# ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor of Philosophy by:

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# ABSTRACT

**Introduction:** HIV/AIDS is recognised to affect both the life expectancy and the quality of life of HIV infected individuals. Antiretroviral therapy (ART) has proved to be an effective intervention for improving the quality of life of HIV infected individuals by extending the number of survival years and reducing morbidity outcomes. Health Related Quality of Life (HRQoL) measurement provides a more comprehensive assessment of individual's overall health by measuring the impact of the treatment on the quality of life of the patient. While HRQoL measures including those used in economic evaluation are increasingly being used to evaluate health care interventions in industrialised countries, very few examples are found in resource poor countries and none related to the provision of ART for people living with HIV/AIDS in Uganda.

**Objective:** This thesis aims to understand the interactions of ART with the individual daily activities, emotional and mental health state, physical and working abilities and other dimensions that are affected by HIV/AIDS. It will also assess the validity, feasibility and reliability of these tools to draw insight on their practicality for future studies that attempt to assess the impact of ART provision in Africa.

**Methodology:** A subgroup of the DART trial (an open-label randomised trial evaluating different ART management strategies) participants (CD4<200; ≥18 years) was recruited at Entebbe, Uganda before they started taking ART (ART DART n=276). A comparator group of ART naïve, HIV infected individuals from the Entebbe Cohort study (with CD4>200; ≥18 years) was also recruited (Non ART EC n=159). Participants were interviewed face-to-face in the local language (Luganda) and were asked to: a) rate their own health state using Visual Analogue Scale; b) rank and evaluate three predetermined health states (symptomatic HIV infection (SHI), minor AIDS defining illness (MIADI) and major AIDS defining illness (MAADI)) with VAS; c) reconsider the evaluation of their own health with VAS and d) evaluate the HIV/AIDS predetermined health states using Time Trade-Off (TTO) and Standard Gamble (SG) relative to an 'improved' health state (IHS) using cartoon aids. In addition, individuals answered three HRQoL disease specific questionnaires (MOS-HIV and WHOQOL-HIV BREF) and provided information on their socio-demographic characteristics.

**Results:** Female participants constituted 64% for ART DART and 76% for Non ART EC groups. The mean age was 36.5 and 36.7 respectively. Participants found the questionnaires easy to understand. ART DART and Non ART EC participants improved their HRQoL at twelve months in the majority of dimensions measured by the MOS-HIV and the WHOQOL-HIV. VAS was found the simplest tool to use and a warming up tool for TTO and SG. In addition, participants were willing to give up more years and to take gambles that had attached higher risks in seeking to improve the worst health state (MAADI) than with other health states. In general health state valuations with TTO, SG and VAS were unrelated to characteristics such as age and sex but were related to individual's own health state assessment.

**Discussion:** The results from this study revealed that HRQoL tools available for industrialised countries provide valuable information for understanding the impact of HIV/AIDS and ART in HIV infected individuals receiving and not receiving ART in Uganda. Although none of the tools used in this study came across as dominant, the psychometric analyses of all the questionnaires used, help to further understand which methodologies are more feasible, reliable and perform better in terms of construct and empirical validity in a resource poor setting where levels of education tend to be low.

# DECLARATION

This thesis has been written exclusively by the Ph.D. candidate, María Antonieta del Carmen Medina Lara.

At no previous time was this work submitted for a degree.

All quotations have been distinguished by quotation marks and sources of information acknowledged.

María Antonieta del Carmen Medina Lara

# DEDICATION

This thesis is dedicated to Charlie and Dave for believing in the importance of improving the quality of life of HIV-infected individuals in Africa.

To my soul mate and best friend, Dr. Rubén E Mújica Mota for being so wonderfully mad and for embarking in this great adventure with me. We have grown, cried and laughed together throughout – what a team we are!

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# PUBLICATIONS AND PRESENTATIONS ARISING FROM THE RESEARCH INCLUDED IN THE THESIS

## Publications

**Medina Lara A**, Mujica Mota R and Hughes D. Approaches to pharmacoeconomics analysis. Chapter 5 in Walley T, Haycox A, and Boland A. *Pharmacoeconomics*, Elsevier Health Sciences, 2003.

**Medina Lara A**, Nyanzi Wakholi B, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. Utility assessment of HIV/AIDS related health states in HIV infected Ugandans. AIDS forthcoming.

## Oral presentations

**Medina Lara A**. "Health Related Quality of Life Assessment of PLWAs", WHO/UNAIDS Workshop on Strategic Information for Anti-Retroviral Therapy Programmes, Geneva, July 2003.

**Medina Lara A** and Haran D. Quality of life assessment as an outcome measure for PLWAS. Securing treatment and care for people living with HIV low-income countries: where are we now? Florence, January, 2004.

**Medina Lara A**, The use of Cost-utility analysis and Preference Eliciatation Methods in Resource Poor settings. *HIV/AIDS Interventions in Developing Countries: using Cost Benefit and Cost Effectiveness Analysis to Help Guide Policy and Action,* September 13-15, 2006.

**Medina Lara A**, Nyanzi Wakholi B, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. Assessment of Quality of Life in HIV infected Ugandans using the Visual Analogue Scale (VAS) and the MOS-HIV Health Survey. *13th Annual Conference of the International Society for Quality of Life Research,* October 10 - 14, Lisbon Portugal, 2006.

## Poster presentations

**Medina Lara A**, Nyanzi Wakholi B, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. Evaluating HIV/AIDS related health states in HIV infected Ugandans. *4TH World Congress International Health Economics Association* July, Barcelona, 2004.

**Medina Lara A**, Nyanzi Wakholi B, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. Performance assessment of the MOS-HIV health survey in HIV-infected individuals in Entebbe, Uganda. *17th International AIDS Conference* 13-18 August, Toronto Canada.

Nyanzi Wakholi B, **Medina Lara A**, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. Perceived changes and challenges in the quality of life of HIV infected individuals on ART: A qualitative study in Uganda. *17th International AIDS Conference* 13-18 August, Toronto Canada.

Nyanzi Wakholi B, **Medina Lara A**, Munderi P, Watera C, Gilks CF, Grosskurth H, on behalf of the DART Trial Team. HRQoL dimensions affected by antiretroviral therapy: a qualitative study in HIV-infected Ugandans. *13th Annual Conference of the International Society for Quality of Life Research,* October 10 - 14, Lisbon Portugal, 2006.

# GLOSSARY OF TERMS

| | |
|---|---|
| **ABCD** | Assessment of Body Change and Distress |
| **ACTG-QoL** | AIDS Clinical Trials Group Quality of Life Questionnaire |
| **ACP** | AIDS Control Programme |
| **AIC** | AIDS Information Centre |
| **AIDS** | Acquired Immune Deficiency Syndrome |
| **AIDS-HAQ** | AIDS-Health Assessment Questionnaire |
| **ANCs** | AnteNatal Clinics |
| **AOLS Index** | Asset of Living Standards Index |
| **ARC** | AIDS-related Complex |
| **ART** | Antiretroviral Therapy |
| **ARVs** | Antiretrovirals |
| **CBA** | Cost Benefit Analysis |
| **CEA** | Cost Effectiveness Analysis |
| **CI** | Confidence Intervals |
| **CMA** | Cost Minimisation Analysis |
| **CMO** | Clinical Monitoring Only |
| **COOP** | Dartmouth Primary Care Cooperative Information Project Charts |
| **CRD** | Centre for Reviews and Dissemination |
| **CUA** | Cost Utility Analysis |
| **CV** | Contingent Valuation |
| **DALYs** | Disability Adjusted Life Years |
| **DARE** | Database of Abstracts of Reviews of Effects |
| **DART** | Development of AntiRetroviral Therapy in Africa |
| **EC** | Entebbe Cohort |
| **EQ-5D** | EuroQol 5-Dimension Questionnaire |
| **FACT-G** | Functional Assessment of Cancer Therapy – General |
| **FAD** | Food and Drug Administration |
| **FAHI** | Functional Assessment of Human Immunodeficiency Virus Infection |
| **FDA** | Food and Drug Administration |
| **FGDs** | Focus Group Discussions |
| **FQLS** | Fanning Quality of Life Scales |
| **GBD** | Global Burden of Disease |
| **GFAMT** | Global Fund to fight AIDS, Malaria and Tuberculosis |
| **GHSA** | General Health Self Assessment |

| | |
|---|---|
| **GHQ** | General Health Questionnaire |
| **HAART** | Highly Active Antiretroviral Therapy |
| **HAT-QoL** | HIV/AIDS Targeted Quality of Life Instrument |
| **HCA** | Human Capital Approach |
| **HCSUS** | HIV/AIDS Cost and Service Utilization Study |
| **HEALY** | Healthy Life Years |
| **HHV-8** | High prevalence of Human Herpesvirus type 8 |
| **HIV** | Human Immunodeficiency Virus |
| **HIV PARSE** | HIV Patient Reported Status and Experience Survey |
| **HIV-QoL** | HIV Quality of Life |
| **HIV-QL31** | HIV-Quality of Life Questionnaire 31 |
| **HOPES** | HIV Overview of Problems Evaluation System |
| **HRQoL** | Health Related Quality of Life |
| **HS** | Health State(s) |
| **HTA** | Health Technology Assessment Database |
| **HUI** | Health Utility Index |
| **HYEs** | Healthy Years Equivalent |
| **ICER** | Incremental Cost Effectiveness Ratio |
| **HIS** | Improved Health State |
| **IPQ** | Illness Perception Questionnaire |
| **IQR** | Inter-Quartile Range |
| **ISOQOL** | International Society for Quality of Life Research |
| **ISPOR** | International Society for Pharmacoeconomics and Outcomes Research |
| **KP** | Kaposi's Sarcoma |
| **KPI** | Karfnosky Performance Index |
| **KPS** | Karfnosky Performance Scale |
| **LASA** | Linear Analogue Self-Assessment Scale |
| **LCM** | Laboratory plus Clinical Monitoring |
| **LWH** | Living with HIV |
| **MAADI** | Major AIDS Defining Illness |
| **MEDLINE** | Database of the U.S. National Library of Medicine |
| **MHIQ** | McMaster Health Index Questionnaire |
| **MIADI** | Minor AIDS Defining Illness |
| **MOH** | Ministry of Health |
| **MOS** | Medical Outcome Study |
| **MOS-HIV** | Medical Outcome Study Health Survey for Human Immunodeficiency Virus |

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|---|---|
| **MOS-SF** | Medical Outcome Study Health Survey Report Short Form |
| **M-QOL** | McGill Quality of Life Questionnaire |
| **MQOL-HIV** | Multidimensional Quality of Life Questionnaire |
| **MRC** | Medical Research Council |
| **MSF** | Medicins Sans Frontiere |
| **MTCT** | Mother-to-Child-Transmission |
| **NACP** | National AIDS Control Programme |
| **NCPA** | National Committee for the Prevention of AIDS |
| **NGO** | Non-Governmental Organization |
| **NHP** | Nottingham Health Profile |
| **NHS** | National Health Service |
| **NPV** | Nevirapine |
| **NHS EED** | NHS Economic Evaluation Database |
| **OIs** | Opportunistic Infections |
| **PEM** | Preference Elicitation Methods |
| **PEPFAR** | President's Emergency Plan for AIDS Relief |
| **PLWHA** | People Living with HIV/AIDS |
| **PPD** | Purified Protein Derivative test |
| **PRO** | Patient Reported Outcomes |
| **QALYs** | Quality Adjusted Life Years |
| **QLI** | Quality of Life Index |
| **QoL** | Quality of Life |
| **Q-Twist** | Quality Adjusted Time Without Symptoms of Disease and Toxicity of Treatment |
| **QWBS** | Quality of Well-Being Scale |
| **SD** | Standard Deviation |
| **SDS** | Symptom Distress Scale |
| **SHI** | Symptomatic HIV Infection |
| **SQLI** | Spitzer's Quality of Life Index |
| **SQOLI-HIV** | Specific Quality of Life Questionnaire for HIV |
| **RCTs** | Randomised Control Trials |
| **SF-20** | Short Form 20 item Health Survey Questionnaire |
| **SF-36** | Short-Form 36 Health Survey Questionnaire |
| **SG** | Standard Gamble |
| **SIP** | Sickness Impact Profile |
| **STDs** | Sexually Transmitted Diseases |
| **SWED-QUAL** | Swedish Health-Related Quality of Life Survey |
| **TASO** | The AIDS Support Organization |

| | |
|---|---|
| **TB** | Tuberculosis |
| **TDF** | Tenofovir |
| **TTO** | Time Trade-Off |
| **UAC** | Uganda AIDS Commission |
| **UBOS** | Uganda Bureau of Statistics |
| **UNAIDS** | Joint United Nations Programme on HIV/AIDS |
| **UNGASS** | United Nations General Assembly Special Session |
| **UNHS** | Uganda National Household Survey |
| **UVRI** | Uganda Virus Research Institute |
| **VAS** | Visual Analogue Scale |
| **VCT** | Voluntary Counselling and Testing |
| **WHO** | World Health Organization |
| **WHOQOL** | World Health Organization Quality of Life |
| **WHOQOL-BREF** | World Health Organization Quality of Life Brief Version |
| **WHOQOL-HIV** | World Health Organization Quality of Life for HIV |
| **WTA** | Willingness To Accept |
| **WTP** | Willingness To Pay |
| **ZDV** | Zidovudine |
| **3TC** | Lamivudine |

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# CHAPTER 1

# INTRODUCTION

*"Don't get angry at people who insult you because you have the virus. Say yes I have the virus and I live with it. I will live for long and I am not about to die". Female participant.*

## 1.1 BACKGROUND

Acquired Immune Deficiency Syndrome (AIDS) is caused by the Human Immunodeficiency Virus (HIV). HIV infects CD4 cell counts that allow the body to fight off infections; once too many CD4 cells are infected, the immune system is more likely to be overcome by external agents of opportunistic infections (OIs). HIV spreads through fluids such as blood, semen, vaginal fluids or breast milk. The most common ways in which HIV is transmitted are: among adults, through reusing and sharing needles, and unprotected sex; from mother-to-child, during pregnancy and birth or through breastfeeding. The progression of HIV infection can be divided into four distinct stages: primary infection, clinically asymptomatic stage, symptomatic HIV infection, and progression from HIV to AIDS (Sharp *et al,* 1999).

More than twenty years have passed since the first death from AIDS, yet recent estimates suggest that more than 20 million people have died and another 38.6 million [33.4 million – 46.0 million] are living with HIV/AIDS around the world, with Sub-Saharan Africa accounting for 24.5 million [21.6 million – 27.4 million] infected individuals (UNAIDS, 2006). The epidemic in Sub-Saharan Africa is generalised, affecting both urban and rural populations and with heterosexual sex and mother to child transmission as the main modes for HIV transmission (Piot *et al,* 2001).

HIV/AIDS is recognised to affect both the life expectancy and the quality of life of patients (Wu *et al,* 1997). Although AIDS is as yet an incurable disease, antiretroviral therapy (ART), the most effective, known treatment for HIV or AIDS, slows down the replication of HIV within the body. Evidence from clinical trials has demonstrated that ART is an effective intervention for improving the quality of life of HIV infected individuals by extending the number of survival years and reducing morbidity outcomes up to 85% (Wachtel *et al;* 1992; Globe, *et al;* 1999). The introduction of ART has effectively transformed the management of HIV infection into that of a chronic disease (Flepp *et al,* 2001).

Until recently, resource poor settings had no access to ART through the public sector. One of the main reasons given for the lack of provision of ART in these settings is the high cost of the drugs, with treatment costs per patient per year ranging from $350 to $1200 (www.who.int). Although AntiRetroviral (ARV) drug prices have decreased considerably, they are still inaccessible for most African

countries, where annual expenditure per capita in health care is as low as $5 (Harries *et al,* 2004).

The cost of ART is not the only challenge for accessing treatment in developing countries. Monitoring for toxicity, haematology levels, CD4 counts and liver function is routine in the management of HIV patients in developed settings (Kannangai *et al,* 2001). Yet in Africa, where most of the laboratories are under-funded and under-staffed, the prices of the tests are costly and, if available, only offered at district level, routine monitoring is difficult, especially in rural areas (Mundy *et al,* 2003).

However, the international support for expanding access to ART in these countries has increased considerably in the last three years. The list of the international efforts presented here is not exhaustive but provides a general idea of the level of funding and ongoing programmes:

- On AIDS Day 2003, the World Health Organization (WHO) launched the 3 by 5 initiative with the objective of expanding treatment access programmes in resource limited settings by providing 3 million people with ARVs by the end of 2005; a total of US$5.5 billion were allocated to facilitate accomplishing this target (WHO, 2003). This initiative is supported primarily by UNAIDS and driven by the most affected countries (UNAIDS, 2006). Although by the middle of 2005 it was clear that the target was not going to be reached since only 1.6 million HIV infected individuals around the world were receiving treatment (Boerma et al., 2006); this initiative has helped to scale up coverage and it was seen as a step forward towards universal access to treatment, prevention, care and support services in line with national targets.

- Grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFAMT), will allow 700,000 people to access ART treatment (http://www1.theglobalfund.org/en/). In its first two rounds of resource allocation 61% of the US$1.5 billion budget will be allocated to sub-Saharan Africa and nearly two thirds of the total approved disbursements are "for AIDS" (http://www1.theglobalfund.org/en/about/how).

- The new President's Emergency Plan for AIDS Relief (PEPFAR) will provide by 2008 HIV treatment for 2 million people in Africa and the Caribbean (www.whitehouse.gov/news/relaeses/2003). In September 2006, the

programme reported the provision of ART for "approximately 822,000 people" in 15 'focus' countries.

- One of the main initiatives of the World Bank in HIV/AIDS is the Multi-Country AIDS Program in Africa (Africa MAP). Nevertheless, the Bank's HIV/AIDS support programme for treatment provision is the Treatment Acceleration Programme for Mozambique, Burquina Faso and Ghana which was launched in 2004 to look for ways to provide and monitor treatment. This programme was supported by the World Bank that committed over US$60 million in these pilot centres in Africa (www.worldbank.org).

