |
|-------|-----------|------------|--------------|
| 0     | 40        | 19.4%      | 19.4%        |
| 1     | 4         | 1.9%       | 21.4%        |
| 2     | 18        | 8.7%       | 30.1%        |
| 3     | 20        | 9.7%       | 39.8%        |
| 4     | 23        | 11.2%      | 51.0%        |
| 5     | 25        | 12.1%      | 63.1%        |
| 6     | 76        | 36.9%      | 100%         |
| TOTAL | 206       | 100%       |              |

**Table III: Frequency Distribution of Social Functioning Score (n=204).**

| SCORE | Frequency | Percentage | Cumulative % |
|-------|-----------|------------|--------------|
| 1     | 1         | 0.5%       | 0.5%         |
| 2     | 7         | 3.4%       | 3.9%         |
| 3     | 25        | 12.3%      | 16.2%        |
| 4     | 36        | 17.6%      | 33.8%        |
| 5     | 39        | 19.1%      | 52.9%        |
| 6     | 59        | 28.9%      | 81.9%        |
| 7     | 24        | 11.8%      | 93.6%        |
| 8     | 13        | 6.4%       | 100%         |
| TOTAL | 204       | 100%       |              |

# APPENDIX III

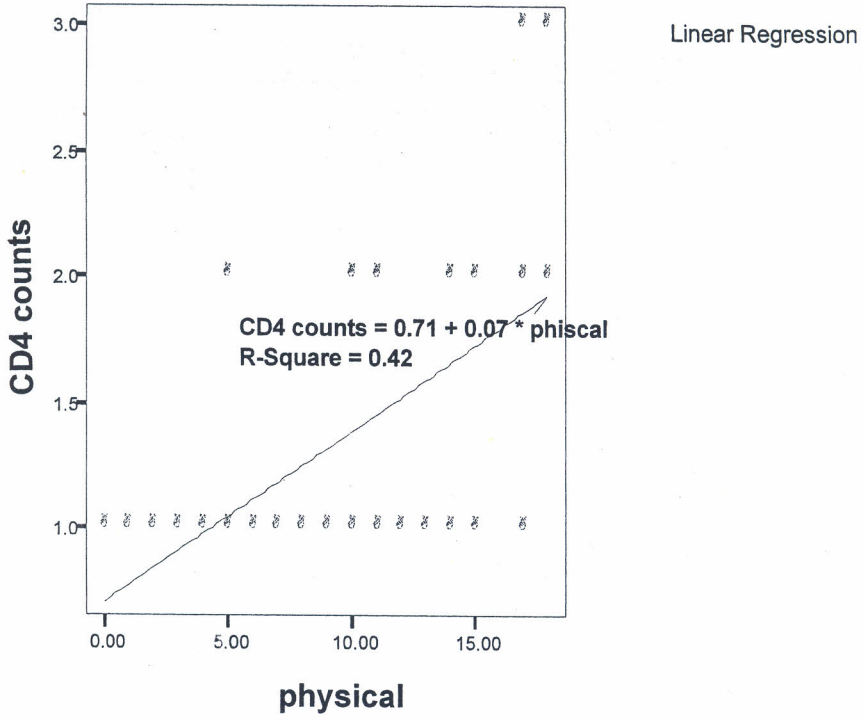


Figure I: Correlation between CD4 count and HRQOL

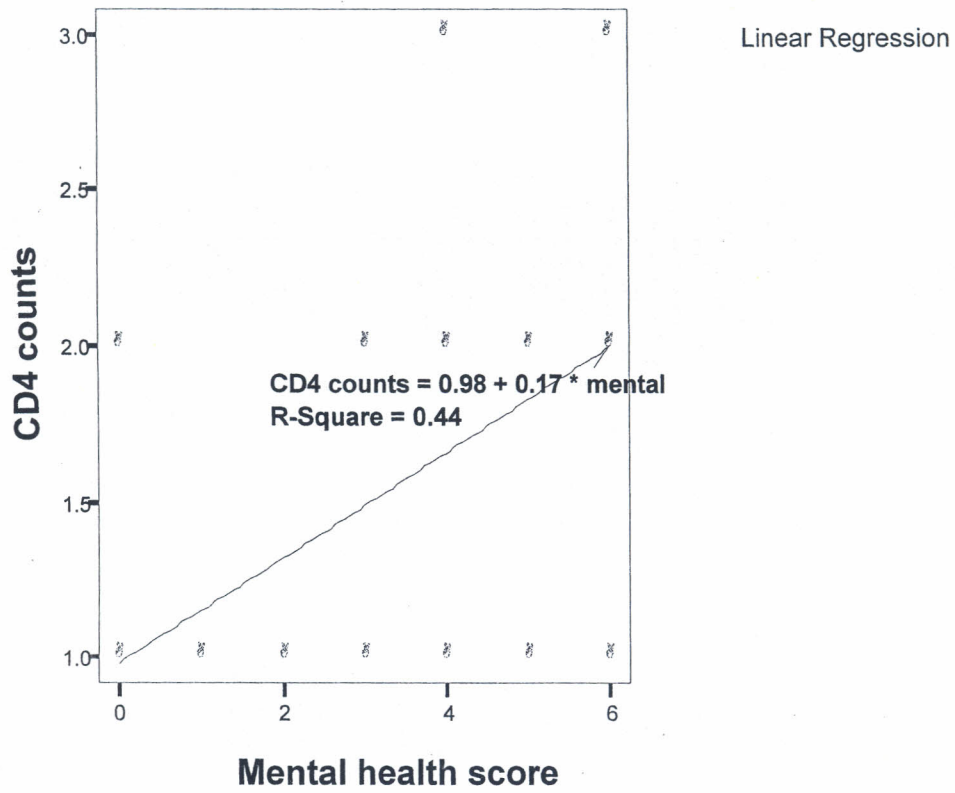


Figure II: Correlation between CD4 count and Mental Health Score

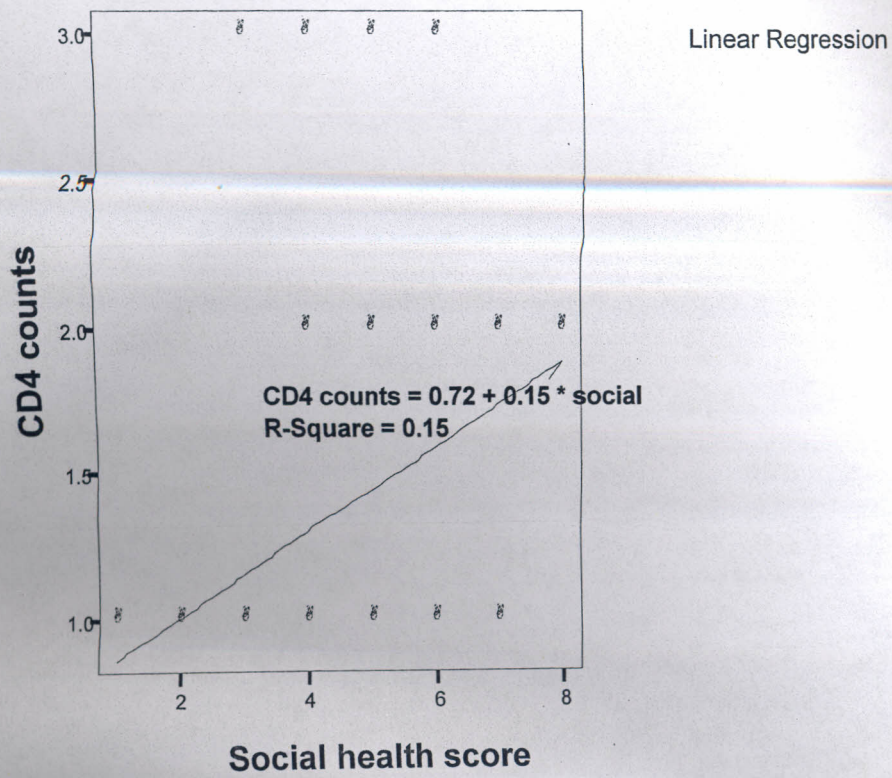


Figure III: Correlation between CD4 count and Social Health



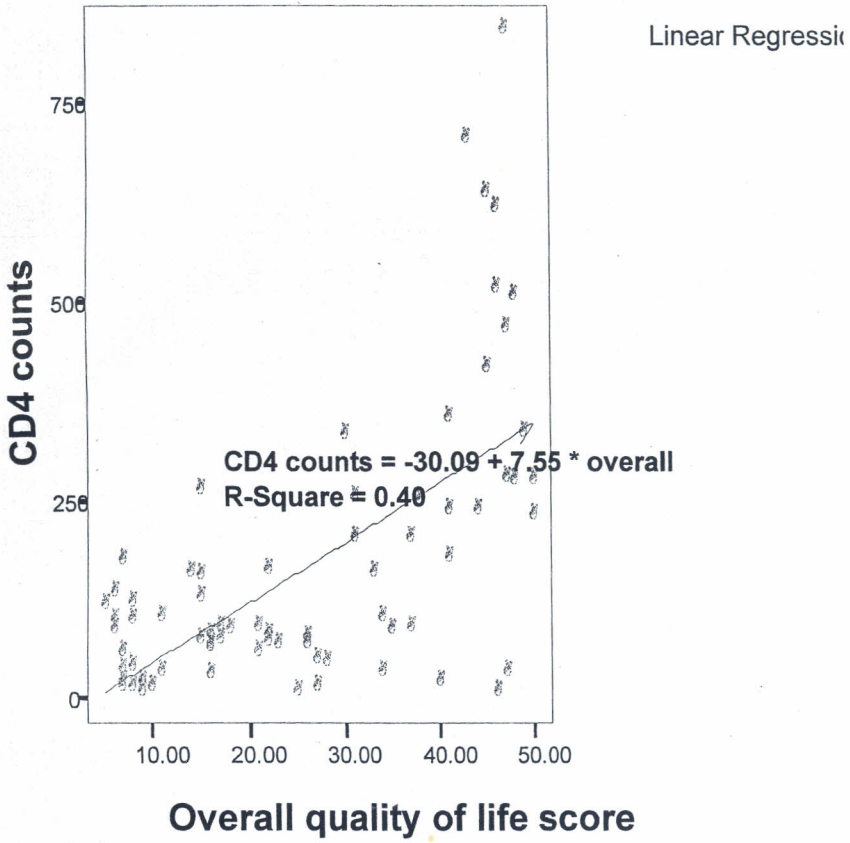


Figure IV: Correlation between CD4 counts and Overall HRQOL