These initiatives derive from a global consensus on prioritising resources to enable more HIV infected people in resource poor settings to access ART (Draft Declaration of Commitment 2000 Millennium Summit, at www.un.org/ga/aids). However, it is without doubt that even with the support from international donors, the provision of ART will impose an extra burden on the already stretched health systems of resource poor countries.

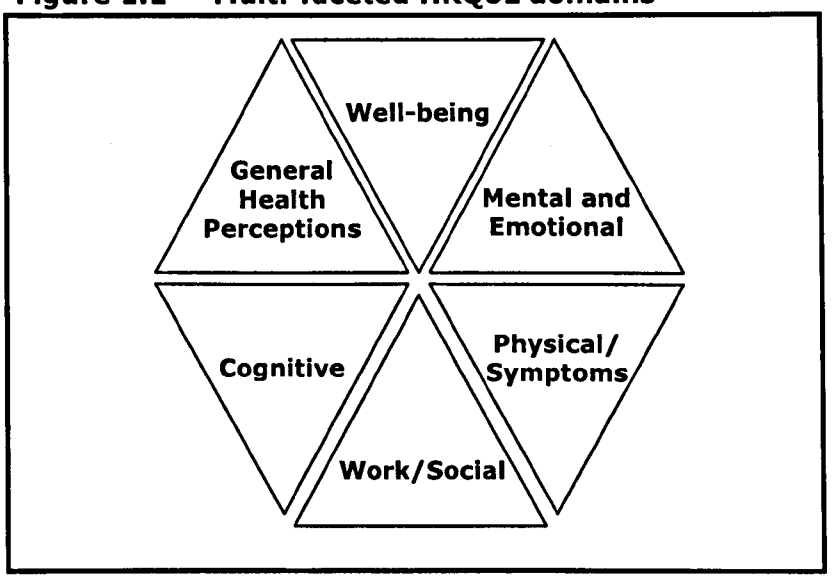
## 1.2 HEALTH RELATED QUALITY OF LIFE (HRQoL)

In 1948, WHO adopted the definition of health as "*a state of complete physical, mental and social well-being, and not merely the absence of disease*"[1]. Nevertheless, health care interventions are evaluated primarily focused on patient's improvements in clinical biomedical outcomes e.g., infections avoided, survival, deaths averted, ignoring the intervention's impact on other aspects of the recipient's life.

Health Related Quality of Life (HRQoL) measurement describes general or disease specific health states i.e., a combination of statements about multiple aspects that affect individual's wellbeing; these aspects are assessed in areas such as symptoms, physical functioning, work, social activities, and mental health as represented by the triangles in Figure 1.1 below. Only recently HRQoL has been recognised as a key outcome in clinical trials (Hobart *et al;* 1996), thus providing a more comprehensive assessment of individual's overall health by measuring the impact of the treatment or intervention on the quality of life of the patient.

[1] This definition emerged after the International Health Conference in June, 1946. It was later signed by representatives of 61 States and adopted officially on April 7th 1948.

**Figure 1.1 Multi-faceted HRQoL domains**




From an economic point of view, the interaction between physicians, as suppliers of health care, and patients, as consumers, differs from those in other markets, due to the consumer's lack of comprehensive information concerning the incidence of the disease, its duration, cause and appropriate treatment. Kenneth Arrow referred to the *product uncertainty* of treatment and the resulting *agency relationship,* which effectively means that the patient has to rely on the doctor's judgement in order to select the most appropriate treatment for his/her condition (Arrow, 1963).

Arrow argued that the principles and implications of the standard demand paradigm do not apply to the analysis of the health care market. In effect, the agency relationship implies that, in choosing treatment, the doctor acts as imperfect agent for the patient on the basis of his/her superior knowledge, information and experience of the disease and its treatment. From the point of view of society, one could then argue that this imperfect agency relationship may lead to suboptimal treatment choices and therefore to the need to undertake independent economic assessments of health care technologies. This in turn may suggest the idea that obtaining the patient's view about the value of health outcomes in addition to the clinical expert's should lead to more accurate assessments and better decisions. These and other ideas initiated the health economics sub-discipline, and in the last forty years health economics has expanded to try to answer theoretically and empirically some of the questions raised in Arrow's paper.

Economic evaluation is used in health economics as a tool for identifying the socially optimal treatment option by comparing costs and benefits. Furthermore, cost-utility analysis, one particular methodology of economic evaluation in health care, attempts to measure health benefits as changes in quality of life (morbidity) and quantity of life (mortality) and incorporate them into a single utility index. In principle, this index is meant to capture the values to individuals of such changes.

While HRQoL measures including those used in economic evaluation are increasingly being used to evaluate health care interventions in industrialised countries, very few examples are found in resource poor countries and none related to the provision of ART for people living with HIV/AIDS in Uganda.

One of the reasons for this dearth of evidence is the amount of work involved in the cultural adjustment, validation and use of existing research tools, which are designed for industrialised country settings. Moreover, there are identifiable differences in the concept of 'health' between industrialised and other countries (Sen, 2002). In addition, an individual's understanding of quality of life can be influenced by the level of political and economic instability, whether institutions are able to address citizens' needs, cultural and religious practices or, in the case of health care, the level of access to prevention, treatment and care, and satisfaction with these services (Hays and Fayers, 2000).

This thesis seeks to elucidate the clinical, economic and quality of life implications of ART provision in HIV infected individuals in Uganda. It attempts to address some of the gaps regarding how HIV infected in particular in Uganda perceive the impact of ART on their lives by using HRQoL questionnaires that are specific to HIV/AIDS and tools that are used in economic evaluation.

This thesis aims to understand the interactions of ART with the individual day to day activities, emotional and mental health state, physical and working abilities and other dimensions that are affected by HIV/AIDS. It will also assess the validity, feasibility and reliability of these tools to draw insight on their practicality for future studies that attempt to assess the impact of ART provision in Africa.

One of the main issues when designing a HRQoL study is whether to use a disease specific or a generic questionnaire. Disease specific questionnaires

attempt to measure those dimensions (mental, physical, mobility, etc.) that are directly affected by the disease under study; while generic measures can be used for any population and disease under study. The former have the important advantage of being sensitive to small changes but cannot produce information comparable across diseases or from a wide variety of populations. The choice of HRQoL instruments for implementation in this thesis and its justification will be presented in Chapter three.

The conceptual model shown in Figure 1.2 is an abstraction of the key variables that are assumed to influence the HRQoL of HIV infected individuals; it also presents the relationship between these variables and outcomes. ART, among other patient management and lifestyle interventions, is conceptualised in the model as a modifying factor of such basic relationships.

**Figure 1.2 HIV/AIDS conceptual model**

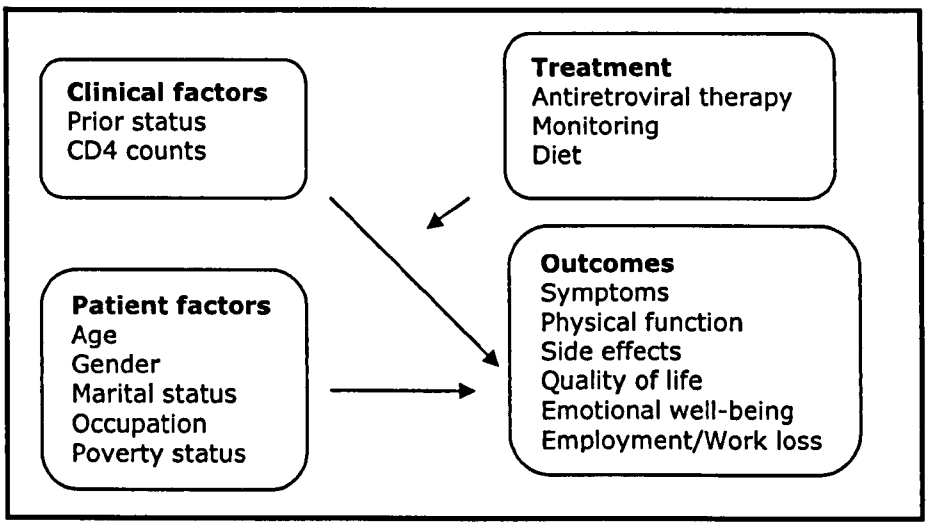
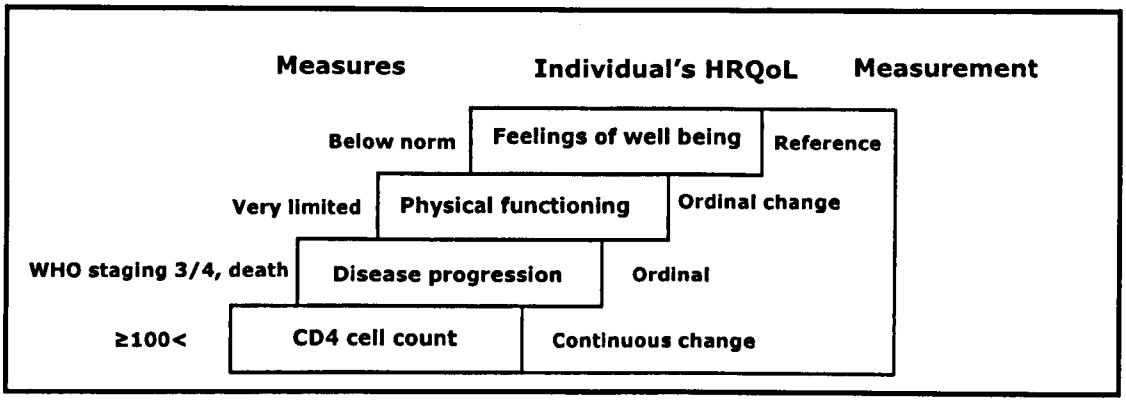



Figure 1.3 presents the different domains that are affected by HIV/AIDS. Physiological changes will be assessed through CD4 cell counts over time; clinical improvement will be represented by the number of HIV infected individuals receiving or not receiving ART that progress to a new WHO stage or die; while quality of life changes will be assessed through the variation in the indexes provided by HRQoL instruments that measure activity levels, functional ability (sexual and social), emotional health, cognition, role performance, an individual's worries about death, disease progression, expectations. The economic consequences of providing ART will be discussed and inferences will be

drawn from the data reported by patients on salaries forgone, out-of-pocket costs and, from the viewpoint of society, in relation to productivity losses.

**Figure 1.3 Disease specific assessment - HIV/AIDS**




## 1.3 HYPOTHESIS

The presumption of this thesis is that any evaluation of health care may be improved by including the perceptions of those directly affected, in this case of HIV-infected individuals, and that routine HRQoL evaluation of HIV infected individuals will increase the overall understanding of the effects of the disease and its treatment.

The main hypothesis is that currently available HRQoL tools can be used in routine assessment of HRQoL of HIV infected people in Uganda and by extension in resource poor settings. However, HRQoL tools that have been constructed for use in an industrialised setting may need a careful cross-cultural adaptation and validation for their use in a setting such as Uganda. In addition, the use of qualitative methods is essential for complementing quantitative HRQoL results as well as informing their interpretation. If this hypothesis receives support, it will be important to identify the best instrument in terms of validity, feasibility and reliability, this will enable it to inform decisions at the clinical, programme and policy making levels. If on the other hand, the evidence collected produces no support, the research question remains open about how to incorporate individual preferences and individual's perceptions of their HRQoL into routine assessment in HIV/AIDS. This general hypothesis will be tested through a set of specific research hypotheses presented in 1.3.1 below.

### 1.3.1 Specific research hypotheses

The empirical research will seek insight into the following specific research hypotheses:

1. At ***baseline*** participants that have just enrolled in the DART trial will be assumed to be sicker and will value their HRQoL lower, than those in the comparator group.

2. At ***twelve months*** the health improvements of ART recipients are expected to correspond with an increase in their HRQoL valuation relative to that at ***baseline***, while the comparator group in absence of treatment will have a deteriorated health and reduced HRQoL valuation.

3. Sicker individuals (DART participants ***at baseline*** and Entebbe Cohort participants ***at twelve months***) will have a higher willingness to give up time and accept riskier treatment prospects in order to attain a better health state.

4. ***Worse health states*** are expected to be equivalent to riskier treatment gambles and associated with greater willingness from individuals to give up time in order to attain a better health state.

5. By ***twelve months*** the health improvements of DART participants will be expected to contribute positively in their personal income and perceived economic situation, while deterioration in health from the comparator group will be expected to have a negative impact.

Research hypotheses one and two will be measured through the results of the disease specific HRQoL questionnaires. Hypotheses three and four will be tested through the values obtained during the follow up period for tools used in economic evaluation, while analysing the importance of HRQoL results in relation to socio-economic characteristics will be used to test hypothesis five.

## 1.4 STUDY SETTING

### 1.4.1 Empirical work

In order to test the hypothesis a longitudinal study was conducted in Uganda based at the Medical Research Council (MRC) Unit on AIDS in Uganda. The aim of the study was to culturally adjust, test and evaluate over a period of one year the performance of HRQoL tools for use with HIV-infected Ugandans, to assess the impact of antiretroviral therapy on the perceived HRQoL of HIV infected

individuals and to contrast these HRQoL results with those from HIV infected individuals that did not receive antiretroviral therapy.

Two groups of HIV-infected individuals were recruited: the first group was from the Development of AntiRetroviral Therapy in Africa (DART) trial, evaluating the management of ART in symptomatic HIV infected adults; the second group formed part of the Entebbe Cohort, composed of HIV-infected individuals that were not receiving ART (comparator group). The comparator group compromised HIV infected individuals with CD4 cell counts greater than 200 and thus clinically ineligible for treatment at the start of this research. The clinical interventions will be described in more detail in Chapter four. The following sub-sections present background information regarding Uganda, and the HIV/AIDS epidemic in the country.

### 1.4.2 Uganda

Uganda is situated in the heart of Sub-Saharan Africa with a total area of about 241,000 square kilometres divided into 45 Districts. The country is bordered by Sudan to the north, the Democratic Republic of Congo to the west, Kenya to the east, and Tanzania and Rwanda to the south (see Figure 1.4). In the 2002 census the population of Uganda was estimated to be 24.9 million with an annual growth rate of 2.9% and life expectancy of 42 years (Uganda Bureau of Statistics (UBOS), 2001). Estimates from the World Bank give a figure of $14 for annual public and private health expenditure per-capita during the 1990s (World Bank, 1999) while estimates of the average annual household income from the Uganda National Household Survey (UNHS) are reported to be $840 for 2003 (UBOS, 2003).

**Figure 1.4 Map of Uganda**


Map No. 3962 Rev. 4 UNITED NATIONS May 2003

Department of Public Information Cartographic Section

### 1.4.3 The HIV/AIDS epidemic in Uganda

In the early 80s people from Rakai District started dying from a 'wasting disease', known by the population as *'slim'* disease. Patients attending hospitals presented with symptoms such as excessive weight loss, diarrhoea, oral candidiasis, fever and respiratory problems. The symptoms from slim patients were recognised as very similar to those from AIDS cases in neighbouring countries with the distinction from other African populations of a high incidence of aggressive Kaposi's sarcoma (Serwadda *et al,* 1985). It was not until 1994 that scientists discovered that the high incidence of Kaposi's sarcoma was due to the high prevalence of human herpes virus type 8 (HHV-8) in Ugandans, which is necessary although not sufficient for Kaposi's sarcoma disease to appear (Schwartz, 2004).

A key factor that contributed to the appearance of the first AIDS cases in Rakai District was the district's geographical situation alongside a trade route when, in the late 70s, it was inhabited by military forces from both Uganda and Tanzania (Hooper, 1999). This issue was also supported in 2001 by the Uganda AIDS Commission (UAC), reporting that urban or rural areas where trade routes

crossed and districts that had been affected by war, had the highest HIV prevalence (UAC, 2000). It is now recognised that one of the main reasons for high transmission of the virus is the high labour mobility and transport communications within the region (Piot *et al,* 2001).

Data collected by the Ministry of Health (MoH) on women attending antenatal clinics (ANCs) showed that in the 90s Uganda had one of the highest rates (20%) of HIV prevalence (MOH, 2001). Although this rate should be considered with caution since the 1990 Uganda population census reported less than 40% of women attending ANCs in their course of pregnancy (UBOS, 1991). Nevertheless, the decline in prevalence has been optimistic and showed that by the end of 2003 the rate for adults (15 – 49) living with HIV in Uganda was 4.1% (UNAIDS, 2006), other indicators produced by the UNAIDS 2006 Report on the global AIDS epidemic are presented in Table 1.1 below.

**Table 1.1 Adults (aged 15 – 49 years) HIV prevalence (%)**

| | **Uganda** |
|---|---|
| Median HIV prevalence (%) among women attending antenatal clinics 2003-2004* | 6.2[a] |
| Population-based survey prevalence (%) year | 7.1 (2004-5) |
| 2003 HIV prevalence (%) reported in 2004 report on the global AIDS epidemic | 4.1 |
| Adjusted 2003 HIV prevalence (%) in current report | 6.8 |
| 2005 HIV prevalence (%) in current report | 6.7 |
| Trend in prevalence | Stable |

* WHO Africa (2005). HIV/AIDS epidemiological surveillance report for the WHO African region 2005, Update (Geneva: WHO AFRO).
a Estimate based on country report 2002 (2003). Ministry of Health Uganda. STD/HIV/AIDS surveillance report. STD/AIDS control programme, Kampala.
Source: UNAIDS, 2006 Report on the Global AIDS epidemic.

One of the key developments for responding to the epidemic was the recognition in 1986 by the president of Uganda, Mr. Yoweri Museveni, that AIDS was a national health problem (Zuniga, 1999). He convinced the public, including religious leaders and Non-Governmental Organisations (NGOs), about his commitment to fight HIV/AIDS by acknowledging scientific and medical evidence of HIV/AIDS, introducing the public sector as the main provider of health care for HIV infected individuals and regulating the activities of private providers. Museveni protected the rights of women and children, and was most influential

in his campaign of *all out* for educating Ugandans in rural areas through continuous seminars about HIV/AIDS transmission (Putzel, 2004).

It has to be recognised that the situation in Uganda was unique; the political upheaval had brought instability and economic crisis that allowed the government the freedom to take early and drastic actions in combating HIV/AIDS without weakening sectors of the economy or deterring foreign investment. The political commitment to fight HIV/AIDS also won the confidence of other international donors to financially assist the reconstruction of the country (Putzel, 2004). Ugandan NGOs and religious organisations have also played a pivotal role in transmitting messages on behavioural change to communities, combating stigma and breaking down prejudice (Hogle, 2002).

In 1987 Uganda set up an AIDS Control Programme, the first of its kind in Africa. This was a five-year action plan drawn up by the Ministry of Health (MOH) and WHO to combat HIV/AIDS, endowed with a budget of $6.9 million for the first year and $14 million for the remaining four years (Hooper, 1990). The National AIDS Control Programme (NACP) was created with the objective to conduct epidemiologic surveillance, guarantee safe blood supply, provide HIV/AIDS information, education and communication, patient care and counselling, and to prevent and control sexually transmitted infections (STDs) (www.aidsuganda.org).

Some of the most important interventions undertaken by the government were:

- *Mass media*; radio and television commercials, posters and pamphlets that were used to educate people on how HIV/AIDS was transmitted and to promote less risky sexual behaviours. The AIDS campaigns messages during the 90s were:

  > *"Love carefully", "Love faithfully", "Zero Grazing" or being faithful to one's sexual partner or partners – for polygamous marriages (UAC, 2002)*

- *Encouragement of community mobilization*; the main example was the creation of The AIDS Support Organisation (TASO), the first service organisation offering AIDS education to communities and provision of care and support to People living with HIV/AIDS (PLWHA); this was founded by PLWHA and family members, and currently is the largest service organisation (TASO, 2002; www.tasouganda.org).

- Adoption of *government policy of condom promotion* in line with the medical evidence for controlling HIV/AIDS transmission. Condoms are at present promoted in Uganda through social marketing offering condoms at affordable prices, family planning programmes subsidised by the public sector and through private-for-profit organisations in both rural and urban areas.

- *Development of HIV counselling and testing by the Ugandan government.* Initially the first point for testing individual's HIV status was through donating blood, but existing blood banks were soon insufficient to provide HIV testing and unable to provide counselling. Consequently in the 90s a new organisation, the AIDS Information and Testing Centre (AIC), was opened to offer counselling and testing services; over time the AIC changed from providing services in centres initially set up in Kampala and in other major urban areas to rural areas (www.aicug.org).

- Blood screening; from the late 80s, regional blood banks have screened all donated blood for HIV infection. These blood banks have then distributed the screened blood to all the hospitals in the country. This measure reduced the incidence of HIV in donated blood from 14% in 1989 to 1.5% in 2002 (Evanson, 2002).

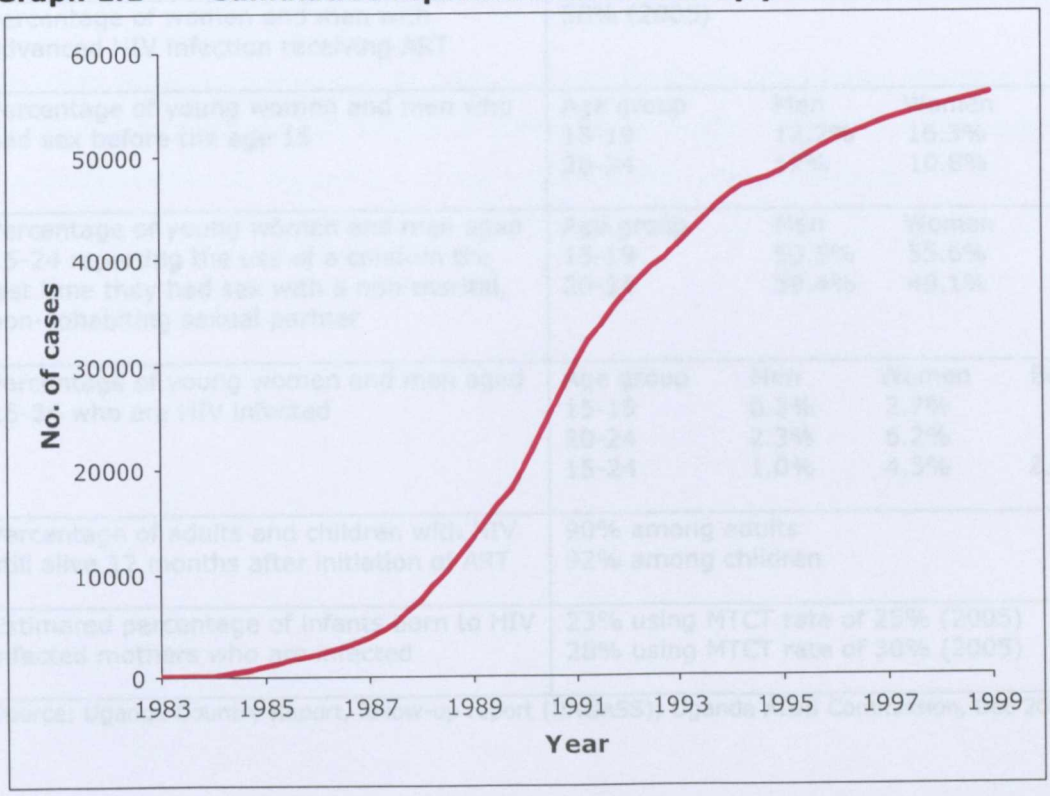
### 1.4.4 AIDS cases

The information on the number of AIDS cases available in Uganda is gathered from reports at district health units, making the data unreliable. Although modelling could provide estimates of the number of AIDS cases, the figures collected by district health units were used as an indicator of the magnitude of the impact of the disease on the country.

The magnitude of the epidemic varies across areas of the country. Data on number of AIDS cases from the MoH has shown that the sites with highest number of AIDS cases are Kampala, Jinja, Rakai and Masaka, in that order. The high number in the first two sites can be attributable to high concentration of people, while Rakai and Masaka districts have the highest prevalence of HIV/AIDS and were also the first to report HIV/AIDS cases, back in the early 80s (MOH, 2001).

Data from the MoH and ACP stated that by the end of 1999 there were 55,861 cumulative reported AIDS cases; of these cases almost 90% were adults aged twelve years old and above, and approximately 55% were women (MOH, 2001). Also as it can be seen from Graph 1.1, there has been a continuous increase in the reported cumulative number of AIDS cases from 1983 to 1999.

**Graph 1.1 Cumulative reported AIDS cases by year**




Source: Ministry of Health HIV/AIDS Surveillance Reports.

The AIDS Commission estimated in 2000 that up to 12% of the total annual deaths could be attributed to AIDS (UAC, 2000); with respect to the annual number of deaths due to AIDS by the end of 2001 and 2003 were estimated to be 94,000 and 78,000 respectively (UNAIDS, 2004). By 1998, a total of 1.9 million Ugandan children had lost one or both parents. Recent figures from the UNAIDS report show that the number of orphans of both parents aged 0 to 17 years at the end of 2001 and 2003 were 910,000 and 940,000 respectively (UNAIDS, 2004).

Some of the most important and recent indicators from January 2003 to December 2005 from a follow up report to the Declaration of Commitment on HIV/AIDS (UNGASS) from Uganda AIDS Commission are presented in Table 1.2 below.

**Table 1.2 Selected performance indicators for Uganda 2003-2005**

| | Indicator | Achievement |
|---|---|---|
| National programmes | Percentage of large enterprises/companies which have HIV/AIDS workplace policies and programmes | 72% of 25 private large companies and 1 of 5 government ministries have adopted workplace policies |
| | Percentage of HIV-positive pregnant women receiving a complete course of ART to reduce risk of mother - to - child transmission | 12% (2005) |
| | Percentage of women and men with advanced HIV infection receiving ART | 56% (2005) |
| Knowledge and behaviour | Percentage of young women and men who had sex before the age 15 | Age group / Men / Women<br>15-19 / 12.2% / 16.3%<br>20-24 / 17% / 10.8% |
| | Percentage of young women and men aged 15-24 reporting the use of a condom the last time they had sex with a non-marital, non-cohabiting sexual partner | Age group / Men / Women<br>15-19 / 50.5% / 55.6%<br>20-24 / 59.4% / 49.1% |
| Impact | Percentage of young women and men aged 15-24 who are HIV infected | Age group / Men / Women / Both<br>15-19 / 0.3% / 2.7%<br>20-24 / 2.3% / 6.2%<br>15-24 / 1.0% / 4.3% / 2.9% |
| | Percentage of adults and children with HIV still alive 12 months after initiation of ART | 90% among adults<br>92% among children |
| | Estimated percentage of infants born to HIV infected mothers who are infected | 23% using MTCT rate of 25% (2005)<br>28% using MTCT rate of 30% (2005) |

Source: Uganda Country Report, follow-up report (UNGASS); Uganda AIDS Commission, Dec 2005.

## 1.5 THESIS STRUCTURE

**Chapter two** splits in two parts; part one describes utility theory and presents the theoretical foundations of the standard gamble (SG) and time-trade-off (TTO) tools used in economic evaluation for obtaining utility values for health care interventions; part two provides a revision of economic evaluation methodologies and gives examples on how these methodologies have been used in resource poor settings in the clinical area of HIV/AIDS.

**Chapter three** summarises the findings of studies that have reviewed generic and HIV/AIDS specific HRQoL instruments and reviews the studies that have attempted to measure HRQoL in HIV infected individuals in Africa.

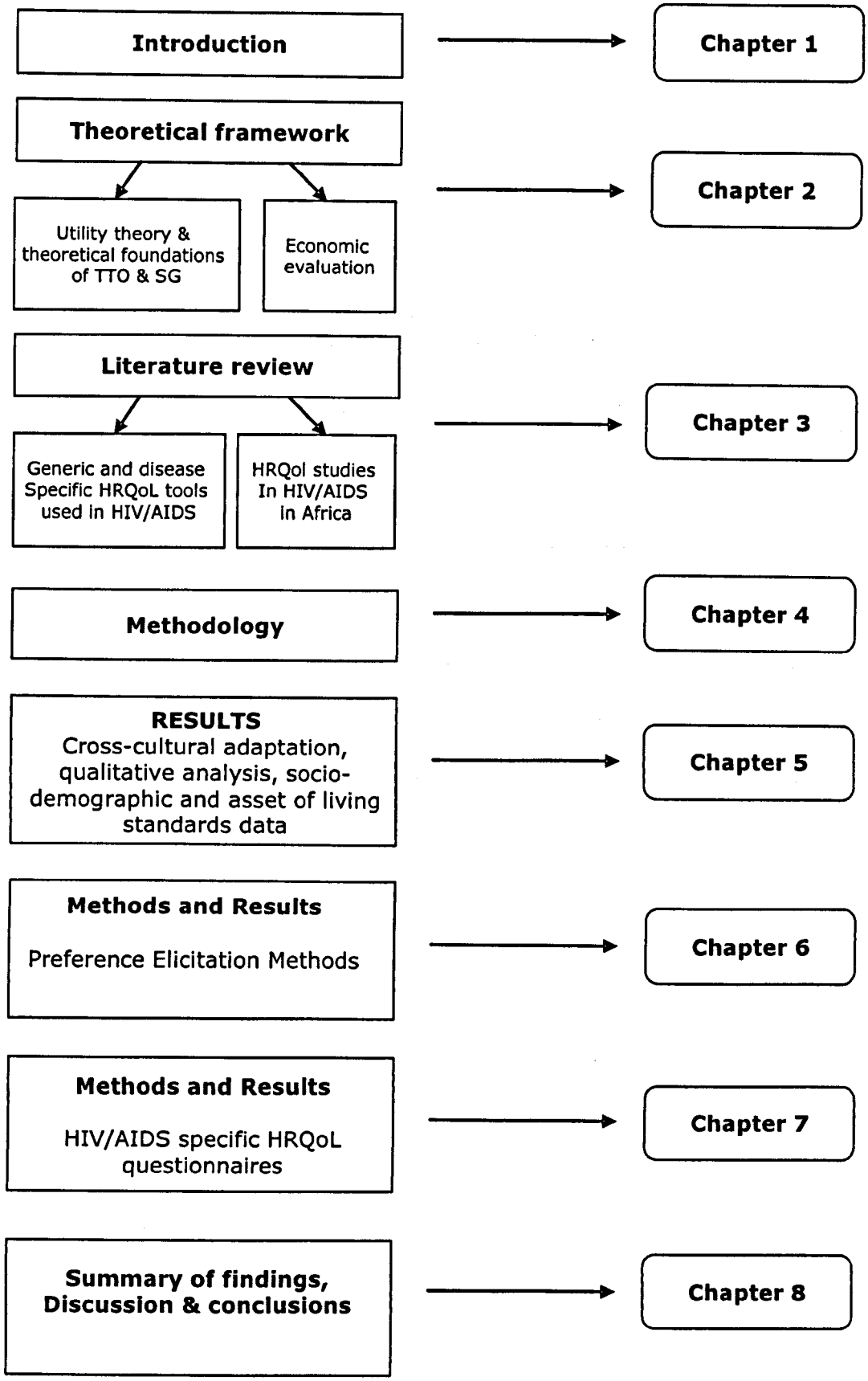
**Chapter four** describes the methodology used for the cross-cultural adaptation of the tools, pilot study, the analysis of socio-demographic data, and the construction of the asset-index of living standards.

**Chapter five** provides the results from the cross-cultural adaptation, the pilot study, the socio-demographic data collected at baseline, six and twelve months and the asset-index of living standards.

**Chapters six and seven** present the methods and results of using the Preference Elicitation Methods (PEM) tools and the HIV/AIDS specific HRQoL questionnaires.

**Chapter eight** presents the summary of key findings, discussion, caveats of the study, conclusions and attempts to recommend further research lines based on the evidence found. Figure 1.5 below provides the thesis structure.

**Figure 1.5 Thesis structure**



# CHAPTER 2

# THEORETICAL FRAMEWORK

*"The most effective policy approaches come from listening to those who have experienced such problems first hand, who can provide needed perspectives, improve understanding and offer creative solutions so that resources may be used creatively". Noeleen Heyzer, Executive Director, the United Nations Development Fund for Women.*

## 2.1 INTRODUCTION

The objective of this chapter is firstly to summarise the theoretical discussions of utility theory. Secondly, it will describe individual's choices under uncertainty and certainty and how these decisions relate to the tools used in cost utility analysis for obtaining direct utility measure i.e., Standard Gamble (SG) and Time-Trade-Off (TTO). Finally, it will then discuss the current arguments for and against each of these instruments as well as the theoretical interpretation to empirical results. Since cost utility analysis is one of the methodologies used in economic evaluation, the methods commonly used will be reviewed with examples of the application of these methodologies from developing countries in the area of HIV/AIDS.

## 2.2 UTILITY THEORY

Economics is concerned with the allocation of resources in a world in which needs are infinite but resources are finite (Walley *et al,* 2003). It is based on the principle of scarcity of resources (both financial and physical), implying that not everything that is desired can be acquired, and that an efficient choice must be made among competing uses of those limited resources. Under the scarcity principle a key question that has been persistent is what type of utility (well-being or pleasure) a good or set of goods provides to the consumer and how they could be captured and measured under economic theory.

The term 'utility' has been around since the early 1800s. Adam Smith in his analysis of the division of labour introduces the term utility as the value of a particular good (*value in use*) and refers to the power a good has for buying other good(s) as the *value in exchange* (Smith, 1776).

Utility as a theory, was formalized primarily through the writings of the philosopher, Jeremy Bentham (1748 – 1832) and is known as Bentham's greatest happiness principle whose main argument is that: "*individuals aim to maximise their happiness*"; where happiness was defined as the surplus of pleasures over pains and these in turn were defined as human feelings or desires such as love, duty, hate, desire for freedom, etc. (Bentham, 1789).

To Bentham, individuals are able to differentiate four dimensions of pleasure or pain:

1. Its intensity
2. Its duration

3. Its certainty or uncertainty
4. Its propinquity or remoteness

A proxy measure of pleasure or pain was obtained by multiplying its intensity by its duration, while uncertainty and remoteness are interpreted as the causes that would influence an individual's perception or response to pleasure or pain (Stigler, 1950). Benthamite utility, while logical, fails to recognise that individuals might choose suboptimal actions; for example, the choice of a drug addict between consuming drugs or not. So to know an individual's desires will not necessarily provide information about what an individual should have, making this theory a positive interpretation of individuals' choices as the pursuit of pleasure and avoidance of pain.

One difficulty with Bentham's utility theory is that it never described how to practically implement it. Bentham never explained a method of quantifying utility. However, his main goal was to persuade the British government in particular and, for that matter, any government that it was their moral obligation to promote the welfare (happiness/utility) of their citizens (Rosenblum, 1978).

After the appearance of the Benthamite utility theory, economists have proposed ways of measuring utility directly. But it is Smith's paradox of the *value in exchange* that motivates a new debate around the theory. Smith argues that: "*Water has a great value of use for any human life (human beings can't survive without water for ever), however, water scarcely has any value in exchange, what other goods would you buy with water while others, such as diamonds, although of little use, have a great power to buy other goods*" (Smith, 1776).

This paradox served as the benchmark to formalize marginal utility, as referring to the pleasure or pain that an additional unit of a good or set of goods provides. This notion has been widely used in economic analysis since the late nineteenth century (Stigler, 1950). The idea of marginal utility encouraged the development of a new sphere of theorists known as the modern marginal utility theorists or the renowned trinity (William Stanley Jevons (1835 – 1882); Carl Menger (1840 – 1921) and; Leon Walras (1834 – 1910)) (Roll, 1992). Other marginalists included Hermann Heinrich Gossen (1810 – 1858), Marshall (1842 – 1924) and Edgeworth (1845 – 1926).

The idea of exchange-value proposed by Smith re-emerges as a way of explaining utility by the marginalists (Roll, 1992). Gossen expressed that: "*A person maximises his total life pleasure if he distributes his entire money income...among the various enjoyments...so that the last atom of money spent on each single pleasure yields the same amount of pleasure*" (Georgescu-Roegen, 1968; p. 244). This can be expressed by the following equation:

$$\frac{MU_1}{p_1} = \frac{MU_2}{p_2} = \frac{MU_i}{p_i}, \text{ for all } i$$

Where $MU_i$ is the marginal utility of good i and $p_i$ is its price.

Marginal utility took away the need of measuring total pleasure or pain, but retained a degree of cardinal measurability in that differences between increments might be understood as those on a ratio scale. Nevertheless, since utilities are not independent, the marginal utility obtained from a good would be dependent up on what other goods you own and their utility.

A more elegant mathematical interpretation in economics emerged, where 'utility' was defined as a numerical indicator of an individual's overall well-being or person's happiness. It was Edgeworth who proposed to measure utility as a bundle of goods faced by a consumer:

$$U = U(x_1, x_2, x_3, x_4, \ldots, x_n)$$

where $x_1, x_2, x_3, x_4, \ldots, x_n$ are different individual goods.

This proposition enabled Edgeworth to go a step further in order to explain the exchange between two goods and two individuals and to draw indifference curves which are an individual's preferences in pairwise comparisons between possible consumption bundles[1] that will map the individual's utility of all possible bundles (Edgeworth, 1879).

Pareto expressed that the prediction of an individual's choice of bundles under a given budget constraint can be obtained by determining which bundles of goods achieve the highest indifference curve (Pareto 1903). As Roll says "*Pareto is unclear at this point about the 'ordinal' character of utility...and concentrates on*

[1] So individual A can be indifferent between bundles or prefer one bundle over another.

*the empirical fact of choice"* (Roll 1992, page 374). For example, if indifference curves are assigned with numbers it should not matter which number they are assigned as long as the higher the indifference curve the higher the number assigned. However, what is clear from Pareto's proposition is the abandonment of Bentham's utilitarianism by: a) utility not having any relationship with happiness; b) the impossibility of combining across people the numbers assigned to bundles and; c) the lack of comparability of the differences between these numbers (Roll, 1992).

The ideas behind ordinal or cardinal utility require further explanation. In simple terms, if the object of the utility function is the *ordering* (ranking) of the baskets of goods and not the magnitude of their value, then utility is known as ***ordinal utility***. On the other hand, if the focus is on the magnitude of the utility function, the size of the utility difference between two baskets of goods or in other words, on the strength of the preferences, then utility is known as ***cardinal utility.***

Transferring these concepts to the health economics arena can be straight forward. For example if a researcher wanted to know the ranking of different health states from greatest to lowest utility (well-being) perceived by the individual, the values obtained would be of ordinal nature:

$U(x_1) > U(x_2) > \ldots > U(x_n)$

Where $x_1$ is the health state 1 and $x_n$ is the health state n. This ranking provides information in saying that health state 1 gives greater utility than health state n, in order words $x_1$ is preferred to $x_n$; but it is impossible to say anything about the magnitude of the utility or the distance, in terms of utility, between the health states (Dasgupta and Pearce, 1972).

However, the issue of how an individual chooses between different baskets of goods still remains to be discussed under certainty and uncertainty conditions which are explained below.

### 2.2.1 Choice under certainty conditions

An individual can choose between different consumption bundles, $z_1$, $z_2$ and $z_3$ (each bundle is a combination of different goods and services). Where $z_1 \geq z_2$, means that the $z_1$ is at least as good as $z_2$; $z_1 > z_2$ means that $z_1$ is strictly

preferred to $z_2$ and $z_1 \sim z_2$ means that the individual is indifferent between $z_1$ and $z_2$. In addition, an individual's preferences should meet the following conditions:

a) ***Reflexivity***, any consumption bundle is always as good as itself.

b) ***Completeness***, any two consumption bundles can always be compared and ranked.

c) ***Transitivity***, if bundle $z_1$ is preferred to $z_2$, and $z_2$ to $z_3$, then $z_1$ should be preferred to $z_3$.

d) ***Continuity***, given any two goods in a bundle, it will always be possible to define another bundle which is indifferent to the first; meaning that there is no good in a bundle which is absolutely necessary in some amount and which cannot be traded off at the margin for another good.

When reflexivity, completeness and transitivity hold, the individual's preference ordering is defined, and when d is included, the individual's preferences can be represented in a utility function.

A utility function can be interpreted as a way of giving a numerical value to every possible consumption bundle as mentioned before. It also implies that it should be unique up to a monotonic transformation in which consumption bundles assigned with larger numbers are more preferred to those with lower numbers and when the two bundles being compared have the same assigned number indifference between the bundles exists.

### 2.2.2 Choice under uncertainty conditions

If utility is approached through cardinalisation, rational behaviour is analysed under uncertainty, so an individual would act as to maximise expected utility. In this case the individual is not only faced with a choice between bundles but also by the combination of probabilities between the bundles; the probability of obtaining x equals p and the probability of getting y is 1 – p, (where $0 < p < 1$). For example p=0.2 means that there is 20:80 chance of achieving either x or y respectively (Dasgupta and Pearce, 1972).

von Neumann and Morgenstern (1947) formalized the analysis under uncertainty by adding the following conditions to the previous four that also hold for this analysis:

a) ***Preference increasing with probability***, if $x > y$ and $w_i = (x, y; p_i, 1 - p_i)$ and $w_j = (x, y; p_j, 1 - p_j)$ then $w_i > w_j$ if and only if $p_i > p_j$.

b) ***Continuity***, if $x \geq z \geq y$, then there exists some probability p such that $(x, y; p, 1\text{-}p) \sim z$.

c) ***Strong independence***, considering x, y and z and $p \in (0, 1)$ we have $x \geq z$ if and only if $px + (1 - p)\, y \geq pz + (1 - p)\, y$. It means that any component can be replaced by an indifferent component and there will be indifference between the resulting component and the original one.

d) ***Usual rules for combining probabilities***, a utility function U has an expected utility form if there is an assignment of numbers $(u_1,...u_n)$ such that for every consumption bundle $y= (p_1,...p_n)$ we have $U(y) = u_1p_1+...+u_np_n$.

In other words d implies that if there is a U(x), which is assumed to be unique up to a linear transformation, such that given any two bundles $w = (x, y; p, 1 - p)$ and $w' = (x', y'; p', 1 - p')$, then w is preferred to w' or there is indifference between them if and only if $pU(x) + (1 - p)U(y) \geq p'U(x') + (1 - p')U(y')$ (Varian, 1993).

Kahneman and colleagues have expressed the view that utility is at present used primarily in decision making theory: *"the utility of outcomes and attributes refers to their weight in decisions: utility is inferred from observed choices and is in turn used to explain these choices...so Bentham's idea of utility should be referred as experienced utility while the current usage of utility should be referred as decision utility"* (Kahneman *et al,* 1997; p. 377)

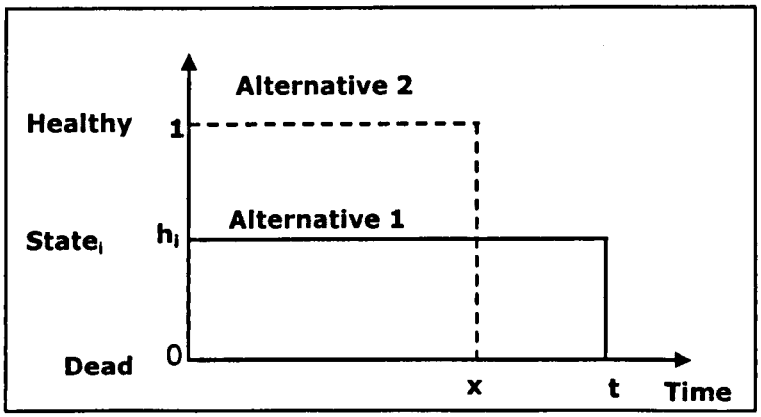
The idea of measuring utility has also been transferred to the sub-discipline of health economics by attempting to capture preferences on quality and quantity of life of an individual choice. This assessment is conducted within the economic evaluation framework of cost-utility analysis. Cost utility analysis attempts to combine health benefits transformed into quality of life weights, or utilities over a given period of time of generic or disease specific health states, into a single

index. In order to obtain utility weights through direct measurement three tools are most often used: Time Trade-Off (TTO), Standard Gamble (SG) and Visual Analogue Scale (VAS). These tools range from extreme values of 1, for full health to 0 for death. However it is important to note that each one of these tools yields different types of valuation as explained below.

### 2.2.3 Time Trade-Off (TTO)

TTO involves asking respondents if they would be willing to trade-off time for an improved health state (Torrance, 1972). This involves asking the participants, for example, if they would be willing to take a drug if doing so made them recover their full health but shortened their life by for example 2 years. The numbers of years are then varied until the respondent is indifferent to the options. Figure 2.1 illustrates this technique.

**Figure 2.1 Time Trade-Off (TTO)**



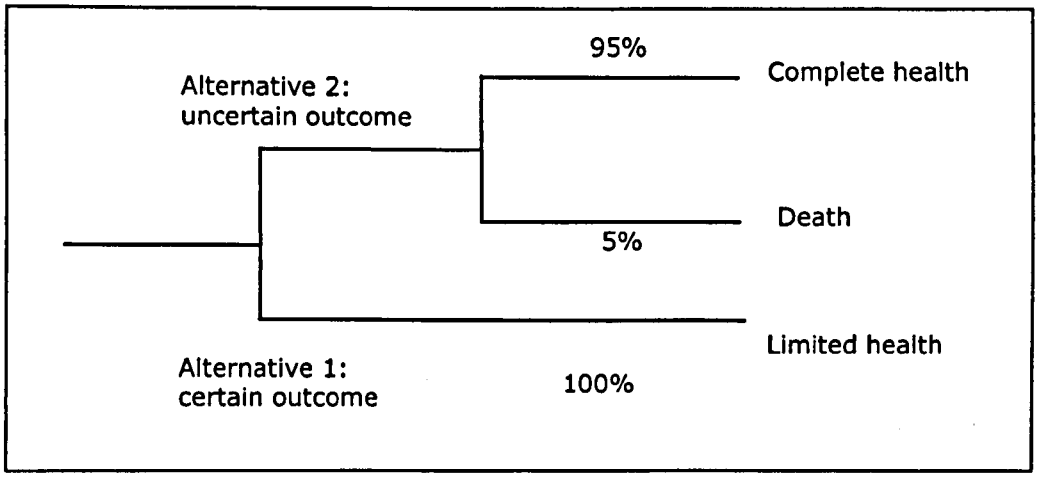

### 2.2.4 Standard Gamble (SG)

In comparison Standard Gamble (SG) involves assessing the level of risk that an individual would be willing to incur in return for a better health state (Torrance *et al,* 1976; Furlong *et al,* 1990). For example a participant might be asked to choose between (see also Figure 2.2):

**Box 2.1 Standard Gamble**

| **Strategy 1**<br>*Without the drug* | **Strategy 2**<br>*To receive a new drug if it had an associated risk of* |
|---|---|
| Live for the next 20 years with mild pain followed by death | 95% chance of recovery to full health for the next 20 years followed by death and,<br><br>5% of sudden death |

**Figure 2.2 Standard Gamble**




The utility weight is then obtained by varying the level of risk until the participant sees no difference in benefit to either strategy. Note that for both strategies the numbers of years are the same. In this example, the utility of living with mild pain until death is equal to 1 minus the risk of sudden death at the point of indifference. The option presented by a SG might be considered more realistic since it is the choice between no treatment with a certain health outcome or treating the condition with a probability of success or failure (Newbold, 1995).

With TTO and SG, the greater the risk/time that the person is willing to take/give up in return for the better prospect offered by the treatment, the lower the value that the person attaches to his or her current state.

### 2.2.5 Theoretical foundations of SG and TTO

The theoretical assumption behind using TTO and/or SG is that these techniques help to evaluate changes in the welfare of individuals as a result of an individual's health change, since health is presumed important for everyone and is one of the arguments in their utility function (Dolan *et al,* 1996).

TTO operates under the certainty scenario where any improvement in health is valued with respect to the amount of time an individual is willing to give up; this assumes utility to be a positive function of longevity. In contrast SG operates under uncertain conditions, where health improvements are valued with respect to the risk (immediate painless death) an individual is willing to take by assuming utility to be a negative function of risk (Dolan *et al,* 1996). The answers to both techniques have been interpreted as a measure of the quality or value of a given health state to the interviewee.

SG is considered by health economists to be the 'gold standard' since it is based in expected utility theory. The idea behind expected utility is that it transforms the choice into the fact that only one outcome among many possible outcomes would actually happen. For example, you will pass your exam or you will fail. This translates into the fact that only one plan of consumption per individual is actually realized.

It has been argued that TTO only gives values since its valuation is under certainty (Johannesson *et al,* 1993). However, Dolan and colleagues refuted this idea and proclaimed that this is *"a narrow interpretation of utility"*, and that actually it depends whether utility is defined as cardinal or ordinal (Dolan *et al,* 1996). Under the previous definition of cardinal and ordinal utility if the view is that individual preferences express only the ordering (ranking) of the bundles of goods or health states (as in the case of health economics), and not their magnitude, then SG should be the only tool capable for obtaining utilities. If, on the other hand, the position is that individual choices reflect the magnitude or the strength of preferences, then utility values can be measured under conditions of certainty or uncertainty and both TTO and SG valuations should give utilities.

Nord and colleagues have argued that the raw judgments – values, of health states i.e. how bad or undesirable a health state is, provide ordinal preferences and not cardinal, since it is easy for an individual to say "I think health state A is worse than B" but difficult to value how bad or good in magnitude a health state is (Nord *et al,* 2006).

Another theoretical argument in favour of the ordinal vie of utility and therefore of using SG derives from the fact that health care decisions are made under uncertain conditions (Mehrez and Gafni, 1991). Although this might in most cases be true, the appropriateness of a method should be based on its ability to model a proxy for utility (Buckingham, 1993). In contrast, Buckingham and colleagues argue the appropriateness of TTO on the basis that the valuation of number of years in full health is equal to that (longer) period in the other (less healthy) state being valued (Buckingham, 1993). The counter-argument is that individuals might not be able to really consider in their evaluation to trade-off a constant proportion of their remaining years of life for an improvement in their health status (Sackett and Torrance, 1978).

This criticism is clearly expressed in algebraic terms; where in TTO the following relationship is obtained at the point of indifference:

$$V(x^*) = U(T), \quad (1)$$

Where $x^*$ is the number of life years in full health at which the individual is indifferent in relation to the alternative of living T years in the (suboptimal) health state being evaluated. TTO assumes that the utility functions are:

$$V(x) = ax \quad (2)$$
$$U(t) = bt,$$

Where a>b; in this setting a,b may be thought of as the additional value (utility) to an individual of an additional year of life. Thus, under this specification (1) results in:

$$ax^* = bT \quad \Rightarrow x^*/T = b/a \equiv u \quad (3)$$

Where u is the 'utility' weight. Equations (2) assume that individuals have the same marginal valuation of life, i.e. a and b are constant, no matter what number of life years in perfect and suboptimal health, x and t, respectively, the individual finds himself in. If one were to assume a nonlinear function such as:

$$V(x) = x^a \quad (2')$$
$$U(t) = t^b$$

Then the following relationship would hold

$$\Rightarrow x^*/T = 1/T^{1-b/a} \equiv u' \quad (3')$$

Since b/a<1, then u', the utility weight as calculated by TTO, would not be constant but would be a declining function of T, the number of years in the suboptimal health state being evaluated. If such a nonlinear function was a better approximation to reality, values obtained with TTO should only be applied to health states of the same expected duration as that used to derive them. In the present example, such weights would underestimate the utility of states with shorter durations than that in the preference elicitation exercise whereas it

would overestimate the utility of such state in longer spells than that referred to in the exercise.

In addition to the theoretical problems, empirical studies have shown that each of the techniques described above tends to produce different values for the same health states (Revicki and Kaplan, 1993), with the majority of them giving an order of instruments in terms of the magnitude of their values, from highest to lowest, of SG, then TTO and last VAS (described below). Through mathematical transformations such as power transformation, the instruments have been found to be related (Stiggelbout *et al,* 1996), and used in economic evaluation studies to obtain SG for cost-utility analysis from TTO and, most frequently, VAS patient data (Torrance and Feeny 1989).

The difficulties of measuring individuals' preferences arise in conceptualising, measuring and obtaining comparative valuations of different levels of quality of life. Firstly, who should make such valuations and on what basis? For example, who has the 'right' to specify that one-year spent in a wheelchair is 'worth' only nine months spent with full mobility? On what basis are such calculations made?

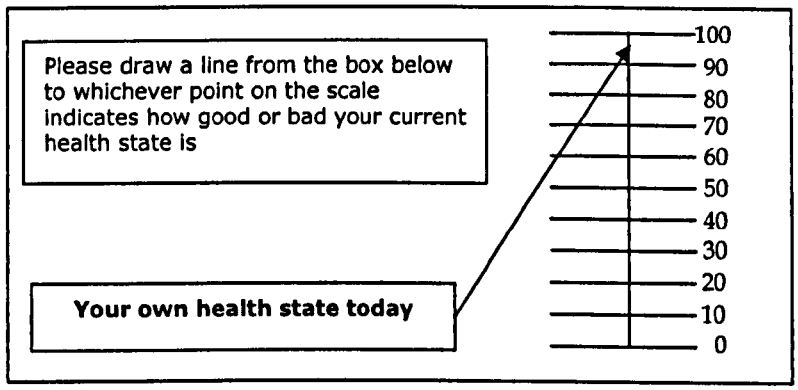
Several authors support the idea that utilities should come from the general public (Weinstein *et al,* 1996; Kaplan, 1995) claiming that these utilities should be blind to self-interests. This could be further explained under a national decision making level within a public health system. Administrators might like to know the opinion from a representative sample of the population on how the government should spend a given health budget. If we assume that this sample have normal health, actually these individuals might not themselves benefit from the health care expenditure so their responses will therefore 'mainly' reflect their opinion on how the money should be spent efficiently and fairly as a way to distribute health care to citizens that are sick. However, empirical studies for specified health states tend to use patients, since it can be argued that individuals affected by the disease are in a better position to judge the pain and suffering that it inflicts. Nevertheless, both approaches exclude the carers and family perspective and in some cases, might be as important as the patient's perspective or the general population. However, these perspectives have little relevance for decision making within private health care systems and are often overlooked in a public one.

A second problem emerges when results are presented as the mean quality of life improvement across individuals regardless of the age, sex, education and socio-demographic characteristics of the beneficiary. For example, a healthy young individual might be willing to give up more years since he/she feels that he/she has his/her life ahead and that losing 5 years of his/her life when your life expectancy is 85 is not a bad trade off for improving your health state. However, this might be different for older individuals that might be unwilling to give up any time.

### 2.2.6 Visual Analogue Scale (VAS)

The last of the tools commonly used in health state valuation is Visual Analogue Scale (VAS). This tool is a choice-less assessment that asks individuals to state how they feel with respect to their health at the time of interview, or 'today' as it is actually phrased, on a thermometer-wise scale from 0 (worst imaginable health state) to 100 (best imaginable health state). This method has been used as a way to familiarise individuals with ranking procedures (Bayoumi *et al,* 1999) and has been found easy to understand within HIV infected individuals through high response rates (Badia *et al,* 1999). Figure 2.3 below, shows a graphical representation of VAS.

**Figure 2.3 Visual Analogue Scale (VAS)**




The main criticism of this tool is that in responding to this prompt, individuals are not faced with any choice, thereby ignoring the idea that the cost of something is what an individual gives up in order to obtain it (opportunity cost). Economists have thus disregarded this method, arguing that it is not based in economic theory (Green *et al,* 2000). Green and colleagues have also commented that: *"The empirical evidence of SG, TTO and VAS casts doubt on the theoretical basis of all the techniques"* (Green *et al,* 2001; page 203).

Under these arguments the decision about which tool to use becomes difficult particularly when the evidence is non-existent such as in the case of HIV/AIDS in Africa. In this case recommendations should be guided by psychometric performance such as their practicality, reliability and validity of empirical studies results.

### 2.2.7 SG, TTO and VAS psychometric performance

The psychometric performance of the tools of SG, TTO and VAS, that would be explained below was based on the results of a review of health status measures used in economic evaluation and, in particular, the comparison of VAS, TTO and SG for valuing health states by Brazier and colleagues (Brazier *et al,* 2001). Brazier and colleagues summarised the results from previous studies that have compared the SG, TTO and VAS as follows:

#### *2.2.7.1 Practicality or feasibility*

The data collection accuracy and practicality of using VAS, TTO and SG has been improved through props and training of interviewers. These tools have been reported easy to understand and gave a high response rate in empirical studies (Froberg and Kane, 1989). In empirical studies VAS has been found the easiest to use with the highest response rate and lowest cost in terms of time spent conducting the interview; following VAS, TTO performs better than SG (van der Donk *et al,* 1995).

#### *2.2.7.2 Reliability*

Previous studies have reported good test-retest reliability for VAS, TTO and SG. Test-retest reliability assesses the stability of the valuations provided by individuals over a short period of time by using correlate readings with correlations higher than 0.80 (O'Connor, 1985).

#### *2.2.7.3 Empirical validity*

This issue relates to testing whether different methods yield similar or different results. Only a few studies that have sought to validate any of the three valuation techniques described here. Clarke and colleagues have reported moderate correlation between VAS and TTO or SG values in Gaucher disease (Clarke *et al,* 1997). Mean values, from TTO assessment in patients with breast cancer have also been found to correlate with the ranking ordering of health states (Ashby *et al,* 1994). There is also evidence that TTO and SG values

correlate reasonably (0.69) with one another when used with the EuroQol classification system in students (Krabbe et al., 1997).

Dolan and colleagues hypothesized that sicker individuals would provide lower values for poor health states and showed this in an empirical study using TTO and SG this holds even after controlling for sex, age, and employment status (Dolan *et al,* 1996).

## 2.3 ECONOMIC EVALUATION

The following sub-sections describe the different methodologies used in economic evaluation with examples of their application in the area of HIV/AIDS.

Economic evaluation provides the necessary information for decision makers in order to make a better informed decision into what to choose between competing health care interventions. It is concerned with identifying, measuring and valuing inputs (costs) and outputs (health related benefits) of programmes with the aim of determining whether these lead to a collective improvement in the welfare of individuals relative to the status quo (current practice) (Drummond *et al,* 1997).

It is important to recognise that economic evaluation only takes efficiency into account, as an ultimate, defined as the best use of resources in a given setting and under constrained conditions.

All types of economic evaluation studies identify, measure and value costs in the same terms, typically in monetary units (e.g. £s or $s) and differ in how benefits are measured. However, how the costs are expressed depends on the question and perspective of the costing analysis. The main types of costs are described below:

1. ***Full cost analysis*** includes the costs of all the resources employed in providing a given health intervention.
2. ***Average cost*** is the total cost per unit of output, which is calculated by dividing total costs by the number of units of output. This type of cost is primarily helpful for budgeting forecasts.
3. ***Marginal cost*** looks at the additional cost of producing one more unit of output. It is more illustrative than average costs since it will help a decision maker to decide, for example, to expand or not and by how much.

4. ***Incremental cost*** look at the additional costs of adding 'new' inputs for providing a new service within an existing organization infrastructure. This approach is appropriate when the new intervention is not the major overall cost structure driver (Creese and Parker, 1994).

While costs are an essential part of any economic evaluation, the focus of this thesis is on how health benefits are identified, valued and measured. Four types of studies can be differentiated, depending on the way benefits are measured: these are:

- Cost Minimisation Analysis (CMA)
- Cost Effectiveness Analysis (CEA)
- Cost Utility Analysis (CUA)
- Cost Benefit Analysis (CBA)

CMA compares therapies solely on the basis of their costs by implicitly assuming that the health benefits between the interventions are the same. CEA goes a step further and bases the comparison on a combination of costs and health benefits measured in natural units. In CUA health benefits are weighed using the effect of morbidity on the values that individuals attach to health outcomes relative to their own valuation of perfect health, and combining such weights with the amount of time spent in each state in an index of 'quality life'. CBA further refines this by transforming health benefits in terms of money according to the individuals' strength of preference, as expressed in the form of their willingness to pay for health benefits. Table 2.1 outlines how different types of economic evaluation studies differ with regard to the benefit measure and the way results are presented.

**Table 2.1 Economic Evaluation Studies**

| Type of economic evaluation | Measurement of outcome (health benefits) | Synthesis of costs and benefits |
|---|---|---|
| CMA | Assumed to be equivalent and can take any form (e.g. number of cases detected) | Additional costs of therapy A relative to B |
| CEA | One therapeutic goal is measured in similar natural units | Cost per life saved<br>Cost per patient cured |
| CUA | The valuation of health benefits are based on individual preferences across therapies | Cost per QALY gained<br>Cost per HYE gained |
| CBA | Measured in monetary units e.g., willingness to pay for a new programme | Benefit - cost ratio = benefits/costs |

### 2.3.1 Cost Minimisation Analysis (CMA)

Cost minimisation analysis is based on the assumption that the health benefit of two or more health care technologies being compared are equivalent and therefore the basis of comparison becomes costs alone. The decision rule used in CMA is:

> If drug X costs more than drug Y, yet is clinically equivalent, then drug Y should be chosen.

The justification often used for adopting a CMA framework is based on finding no statistically significant difference in health outcomes for two therapies. However, Altman and Bland explained that:

> *"By convention a P value greater than 5% (P>0.05) is called "not significant". This term wrongly implies that the study shows that there is no difference, whereas usually all that has been shown is an absence of evidence of a difference...the sample size of controlled trials is generally inadequate, with a consequent lack of power to detect real, and clinically worthwhile, differences in treatment...if there are data we should look for quantification of the association rather than just a P value" (Altman & Bland, 1995).*

In practice however, very few competing healthcare technologies are evaluated in studies that are powered to test for equivalence in health benefits. Unless the clinical trial on which the economic evaluation is based is set out to test the equivalence of the treatments in terms of costs and effects the use of CMA will be misleading (Briggs and O'Brien, 2001), and the simultaneous assessment of costs and health outcomes should be undertaken. If additional dimensions of benefits are considered important for evaluation, it is less likely that there will be evidence of equivalence between two or more competing therapies. Only where strong evidence exists that two therapies produce equivalent health outcomes across all relevant dimensions of health can CMA legitimately be employed. Box 2.2 below provides an example of the application of this methodology applied to HIV/AIDS.

**Box 2.2 Cost Minimisation Analysis (CMA)**

Fluconazole was compared to Amphotericin B for treating acute cryptococcal meningitis for patients living with HIV/AIDS in the UK. Since previous clinical trials reported no statistical significant difference in efficacy between the two drugs in AIDS patients, only costs of healthcare resource utilisation were compared. The costs included in the estimations were: medication, hospitalisation, monitoring and side effects. The results show that although the average cost of fluconazole is higher (£1270.5 vs. £448), the average costs associated with side effects and hospitalisation, are less than those associated with amphotericin for primary treatment (£5973.5 vs £12253.5). Using fluconazole would save between £4,000 and £14,000 in a year. Nevertheless, the authors recognised that direct comparison of patient management is not enough to make an informed decision about the cost consequences of alternative therapies, rather total cost of inclusive resource utilisation was necessary for influencing policy.

Buxton M J, Dubois D J, Turner R R, Schulpher M J, Robinson P A, Searcy C, 1991. Cost implications of alternative treatments for AIDS patient with cryptococcal meningitis. Comparison of fluconazole an amphotericin B-based therapies. *Journal of Infection*; **23**: 17-31.

### 2.3.2 Cost Effectiveness Analysis (CEA)

Cost effectiveness analysis compares different options aimed at achieving a common therapeutic goal. The distinctive characteristic of this type of study is that health benefits are measured in natural or 'physical' units; like re-infections avoided, additional patients cured, saved lives or life years gained. CEA tends to answer the specific question such as 'does drug A represent good value for money?', the answer to which depends on an affirmative response to: is there a single dimension of health outcome in terms of which the relative benefits of competing drug therapies may be measured?

The results of CEA studies are obtained by combining the benefits with the costs in a cost effectiveness ratio. These can be presented as average cost effectiveness ratios or as incremental cost effectiveness ratios:

a. Average cost effectiveness ratios express the cost per unit of benefit, independently of other treatments. Nevertheless, the use of average cost effectiveness ratios to decide between competitive strategies can lead to misleading results as they fail to acknowledge their mutually exclusive character.

b. Incremental cost effectiveness ratios (ICER), estimates the cost per unit of benefit of switching from one treatment to an alternative treatment option the extra cost per unit of extra outcome obtained with the alternative e.g. 'cost per infection avoided', or 'cost per cure' at a given point in time. Box 2.3 presents the formula for calculating ICERs.

**Box 2.3 Incremental Cost Effectiveness**

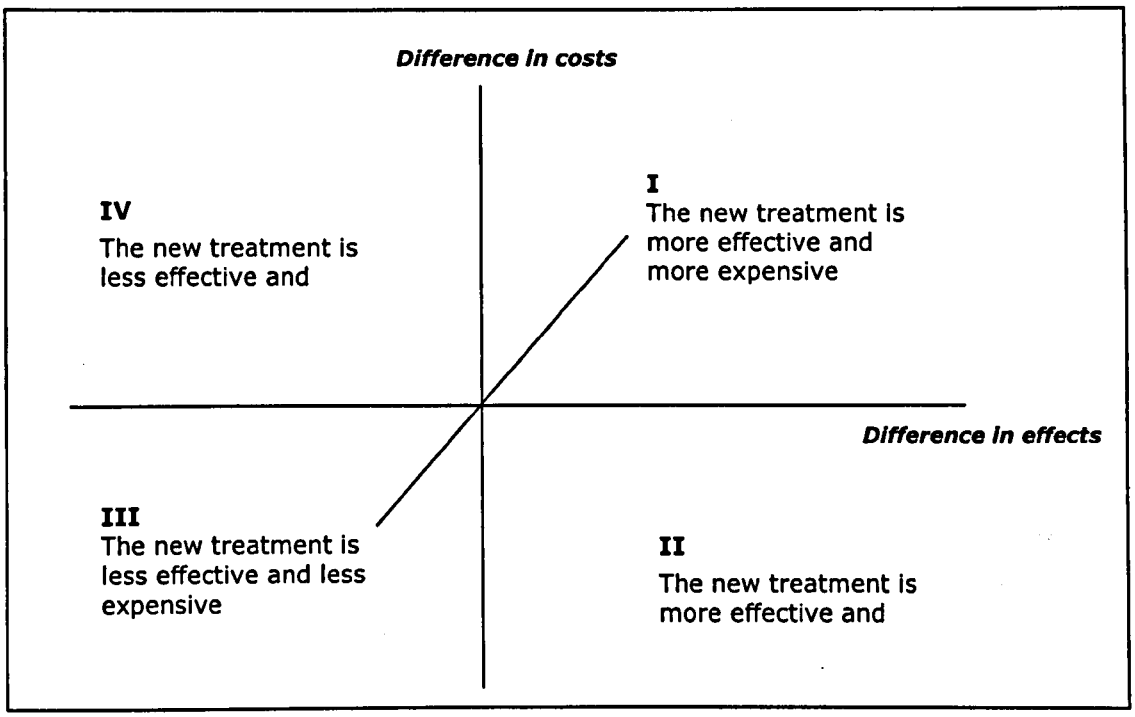
$$\text{Incremental Cost Effectiveness Ratio (ICER)} = \frac{\text{cost of drug A - cost of drug B}}{\text{benefit of drug A - benefit of drug B}}$$

$$= \frac{\text{differences in costs (A - B)}}{\text{differences in benefits (A - B)}}$$

Four qualitative results can be obtained from a cost-effectiveness analysis. These are displayed in figure 2.4 (Black, 1990). Firstly, if costs are lower and health benefits higher for one drug relative to another, the former is said to dominate and would be the preferred treatment (quadrant II). Secondly, if the new drug is more expensive and less effective, then is considered inferior and not recommended for introduction (quadrant IV). The third case is when the new drug is both more effective and more expensive than the standard (quadrant I). On the basis of ICERs, a judgement must be made about whether the additional benefits are worth the extra costs of the new drug and therefore, whether it is 'cost-effective'. In this case, a threshold ICER value is set by the policy makers to determine if it is a cost-effective option. The fourth case is similar to the third, with the roles of the new therapy and the standard reversed (quadrant III). The question now is whether the extra benefits provided by the standard treatment justify the additional costs of retaining it as the preferred treatment when an option of a new, cheaper but less effective, drug exists.

After identifying the most cost-effective treatment option, consideration must be given to the question of whether the preferred option is affordable. In fact, financial restrictions may mean that the best therapeutic option may not be implemented. This decision is in the hands of policy makers but this fact is sometimes ignored in cost-effectiveness analysis. Also it is important to note that if the most cost effective intervention has negative equity consequences this option might not be pursued.

**Figure 2.4 Cost-Effectiveness Plane**




Cost effectiveness analysis, is an easy method to use when comparing two competing mutually exclusive strategies. However, this simplification compromises the validity of the effectiveness measure. For example Randomised Control Trials (RCTs) may have follow-ups that fall short of the time period needed to capture clinically significant patient outcomes, so economic evaluation studies tend to use surrogates or markers, instead of proper effectiveness measures.

CEA studies have been implemented in evaluating different antiretroviral drugs, mother to child transmission strategies, voluntary counselling and testing services. Box 2.4 provides an example of a cost-effectiveness study in HIV/AIDS in South Africa.

**Box 2.4 Cost Effectiveness Analysis (CEA)**

The cost-effectiveness analysis of providing female vs. male condom was conducted in Mpumulanga Province in South Africa, for preventing HIV and STDs among commercial sex workers and their clients. The effectiveness measures were the number of HIV, syphilis and gonorrhea cases averted. Costs included the purchase price of the condom and the costs of promotion, education and marketing. Net cost, i.e., the costs of the female condom programme minus the potential costs of the government in treating syphilis, gonorrhea and HIV/AIDS cases averted were also estimated. Using a mathematical model of a hypothetical population of 1000 commercial sex workers, the results forecast that 6000 female condoms will be distributed at total cost of $4002 and will avert 5.9 HIV, 38 syphilis and 33 gonorrhea cases, which would save the public sector $12,090 in averted HIV/AIDS treatment costs, and $1,074 in averted syphilis and gonorrhea cases, giving a net benefit of $9163. The authors concluded that a well-designed female condom programme oriented to commercial sex workers and other women with casual partners was likely to be highly cost-effective and could save public sector funds in rural South Africa. However, the use of female condoms should be minimised since male condoms are cheaper (bulk purchase price $0.03 vs. $0.66 - South Africa Department of Health).

Marseille E, Kahn J G, Billinghurst K and Saba J, 2001. Cost-effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in rural South Africa. *Social Science and Medicine*; **52**:135-148.

### 2.3.3 Cost Utility Analysis (CUA), Quality Adjusted Life Years (QALYs), Healthy Years Equivalents (HYEs) and Disability Adjusted Life Years (DALYs)

Although in principle a CEA may be used to evaluate therapies designed to improve quality of life at a specific point in time e.g. at 6 months after the start of therapy, more often the relevant question resides in the trade-off between quantity and quality of life, and in these circumstances CEA is not suitable. This then leads to a broader, more general framework of evaluation, cost utility analysis.

#### *2.3.3.1 CUA*

Cost utility analysis, as mentioned before, attempts to combine preferences from individuals, either patients, general population or experts, by assessing the health benefit of the health care intervention in terms of their quality of life, which is then interpreted as quality of life weights, or utilities. In order to obtain weights an assessment of health states is required. A health state is defined as a set of statements that describe the health of an individual in terms of specific health domains; for example, physical functioning is captured by questions such

as: 'are you able to perform normal activities?', or 'are you suffering any pain or discomfort?'. Health states are then weighted using direct measurement (e.g. SG, TTO or VAS), by imputation from sources in the literature or expert opinion.

Once the weights for a set of health states are obtained these are transformed into a health measure by including a quantity of time into the measure. There are several methods that attempt to combine quality and quantity of life and integrate these aspects of health across health states and individuals. The best known of these methods is the QALY (Torrance, 1970; Culyer *et al,* 1971).

In the QALY approach, any health state of illness or disability is assigned a numerical score or 'utility' weight. QALYs are then calculated by aggregating the number of years gained from a drug or healthcare intervention, weighted by a proportion that represents the relative value attached to the health state that the patient happened to fall into at the time. In other words, the health benefit of any health care intervention using QALYs, is calculated as the product of the increase in utility that it may cause and the time in years over which it may be enjoyed. Therefore, to calculate QALYs, information about survival a description of the health states and the weights for health states (utilities) are needed.

The QALY calculation takes into account four characteristics: 1) the number of potential patients that would receive the treatment; 2) the probability of the treatment success; 3) the potential average survival gain if the treatment is successful and; 4) the gain of health related quality of life due to treatment success (Bryan *et al,* 2002). Results are presented as cost per QALY gained, or strictly speaking, incremental cost per QALY gained, thereby taking into account the costs and benefits of the competing interventions.

The survival time in the QALY is an unambiguous result, dichotomised between 'alive' and 'dead'. Though the extension of life can normally be considered a desirable outcome, survival where the patient is confined to bed and in constant pain provides very different levels of benefit per unit of time than survival where the patient is pain-free and experiences full mobility, which includes valuations where death might be preferable i.e., have a higher utility value than life living in pain.

Results from cost utility analysis are arranged in a QALY league table where different programmes are ranked according to their cost per QALY ratio; funds

should be allocated progressively to programmes on an ascending order of the marginal cost per QALY rank, until the available budget is exhausted. However, few countries have such league tables and, even attempts at using this approach in decision-making there are still serious ethical issues that limit its applicability (Kaplan, 1994).

Although from the economist's point of view the QALYs measure is based on a utility model, for the majority, particularly the users, QALYs are seen merely as an index of years of life adjusted for their quality. Gafni and Birch wrote that *"QALYs mean different things to different people"* (Gafni and Birch, 1997; p. 602).

An alternative to the QALY approach is the HYEs. Since preferences of an individual can be expressed as a utility function, health (defined as a series of health states over time) should be one of the variables in the utility function (Gafni and Birch, 1997). As explained by Mehrez and Gafni: *HYE is an attempt to reflect individuals' preferences over uncertain health profiles using one argument in their utility function (i.e. duration) holding health status constant (i.e. full health)* (Mehrez and Gafni, 1989).

HYEs approach differs from the QALY approach in that it measure all the different health states that an individual may experience as a result of a disease, instead of asking only about a limited subset of health states as in the QALY model. It has been argued that HYEs provides a more comprehensive spectrum for managers, practitioners, researchers and consumers and a 'user friendly' metric (Gafni and Birch, 1997). The HYEs differ from the assumptions used with QALYs, primarily from using SG with its decision framework rooted in the von Neumann J and Morgenstern O axioms of expected utility (Gafni *et al,* 1993). The only requisite of using HYEs is that preferences for a health profile be measured under conditions of uncertainty (Ben-Zion and Gafni, 1983). It is important to note that the HYEs requires the individuals to value all the potential lifetime health profiles; this aspect of the technique complicates its use, adding extra burden to the respondent and the interviewer (Mehrez and Gafni, 1991).

Another outcome measure that is often used to combine morbidity and mortality into a single index is the DALYs. Although this technique accounts for diminished quality of life from disability, its implicit valuation of morbidity is not based on individual preferences (Murray and Acharya, 1997). The rationale behind

measuring the global burden of disease and injury follows that behind health economic evaluation i.e., scarce resources and infinite health needs inevitably result in the need to make choices between health interventions. The use of DALYs was developed as a way of comparing the health needs of different countries, as a priority setting tool and for guiding research activities.

In the early 90s a study conducted by the World Bank, the World Health Organisation and a group of researchers from the Harvard School of Public Health was set up to quantify the global burden of disease for different geographical regions that will differentiate between age-ranges and sex (Murray and Lopez, 1996). The primary objective was to create an accurate measure for quantifying the burden of disease and injury (health needs) for the global population that could also be used for cost-effectiveness analysis.

Disability Adjusted Life Years (DALY) attempts to measure the difference between the actual health status of the population being evaluated with a specified reference health status, also called 'ideal'; DALYs are estimated by summing up the years of life lost and the years of life lived with disability (Murray and Acharya, 1997). Using the DALY approach each health state is given a disability weight that goes from zero (perfect health) to one (death), from values provided by a panel of experts (Murray and Lopez, 1996). The burden of a disease is calculated by the disability weight multiplied by the number of years lived in that health state added to the number of life years lost due to the specific disease (Murray and Lopez, 1996).

Four components are integrated into the DALY measure:

a) The length of time lost due to premature death at each age cut off point (calculation of the years of life lost)
b) The time lived at different ages (weighting functions to value the life at different ages according to social preferences)
c) Non-fatal health outcomes (the calculation of the years lived with disability weighted by a set of disability weights to reflect the severity of different disabilities)
d) Discount rate (discount the value of future health benefits)

Several important points should be made about the DALY approach:
The GBD uses the maximum life expectancy observed in the world i.e., the Japanese society (82.5 years for women and 80 for men). The rationale behind

using these numbers is that it is an 'equitable' way of accounting for all deaths at different ages to obtain the Global years of life lost to premature death, carrying the same weight irrespective of the country in the overall disease burden. The use of 82.5 years for women and 80 years for men is debatable, particularly in a country such as Malawi with a life expectancy of 39 years, is unhelpful and may mislead policy makers (Bowie, 1997).

Policy makers need to decide between investing in saving the life of a child, a young adult or an elderly individual. The standard expected years of life lost approach implies that a child has the opportunity to live more than a young adult; however a young adult may be in the more productive period of her/his life, the loss of which would be detrimental to the well-being of society as a whole. Using this principle higher weights are allocated to middle age individuals and lower values to newborns and elderly individuals.

Another issue to consider when using DALYs is that each country has its own health priorities and different resources to tackle them. DALYs results would be more meaningful for policy makers, although not comparable internationally if the life expectancy in the country or region under analysis was used rather than that of Japanese society.

Fox-Rushby and Hanson have also argued that the DALYs were not created as a tool for collecting data alongside randomised controlled trials or quasi experiments in health care interventions. This limits the use of DALYs in cost-effectiveness analysis since none of the disability weights can be differentiated between alternative health care interventions (Fox-Rushby and Hanson, 2001). In addition, DALYs overlook any non-health benefit of a given intervention and are not based on individual's perceived utility but rather are estimated on the best guesses of experts.

The comment by Williams is instructive in this case "*the use of life expectancy alone as an operational definition of health is a poor and a second best...we do not need measures of the Global Burden of Disease...resources devoted to calculating it should, in the interests of global health, be redirected into measuring the cost-effectiveness of particular activities*" (Williams, 1999; p. 2).

### 2.3.4 Cost Benefit Analysis (CBA)

The last of the methods used in economic evaluation is cost benefit analysis in which health outcomes are valued in the same unit as costs i.e. in monetary units. CBA has been used to evaluate therapies with outcomes that are difficult to measure with the conventional tools of CEA; a new health care service, for example. While CBA is a theoretically and politically appealing tool, there are obstacles to its implementation.

Valuing health outcomes according to individual preferences is considered the most theoretically sound approach for cost benefit analysis. There are three different approaches for measuring benefits within CBA. These are, firstly, the human capital approach; secondly, 'revealed preference' benefit measures and thirdly 'stated preference' measures. The major difference between these is that the last two reflect the preferences of individuals for health outcomes, whereas the first approach is based on the market value of work on such outcomes. These general approaches and their methods are described below.

#### *2.3.4.1 Human Capital Approach (HCA)*

This approach values the benefits of avoiding a premature death or disease by measuring the loss of productivity in work as a result of a negative event (Mishan, 1971; Mushkin, 1978). For a given individual whose life is spared, this technique imputes a benefit equal to the typical gross earnings accrued to people of the same age and sex over the years of life saved. In other words, the value of a saved life is equal to the earnings potential saved with it.

The role of HCA is mostly limited to serve as a rough lower boundary on the estimate of willingness to pay for therapies. While describing the costs to society of avoidable death or disabling disease, it fails to account for benefits other than those which are derived from the productive market activities lost to death or disabling disease.

#### *2.3.4.2 Revealed Preference (RP)*

This method infers the benefits of a transaction to an individual by observing the choices he or she makes in terms of risk and return when buying or selling goods or services in the market (Viscusi, 1978). A substantial amount of work on the value of a life has been conducted by analysing the occupational choices of individuals in relation to job characteristics such as pay and exposure to risks. Revealed preference uses regression analysis to control differences in socio-

demographic and geographical characteristics between individuals, and estimates the average rate at which individuals implicitly trade an increased risk of death while working for an additional salary. The difficulty in assessing the specific factors that influence people's choices and the practical inability to account for the value attached to the process of care itself, are the most important disadvantages of this method.

#### *2.3.4.2.1 Stated Preference - Contingent Valuation (CV)*

This method constructs a hypothetical market for the healthcare intervention in question by asking the participant to state the maximum amount of money he or she would be willing to pay for having the healthcare intervention, or the minimum amount acceptable in compensation for being denied access to it (Johannesson and Jönsson, 1991; Donaldson *et al,* 1997). CV allows the patient, carer on her/his behalf or even the general public to indicate the intensity of their preference through their willingness to pay (WTP) to obtain the therapy or, less commonly, their willingness to accept (WTA) compensation for not having it. The main weakness of CV is the difficulty in recreating a real life situation for the respondent to provide her willingness to pay for a particular intervention. Another methodological issue relates to the negative implications that the link between WTP and ability to pay has for basic notions of equity. This criticism, namely that it is unethical to base decisions on peoples expressed WTP as poor people's preferences will be attached a lower weight than those of a rich person, are easily addressed so that 'wealth effects' are removed at least to some extent (Donaldson and Shackley, 2003).

#### *2.3.4.2.2 Stated Preference (Conjoint Analysis)*

Another technique for deriving WTP values is using hypothetical questions to ask patients or individuals whether they would use a new drug with certain characteristics; such as the cost, side effects, effectiveness and frequency of drug dosing which are variables believed to influence patient preferences for treatment (Ratcliffe, 2000). The same individual is asked a series of similar questions where the values of such variables are changed and the resulting data for a sample of individuals analysed using regression analysis for discrete data e.g. logistic regression, to obtain mean WTP values for the sample. This has the advantage over the stated preference techniques previously discussed, that it can be extended to comparisons of more than two options. Thus instead of presenting the individual with an all or nothing option, a range of options are

presented for him to choose from, thus better resembling the market environment.

In HIV/AIDS examples of cost-benefit analysis are scarce. This can be explained by the complexity of putting a monetary value on a life and the fact that this type of study requires a large sample size and is expensive to conduct.

**Box 2.5 Cost Benefit Analysis (CBA)**

Cost recovery is applicable at public health centres either for consultation or for medicines throughout Kenya, including Voluntary Counselling and Testing (VCT) for HIV -health centres charged in 1998 an average of $1 per full VCT. An iterative payment card approach for estimating client's willingness to pay for VCT services was obtained from clients attending three health centres in Kenya. A total of 519 clients answered the WTP questionnaire. Almost 80% of them were willing and able to pay at least $2; 50% were willing to pay more than $6, and only less than 5% of the clients were willing to pay the full price of the service ($16 in integrated health facilities). Since willingness to pay is correlated with ability to pay, the authors asked the clients to identify the monthly expenditure by their families, as a proxy for income and found that the WTP figure given by the clients represented 10 to 20% of the median monthly expenditure. The authors conclude that some mixture of cost reduction, cost recovery and outside subsidies could make VCT an affordable and sustainable strategy for Kenya.

Forsythe S, Arthur G, Ngatia G, Mutemi R, Odhiambo J and Gilks C, 2002. Assessing the cost and willingness to pay for voluntary HIV counselling and testing in Kenya. *Health Policy and Planning;* **17**(2): 187-195.

## 2.4 SUMMARY

The debates around utility theory have concentrated from a measurement of happiness to the additional unit from pleasure or pain that a "good" or "a set of goods" provides. However, one of the most important considerations is whether utility is interpreted as cardinal or ordinal i.e. whether it is an ordering (ranking) of the bundle of goods or it measures the strength of preferences.

This debate has extended to the sub-discipline of health economics, where choices in health care are an unavoidable fact, and any attempt to reach an efficient resource allocation will benefit the welfare of any society, in the long run. The tools used in cost utility analysis which combines quality and quantity of life into a single utility index, are partly based on the foundations provided by utility theory. However, none of the tools is generally accepted as the gold standard. The discussion of the arguments in pro or against these measures is still ongoing. However, one of the main criticisms of these methods is the concentration of a composite measure into a single index.

Although QALYs might appeal to be the best option of health benefit measure available the fact that most resource poor settings lack QALY league tables to

compare interventions across different diseases limits its usefulness. Other outcome measures such as HYEs and DALYs have the disadvantage of being time consuming, costly for research purposes, not designed to be used in clinical and epidemiological studies and debatable how useful these tools are for resource allocation.

# CHAPTER 3

# LITERATURE REVIEW

*"Many tablets are given to us with the instruction to eat before take the tablets. There are times we do not have anything to eat and yet you need to take the medicine in order to keep living". Male participant.*

## 3.1 INTRODUCTION

This chapter has two purposes:

1) To summarise the findings of previous reviews on HRQoL instruments used in HIV/AIDS.
2) To identify and review empirical studies conducted in Africa in the area of HIV/AIDS that have assessed HRQoL.

The chapter is divided into six sections; section 3.2 summarises the findings of the reviews of HRQoL instruments used in HIV/AIDS. Section 3.3 describes the methodology used for reviewing the HRQoL African studies; section 3.4 discusses the key findings, identifies the gaps and limitations of existing research and section 3.5 concludes.

Quality of life has different connotations depending on individual interpretation, setting and discipline in which it is used. Some economists have attempted to measure quality of life at an aggregate level using per capita income as an indicator of individual welfare; although crude, this measure of quality of life has been used extensively (Theil, 1967). As mentioned in Chapter two, philosophers adopted a utilitarian view of quality of life, translating it into the level of happiness or satisfaction of desires or preferences (Bentham, 1789). Nevertheless, it is in social sciences where quality of life has been defined most extensively, ranging from the ability to live a 'normal life' (Fowlie and Berkeley, 1987) to *"a personal statement of the positive or negative attributes that characterize one's life"*, (Zautra and Goodhart, 1979).

Once health is introduced into the definition of quality of life the concept goes beyond the level of wealth or happiness, and quality of life turns into Health-Related Quality of Life (HRQoL), defined by Greer as the level at which the social, emotional and physical wellbeing of patients is affected by receiving treatment (Greer, 1984). This definition is in line with the one by the WHO presented in Chapter one.

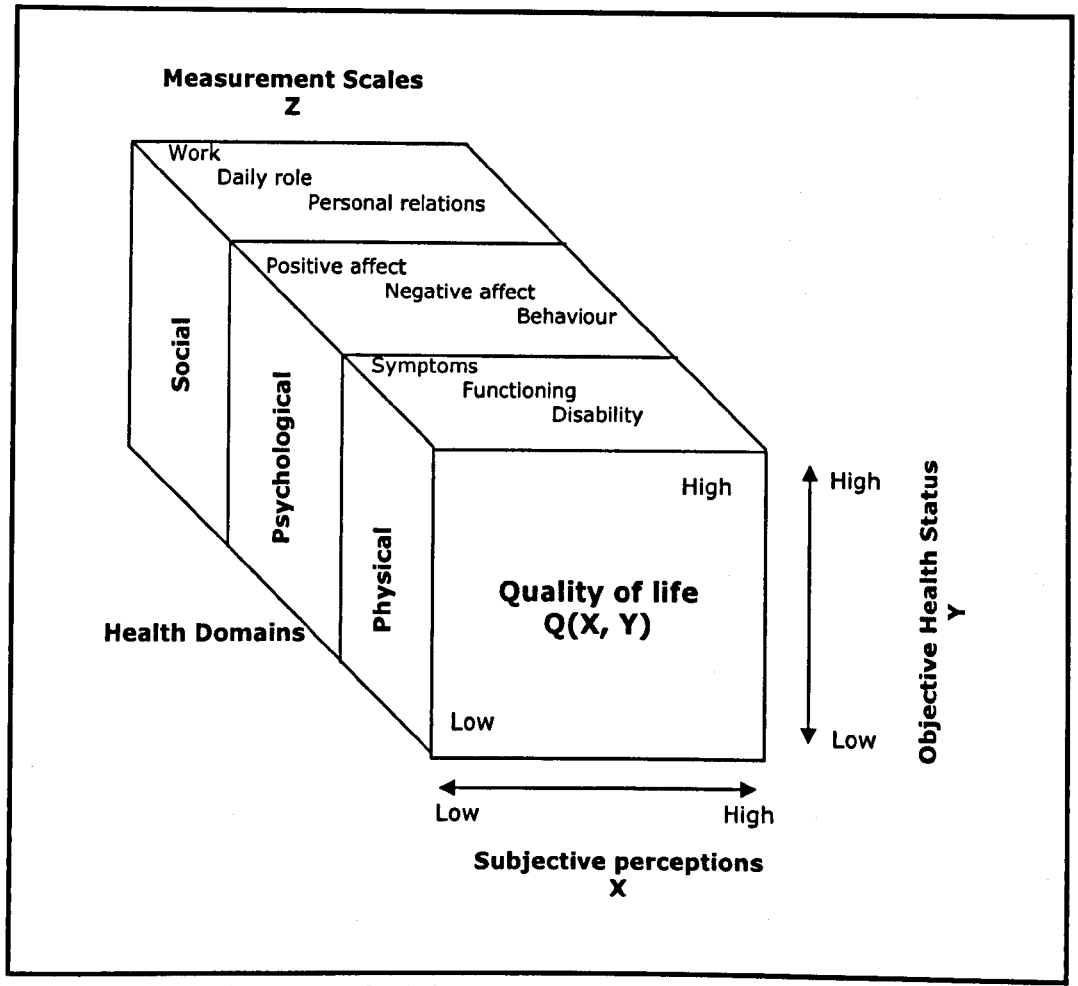
HRQoL attempts to assess the aspects of individual daily lives by defining health states, i.e., a system composed of statements of the potential impact of treatment or intervention and disease on domains such as symptoms, physical functioning, work, social activities, and mental well-being. HRQoL primarily focuses on the ability or inability to lead a fulfilling life (Bullinger *et al*, 1993).

HRQoL assessment seeks to understand the impact of disease not only by evaluating traditional clinical outcomes like mortality and adverse events, but to provide a more accurate spectrum of the treatment's effect. The advantage of HRQoL assessment is that it not only incorporates the positive impact of the treatment or intervention but also the negative one, thereby providing a net effect of the interventions being evaluated.

As a research field the assessment of HRQoL has evolved in the last 30 years with an increasing number of articles, areas of specialisation, specialised journals, conferences and disciplines involved such as psychometrics, social sciences, economics, psychology, etc. (Scientific Advisory Committee of the Medical Outcome Trust, 2002).

The HRQoL domains as explained by Testa and Simonson can be measured objectively through individual's health status (axis y in Figure 3.1) and subjectively by individual's perceptions and expectations of their health (axis x in Figure 3.1); the combination of both objective and subjective assessment of HRQoL constitutes Q in Figure 3.1, i.e. the HRQoL experienced (Testa and Simonson, 1996). As shown in Figure 3.1 each domain contains several components and each component can have in turn different levels, for example in the social domain an individual might be unable to work but at the same time able to perform some activities and daily living, making HRQoL multidimensional.

**Figure 3.1 Conceptual scheme of the domains and variables involved in Quality of Life assessment**




Source: Testa MA and Simonson DC. 1996. Assessment of Quality-of-Life Outcomes. *New England Journal of Medicine;* 334(13):835-840.

The working HRQoL definition adopted in this thesis is:

> *"Health-related quality of life refers to the people's subjective evaluations of the influences of their current health status on their ability to achieve and maintain a level of overall functioning that allows them to pursue life goals and that is reflected in their general well-being. The domains of functioning that are critical to HRQoL include: social, physical and cognitive functioning; mobility and self-care; and emotional well-being* (Shumaker *et al*, 1997; p. 476).

HRQoL has become one of the key elements for assessing health outcomes in clinical trials in industrialised countries. In 2006 the U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research introduced HRQoL into their guidelines for drug approval (FDA Guidelines, 2006). However, HRQoL assessment has been relatively underused in resource poor settings. A literature search on the topic in late 2003 identified only one study by O'Keefe

and Wood (1996), which measured HRQoL of HIV-infected individuals in South Africa.

The wider availability of antiretroviral treatment in resource poor settings, particularly in Africa, financed through international programmes (see Chapter two) such as 3 by 5, the President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFAMT), requires further understanding of the effects of treatment. This should include not only clinical indicators such as survival, CD4 cell count rises and decreasing viral load but also parameters that are measured by HRQoL questionnaires.

## 3.2 REVIEWS ON HRQoL INSTRUMENTS USED IN HIV/AIDS

HRQoL instruments are divided into generic tools i.e. a general description of dimensions that can be used with any population or disease and, disease specific instruments that cover those dimensions that are likely to be affected by the disease under investigation; the latter generally also includes a set of broad general questions of HRQoL. Generic tools are sub-divided in health profiles and quality of life indexes; the main difference is that quality of life *profiles* measure separately each dimension or domain of the health state under evaluation, and the quality of life *indexes* allow an overall valuation across dimensions for each health state i.e. integration of measures for different dimensions of a given health state into a single value (The EuroQol Group, 1990).

The first methodological review of the measurement of HRQoL within HIV infected populations was produced by Hays and Shapiro (Hays and Shapiro, 1992). To date a total of ten reviews (nine published and one unpublished) of both HRQoL generic instruments and HIV/AIDS specific instruments have been conducted (Hays & Shapiro, 1992; de Boer *et al,* 1995; Vanhems *et al,;* 1996; Wu(b) *et al,* 1997[1]; Franchi and Wenzel, 1998; Tsasis, 2000; Davis and Pathak, 2001[2]; Skevington & O'Connell, 2003; Clayson *et al,* 2006). This overview includes all of these and an unpublished review by Rofail and colleagues presented as a poster at the International Society of Quality of Life conference in October 2006 (Rofail *et al,* 2006).

[1] Wu and colleagues provided an extensive review on instruments based on the original MOS. These included the MOS-HIV Health Survey (MOS-HIV) (30-,34 and 35 item versions); SF-36; SF-12; SF-21 and SF-56 which are not discussed in this summary since only the SF-36 and MOS-HIV 35 item versions have been used in empirical studies since the cut-off date of the review by Wu and colleagues.

[2] Davison and colleagues included in their review HIV/AIDS HRQoL specific instruments only.

The review by Rofail and colleagues identified more HRQoL instruments than previous reviews - 15 generic and 11 HIV/AIDS specific HRQoL instruments (Rofail *et al*, 2006). Nevertheless, all the different instruments for each review were written down and the author of this thesis identified a total of 22 generic and 18 HIV/AIDS specific HRQoL instruments. It is important to note that the majority of reviews were based upon some form of the Medical Outcome Study Health Survey (MOS), either as the original questionnaire or any of the other short forms, i.e. SF-20 or SF-36 that include 20 and 36 items respectively.

The reviews evaluated each one of the instruments with respect to their psychometric properties, if available in empirical studies. These properties are similar to those used with TTO, SG and VAS as described in Chapter two. The most recurrent ones are:

- **Feasibility** i.e., the time taken to answer the questionnaire combined with the amount of missing answers.

- **Reliability**, divided into:
  - *Internal consistency reliability* that measures the consistency of answers provided by an individual for a given scale or sub-scale that has more than one item (question); it is usually expressed in terms of Cronbach's alpha coefficient (acceptable internal consistency reliability should preferably exceed 0.70) (Cronbach, 1951).
  - *Test-retest reliability* assesses whether an instrument yields the same answers over a short period of time (less than two weeks) with the same interviewee through Pearson correlation or Kappa statistic coefficients.

- **Validity** investigates whether an instrument actually measures what it claims to measure. In the reviews, primarily construct validity was documented. Construct validity applies if an instrument measures the underlying theoretical construct; this is assessed through the correlation with other instruments that have different constructs (divergent validity) or similar constructs (convergent validity).

- **Responsiveness** attempts to measure the ability of an instrument to detect small clinical changes over time (De Boer *et al,* 1995; Davis and Pathak, 2001; Clayson *et al,* 2006, Rofail *et al,* 2006).

This summary attempts to describe those instruments that have extensively reviewed, as well as to present their advantages and disadvantages.

### 3.2.1 Generic Instruments

The most popular instrument, in terms of number of reviews reporting its use was the Quality of Well-Being Scale (QWBS), followed by the EuroQoL 5-dimension Questionnaire (EQ-5D); the Quality Adjusted Time without Symptoms of Disease and Toxicity of Treatment (Q-Twist); the Medical Outcome Study Short Form (36 –item) Health Survey (SF-36); and the Spitzer's Quality of Life Index (SQLI). All the generic HRQoL instruments that have been used in HIV/AIDS are presented in Table 3.1 and are described below.

**Table 3.1 Health Related Quality of Life (HRQoL) generic instruments used in HIV/AIDS**

| Instrument | Hays & Shapiro, 1992 | de Boer *et al*, 1995 | Vanhems *et al*, 1996 | Wu *et al*, 1997 | Franchi & Wenzel 1998 | Tsasis, 2000 | Skevington & O'Connell, 2003 | Clayson *et al*, 2006 | Rofail *et al*, 2006 |
|---|---|---|---|---|---|---|---|---|---|
| COOP | | | | | | | | | • |
| EQ-5D | | | | • | | | • | • | • |
| Ferrans & Powers QLI | | | | | | | | | • |
| GHQ | | | | | | | | | • |
| GHSA | | | | | | | • | | |
| HUI | | | | | | | • | • | |
| IPQ | | | | | | | | | • |
| KPS Scale | | | • | | • | | | | |
| LASA | | | | | | | | | • |
| MHIQ | | | | | | | | | • |
| MOS | | | • | | • | | | | |
| MOS-SF | | • | | | | | | | |
| NHP | | | | | | • | | | • |
| Q-Twist | | | • | | • | | • | | |
| QWB | • | • | • | | • | • | • | | • |
| SDS | | | | | • | | | | |
| SF-20 | | | | • | | • | | | |
| SF-36 | | • | | • | | | • | • | • |
| SIP | | • | • | | • | | | | • |
| SQLI | | | • | | • | • | | | • |
| SWED-QUAL | | | | | | | | | • |
| WHOQOL-BREF | | | | | | | | | • |

COOP = Dartmouth Primary Care Cooperative Information Project Charts; EQ-5D = EuroQoL 5- dimension Questionnaire; Ferrans & Powers QLI = Ferrans and Powers Quality of Life Index; GHQ = General Health Questionnaire; GHSA = General Health Self Assessment; HUI= Health Utility Index; IPQ = Illness Perception Questionnaire; KPS Scale = Karfnosky Performance Status Scale; LASA= Linear Analogue Self-Assessment Scale; MOS = Medical Outcome Study Health Survey; MOS-SF = Medical Outcome Study Health Survey Short Form; MHIQ = McMaster Health Index Questionnaire; NHP = Nottingham Health Profile; Q-Twist = Quality Adjusted Time without Symptoms of Disease and Toxicity of Treatment; QWB = Quality of Well-Being; SDS = Symptom Distress Scale; SF-20 = Medical Outcome Study Short Form (20-item) Health Survey; SF-36 = Medical Outcome Study Short Form (36 -item) Health Survey; SIP = Sickness Impact Profile; SQLI = Spitzer's Quality of Life Index; SWED-QUAL = Swedish Health-Related Quality of Life Survey; WHOQOL-BREF = World Health Organization Quality of Life Brief Version.

**Quality of Well-Being Scale (QWBS)**

The QWBS attempts to summarise individual's health status into a single index that goes from 0 indicating death, to 1 complete well-being. Values obtained are then used to estimate QALYs (Kaplan and Anderson, 1988). It contains 50 questions and takes approximately 20 minutes to administer (Tsasis, 2000). It is based on a series of questions about symptoms and functioning at mobility, physical, and social levels and includes a couple of questions on mental health (Hays and Shapiro, 1992).

***Advantages***

The arguments in favour of using the QWBS refer to: 1) its practicality, since it transforms all the scores into a single index providing an overall impact of the treatment on the HRQoL of the individuals (Hays and Shapiro, 1992); 2) as a tool for decision making in public health (Vanhems *et al,* 1996); 3) flexibility by including issues around mortality, morbidity and costs, and for use in cost-effectiveness analysis (Skevington and O'Connell, 2003).

In addition, the QWBS has reported to discriminate HIV infected individuals that are seriously ill from those that are HIV asymptomatic (Copfer *et al,* 1996). Rofail and colleagues also reported that this instrument provided valid results (Rofail, *et al,* 2006).

***Disadvantages***

Hays and Shapiro recognised that the results obtained from QWBS are biased towards physical functioning and underweighted towards mental health (Hays and Shapiro, 1992). This issue is tackled again by de Boer and colleagues and by Tsasis making it explicit that the QWBS cannot be compared to other instruments given its lack of a psychological dimension (de Boer *et al,* 1995; Tsasis, 2000). Another drawback comes from the fact that the QWBS requires a trained interviewer making it of limited use in clinical trials and more costly to administer (Hays and Shapiro, 1992; Clayson *et al,* 2006). No evidence with respect to its performance in terms of its internal consistency or reliability of response was found (Rofail *et al,* 2006).

**EuroQoL 5-dimension Questionnaire (EQ-5D)**

The EuroQoL is a standardised non-specific multidimensional self completed questionnaire that describes and values health states, expressing results in a single index value of quality of life (The EuroQol Group, 1990). It is based on a

descriptive classification of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels 'no problem', 'some problem' and 'extreme problem'; death and unconscious health states are added creating a total of 245 health states for the evaluation.

The valuation system of the EuroQoL proceeds in four steps. First, participants are asked to choose for each dimension which statement best describes their own health state on the day. Secondly, participants self-rate their general level of health over the past 12 months i.e., better, much the same as or worse than today. Thirdly, using VAS, participants indicate how their own health state is today. Lastly, individuals are asked randomly to evaluate 16 health states.

The EQ-5D has been used to create a health status profile using the items that were reported with problems. This profile is then used to draw conclusions in terms of the proportion of the population with mobility problems or depression or to relate the mean value of the health states to gender, age and other variables.

For some European countries, including the UK, and USA, general population preferences weights have been obtained (Dolan, 1997; Shaw *et al,* 2005 and Kind 2003).

***Advantages***

The most recent reviews reported that this instrument has shown robust psychometric properties including good validity and responsiveness in several disease areas (Clayson *et al,* 2006; Rofail *et al,* 2006). In the area of HIV/AIDS Clayson and colleagues favoured this instrument since it correlates well with the MOS-HIV, and discriminates between HIV individuals with respect to their viral load and CD4 cell counts (Leplege *et al,* 1997; Delate and Coons, 2001)

***Disadvantages***

One of the drawbacks of EuroQol is the low response rate that is obtained from valuing death on the same scale as other health states (Skevington and O'Connell, 2003). This makes it less sensitive for the worst health states, thus skewing the results; Brazier and co-workers have expressed this problem in terms of ceiling effects[3] (Brazier *et al,* 1993). In addition, contrary to comments

[3] The term ceiling effect refers to the fact that data cannot take on a value higher than some "ceiling", while the opposite applies to floor effect.

by Clayson and colleagues, empirical results have shown poor sensitivity to clinical change (Wu(a) *et al,* 1997).

Wu and colleagues compared the results from the EuroQol and the MOS-HIV with advanced HIV patients (Wu(b) *et al,* 1997) and showed that the EuroQoL tends to underestimate the health status of HIV patients. The practicalities and drawbacks of using the EuroQol with this population were not discussed. No data on test-retest reliability has been found (Rofail *et al,* 2006)

**Quality Adjusted Time without Symptoms of Disease and Toxicity of Treatment (Q-Twist)**

This instrument combines the amount of time that patient's have with and/or without severe symptoms and relates the time to disease progression. It includes standard clinical measures and also side effects and toxicity levels that in turn facilitate to estimate patient's adjusted survival time with respect to the outcome (Skevington and O'Connell, 2003 and Franchi and Wenzel, 1998).

***Advantages***

Vanhems and colleagues claim Q-Twist's main advantage to be the ability to differentiate between medical health improvements including delaying symptoms and HRQoL reduction due to the drug's side effects (Vanhems *et al,* 1996).

**Disadvantages**

The Q-Twist is unable to identify which are the specific HRQoL dimensions affected in HIV infected individuals, making its results less sensitive for HIV infected individuals but also difficult to interpret (Franchi and Wenzel, 1998). No evidence of internal consistency or test-retest reliability or validity was found in the reviews (Vanhems *et al,* 1996; Franchi and Wenzel, 1998).

**Medical Outcomes Study Short Form (36 –item) Health Survey (SF-36)**

The Medical Outcomes Study (MOS) was a four-year observational study that identified 116 items as core indicators of quality of life. It sought to develop a user-friendly tool for monitoring patient outcomes in medical practice. This involved designing questionnaires that assessed dimensions such as physical limitations due to physical health problems, cognitive functioning, depression, anxiety, positive affect, feeling of belonging, role limitations due to emotional problems, energy/fatigue, sleep problems, symptoms, social activity limitations due to health, social functioning, role functioning, health distress and general

health problems (Bozzette *et al,* 1995). Although these instruments provide a comprehensive way of assessing health-related quality of life the number of items included represents a potential problem and a burden for patients that might be very sick.

The SF-36 is a shortened version self-administered questionnaire whose objective is to measure generic subjective health status. A total of eight dimensions are included within the 36 items: physical functioning (10 items), social functioning (2), role limitations due to physical problems (4), role limitations due to emotional problems (3), mental health (5), energy/vitality (4), pain (2) and general health perception (5) and a single item about perceptions of health changes over the past 12 months. The scoring system varies from 'yes/no' to a six point scale from 'none' to 'very severe'. The items are summed and then transformed into a scale from 0 (poor health) to 100 (good health). The results are reported as mean scores for each sub-scale, instead of as a frequency distribution (Hays *et al,* 1993).

***Advantages***

The SF-36 has good reliability, responsiveness and construct validity properties (Rofail *et al,* 2006). Ordonez and colleagues found high internal consistency of assessments that distinguishes patients with more severe immunodepression and might help in forecasting disease progression (Ordonez *et al,* 2001). In addition, changes in HRQoL correlate well with CD4 cell counts, T-cell counts and viral load (Carrieri *et al,* 2003; Saunders *et al,* 2002). This instrument can be widely used in different settings with multiple populations.

***Disadvantages***

SF-36 suffers from floor and ceiling effects for some subscales (Jenkinson, 1999). It also lacks sensitivity to significant changes in cognitive functioning in HIV infected individuals (Wu(b) *et al,* 1997).

**Spitzer's Quality of Life Index (SQLI)**

This instrument covers five dimensions: physical activity, daily (routine) activity, health perceptions, social and family support and future perception. It has been added to instruments that attempt to evaluate clinical status, depression, anxiety and social support. It attempts to assess the degree to which the functional status of a sick individual is affected by the disease. It takes approximately 10 minutes to administer.

***Advantages***

In empirical studies the SQLI has been found to be highly correlated with anxiety and depression in HIV infected individuals and an easy way to assess HRQoL (Williams and Rabkin, 1991).

***Disadvantages***

Rofail and colleagues noted that the SQLI or Spitzer Index has not been validated in terms of internal consistency, test-retest and only superficially in terms of its responsiveness. Tsasis reports variability of results with the SQLI when used repeatedly with the same population that raises questions about the reliability of the instrument (Rofail *et al,* 2006; Tsasis, 2000). Another disadvantage is the lack of discrimination between HIV asymptomatic patients and those with more advanced disease (Franchi and Wenzel, 1998).

### 3.2.2 Disease Specific tools

As mentioned before, disease specific instruments evaluate a series of health dimensions particular to a disease. The purpose of this sub-section is to briefly describe the more frequently used health-related quality of life instruments used in the human immunodeficiency virus research area.

The number of articles and reports that have used HRQoL measures has grown exponentially in recent years. In a recent bibliographic review of quality of life instruments published in 2002, 90(2.3%) of 3921 reports reviewed up until 2000 related to HIV/AIDS. The most common HRQoL tool was reported to be the Medical Outcome Study Health Survey for HIV/AIDS (MOS-HIV) 14(15.5%) (Garratt *et al,* 2002).

Table 3.2 presents those HIV/AIDS specific HRQoL instruments that were examined in the reviews from the previous section. It also includes the review by Davis and Pathak that only reviewed HIV/AIDS specific HRQoL instruments.

**Table 3.2 Health Related Quality of Life (HRQoL) HIV/AIDS specific instruments**

| Instrument | Hays & Shapiro, 1992 | de Boer *et al*, 1995 | Vanhems *et al*, 1996 | Wu *et al*, 1997 | Franchi & Wenzel 1998 | Tsasis 2000 | Davis and Pathak 2001 | Skevington & O'Connell, 2003 | Clayson *et al*, 2006 | Rofail *et al*, 2006 |
|---|---|---|---|---|---|---|---|---|---|---|
| ABCD | | | | | | | | | | • |
| ACTG-QoL | | | | | | | | | | • |
| AIDS-HAQ[4] | • | • | | | • | | • | • | | |
| FAHI | | | | | | | • | • | • | • |
| FQLS | | | • | | | • | | | | |
| GHSA | | | | | | | | • | • | • |
| HAT-QOL | | | | | | | • | • | • | • |
| HCSUS | | | | • | | | | | | • |
| HIV-PARSE | | | | • | | | • | | | |
| HIV-QL30 | | • | | | | | | | | |
| HIV-QL31 | | | | | | | • | • | | • |
| HIV-QoL | | | | | | | • | | | |
| HOPES | • | • | | | | • | • | • | | • |
| LWH | | | | | | | • | | • | |
| MOS-HIV | | • | • | • | • | | • | • | • | • |
| M-QOL | | | | | | • | | • | | |
| MQoL-HIV | | | | | | | | • | • | • |
| WHOQOL-HIV | | | | | | | | • | | |

ABCD = Assessment of Body Change and Distress; ACTG-QoL = AIDS Clinical Trials Group Quality of Life Questionnaire; AIDS-HAQ = AIDS-Health Assessment Questionnaire; FAHI = Functional Assessment of Human Immunodeficiency Virus Infection; FQLS = Fanning Quality of Life Scales; GHSA = General Health Self-Assessment; HAT-QOL = HIV/AIDS-Targeted Quality of Life Instrument; HCSUS = HIV/AIDS Cost and Service Utilization Study; HIV PARSE = HIV Patient Reported Status and Experience Survey; HIV-QL31 = HIV-Quality of Life Questionnaire 31; HIV-QoL = HIV Quality of Life; HOPES = HIV Overview Problems Evaluation System; LWH = Living with HIV; M-QOL = McGill QOL Questionnaire; MOS-HIV = Medical Outcomes Study Health Survey for HIV; MQOL-HIV = Multidimensional Quality of Life Questionnaire.

[4] The AIDS-Health Assessment Questionnaire (AIDS-HAQ) was used in the early 90s but information in terms of its psychometric properties have been reported in any of the reviews and was excluded in this summary.

The Medical Outcomes Study Health Survey for HIV (MOS-HIV) was included in almost all the reviews followed by the HIV Overview Problems Evaluation System (HOPES); the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI); the HIV/AIDS-Targeted Quality of Life Instrument (HAT-QOL); and the Multidimensional Quality of Life Questionnaire (MQOL-HIV).

**The MOS-HIV**

The MOS-HIV is an adaptation of the MOS to the hypothesized stages of health deterioration that can affect the person with HIV disease. The score system is based on a scale that goes from 0 to 100, with higher scores indicating better health. The recall period used is 4 weeks. This instrument has been widely used in clinical trials of people living with HIV and AIDS in the developed world. The MOS-HIV has been culturally adapted and translated to 14 languages (Wachtel *et al,* 1992; Wu *et al,* 1997 and 1991) with ongoing research in Thailand and India (Kemerer, 2003 personal communication). Instruments such as HIV Parse are further adaptations of the MOS questionnaire varying the items and dimensions included in the assessment.

The MOS-HIV questionnaire contains 35 items that evaluate aspects of functioning and well-being by including dimensions such as physical function, social and role function (work), cognitive function, pain, mental health, energy, distress about health, quality of life and overall health (Wu *et al,* 1991). The emphasis of this questionnaire is to assess the functional status of HIV infected individuals in a practical manner for use in clinical trials. Furthermore, this instrument has been administered to HIV positive and negative women that were enrolled in a maternal and child health community programme in Rakai District, Uganda (Mast *et al,* 2004). Although some dimensions were found not reliable, in general the authors conclude that the culturally adapted questionnaire might be an affordable way of assessing the impact of HIV/AIDS and treatment interventions on patients in rural Africa.

***Advantages***

This questionnaire is suitable for use in clinical trials when repeated measures are used (de Boer *et al,* 1995). In psychometric tests of reliability and internal consistency of multi-item subscales and validity, its performance has been found satisfactory (Wu *et al,* 1991; Burgess *et al,* 1993). The MOS-HIV has been able to capture clinical changes and differences between treatment groups in clinical trials (Revicki *et al,* 1995). It also has been able to distinguish between

asymptomatic HIV-infected patients and those at early stages of the disease (Wu *et al,* 1991). Franchi and Wenzel commented that since the MOS-HIV is derived from the generic MOS questionnaire, the dimensions chosen in the MOS-HIV comparison of the values obtained from HIV infected individuals with those from other chronic diseases (Franchi and Wenzel, 1998). MOS-HIV appears to be the only disease specific questionnaire that has included role functioning among their dimensions (Davis and Pathak, 2001). Another advantage is that this instrument has been translated into 14 languages (Wu *et al,* 1997)

***Disadvantages***

Wu and colleagues stated that physical, role and social functioning might tend to have ceiling effects when applying the instrument to healthy individuals, whereas opposite, floor effects might result in sicker populations in the role functioning dimension. It has also been suggested that the questionnaire would benefit from adding items that related to sex life, sleep and eating (Wu *et al,* 1997). Further, Scott-Lennox and colleagues found that the scores of dimensions did not correlate with CD4 cell count or viral load (Scott-Lennox *et al,* 1999; Badia *et al,* 1999).

**The HIV OVERVIEW OF PROBLEMS EVALUATION SYSTEM (HOPES)**

The HIV Overview of Problems Evaluation System (HOPES) measures quality of life and rehabilitation needs of HIV patients (Hays and Shapiro, 1992). It consists of 106-165 items that assess five dimensions translating into 33 sub-scales. Two of the major sub-scales are sexual interest and activities and, sexual functioning. In each sub-scale physical, psychological, social, medical interaction and partner relationship are evaluated (Schag *et al,* 1992).

***Advantages***

The values obtained from this instrument have been found to correlate with CD4 cell counts (de Boer, 1995). It has also been used with patients with chronic liver disease and found to have robust internal consistency but poor performance with the sexually related questions (Unal, 2001). In addition this questionnaire focuses on untangling the problems that HIV infected individuals faced (problem-orientated), and how these results 'ideally' might directly influence the patient's health care management. This questionnaire might prove a useful tool for research in a small group of patients at different WHO staging (Hays and Shapiro, 1992). It is one of the few instruments that include questions about body image, stigma and sexual functioning (Tsasis, 2000).

***Disadvantages***

All the questions included in this questionnaire try to assess problematic areas or how distressed the patient is. Therefore, the formulation has negative phrases that might influence the patient's responses (Hays and Shapiro, 1992). The length of this instrument impedes its use for repeated measures (Tsasis, 2000). In addition, test-retest reliability and validity have not been assessed (Davis and Pathak, 2001; Rofail *et al,* 2006).

**HIV/AIDS-Targeted Quality of Life (HAT-QoL)**

The purpose of HAT-QoL is to measure quality of life concerns in seropositive individuals. Its construction used qualitative research tools with HIV infected individuals to identify positive and negative issues that impacted on their health-related quality of life. It has 42 items and assesses nine dimensions of overall function – physical, role and social function components, sexual function, disclosure, health and financial worries, HIV mastery, life satisfaction, taking medication and relationship with a primary health care provider (Holmes and Shea, 1998).

***Advantages***

The items included in this instrument are those perceived as important by HIV positive individuals (Holmes and Shea, 1998).

***Disadvantages***

HAT-QoL is not as robust as MOS-HIV in terms of internal consistency and construct validity. The test-retest and responsiveness of this instrument has not been assessed (Rofail *et al,* 2006). Holmes and Shea recommend that in order to assess quality of life comprehensively this instrument should be combined with a generic HRQoL instrument, thus complicating its administration (Holmes and Shea, 1999).

**The Functional Assessment of Human Immunodeficiency virus infection (FAHI)**

The FAHI was derived from the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire. It consists of 55 items and includes the following dimensions: physical, functional, emotional, and global well-being. Items reflecting general, HIV specific and HIV treatment related aspects are included (Cella *et al,* 1996).

***Advantages***

This instrument has good internal consistency and (construct) validity and is easy to use in clinical trials (Peterman *et al,* 1997; Davis and Pathak, 2001). Clayson and colleagues reviewed the latest version of the FAHI (FAHI version 3), which displayed improved psychometric properties in relation to internal consistency, convergent validity, discriminant validity and responsiveness to change (Clayson *et al,* 2006).

***Disadvantages***

The 9 items related to the HIV sub-scale perform poorly and revisions to this sub-scale, possibly including additional items, would be necessary for its routine use (Skevington and O'Connell, 2003)

The last of the HIV/AIDS specific HRQoL instruments included in this summary is the WHOQOL-HIV. Although this questionnaire was included only in one of the reviews, it is relevant for the empirical purposes of this thesis since the Department of Mental Health at WHO advocates its role as the gold standard for measuring HRQoL in HIV infected individuals primarily in resource-poor settings.

**The WHOQOL-HIV Questionnaire**

The WHOQOL-HIV is based on the WHOQOL generic instrument in which the domains of physical and psychological health, level of independence, personal beliefs, and social relations are assessed. This cross-cultural instrument identifies integrative items and profiles specifically suitable for the assessment of QoL in HIV-infected patients; it goes a step further than most disease specific questionnaires since it includes a measure of the individual's perception of their position in life in the context of the culture and values systems in which they live in relation to their goals (WHOQOL Group, 1995).

***Advantages***

Skevington and O'Connell report that the WHOQOL-100 has shown acceptable internal reliability and discriminant validity and a difference between sick and better off individuals. O'Connell and colleagues report that the WHOQOL-HIV has been used in rural Zimbabwe with HIV infected individuals and shown to be feasible for use with less educated individuals (Skevington and O'Connell, 2003).

***Disadvantages***

This instrument has the disadvantage of being lengthy (120 questions) and difficult to handle for research purposes or repeated measures. A shortened version of this instrument is available but its psychometric properties have not been documented. Test-retest reliability has not been assessed in this instrument (Rofail *et al,* 2006).

## 3.3 LITERATURE REVIEW OF HRQoL STUDIES CONDUCTED IN AFRICA IN HIV/AIDS

### 3.3.1 Search strategy

A sequential search of the Cochrane Library (2001-2006) and Ovid MEDLINE (1966–2006) databases was performed. The Centre for Reviews and Dissemination[5] (CRD) database was also searched; this database holds the Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA) and the NHS Economic Evaluation Database (NHS OHE EED).

The following combination of terms was used[6]:

a) Quality of life **and** Africa Western or Africa South of the Sahara or Africa Central or Africa Northern or Africa or South Africa or Africa Eastern or Africa Southern **and** HIV infection or acquired immunodeficiency syndrome or aids-related opportunistic infections or HIV seropositivity.

b) Health status **and** Africa Western or Africa South of the Sahara or Africa Central or Africa Northern or Africa or South Africa or Africa Eastern or Africa Southern **and** HIV infection or acquired immunodeficiency syndrome or aids-related opportunistic infections or HIV seropositivity.

c) In addition separate searches were conducted for the following HRQoL instruments, QWBS, EQ-5D, Q-Twist, SF-36, SQLI, HAT-QoL, FAHI and WHOQOL-HIV **and** Africa Western or Africa South of the Sahara or Africa Central or Africa Northern or Africa or South Africa or Africa Eastern or Africa Southern **and** HIV infection or acquired immunodeficiency syndrome or AIDS-related opportunistic infections or HIV seropositivity.

[5] The CRD database only allows 3 keywords, the terms used were: HIV + Quality of Life + Africa; AIDS + Antiretroviral therapy + Africa.
[6] The terms quality of life or health related quality of life retrieved the same articles.

The Quality of Life Research Journal, Journal of AIDS, Social Science and Medicine Journal, the briefs of the annual conferences of the International Society for Quality of Life Research (ISOQOL), the books of abstracts of the International AIDS Conference and the International Conference of African STIs and AIDS were manually searched from 1997 to 2004. The additional references found were retrieved and articles reviewed.

### 3.3.2 Inclusion criteria

All the appropriate abstracts derived from these searches were screened and evaluated; the full articles of all the abstracts that were identified as relevant were retrieved if published. The articles were reviewed if:

a) The participants (adults > 18 years) were HIV infected
b) The study used either or both generic or HIV/AIDS specific HRQoL instruments
c) It was conducted in Africa

### 3.3.3 Results

The search in the Cochrane library shown three protocols but only one was for HIV infected adults, no further were details available to retrieve. The OVID MEDLINE database produced 26 references with search A, 14 with B and 5 with C[7] (see figure 3.1 below for further details). None of the searches conducted in the CRD database produced any reference. Although the journals and the conferences searched had numerous studies that included among their keywords 'quality of life + HIV/AIDS' few of them actually assessed it using any type of HRQoL questionnaire and when the abstracts were cross referenced with Africa several abstracts were found but only one article was retrieved[8]. All retrieved references were inputted to Reference Manager 10.

**Table 3.3 Search A**

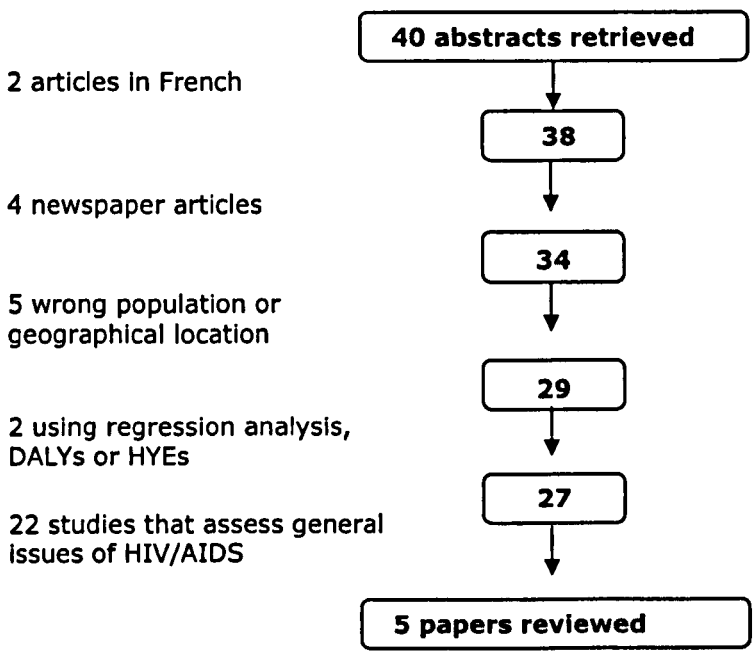
| # | Key word(s) | Results |
|---|---|---|
| 1 | Quality of life | 59263 |
| 2 | Africa, Western/ or Africa South of the Saharan/ or Africa Central/or Africa, Northern/OR Africa/ or Africa/ or South Africa/or Africa, Eastern/ or Africa Southern | 44557 |
| 3 | HIV infections/or acquired immunodeficiency syndrome/ or AIDS-related opportunistic infections/ or HIV seropositivity | 161102 |
| **4** | **Combine searches 1 and 2 and 3** | **26** |

[7] Search D produced 4 references, which are among those retrieved from Search A.
[8] The MOS-HIV has been used in an adult population of HIV infected individuals in Uganda by Mast *et al*; Stangl *et al* and Medina Lara *et al.* Results for the VAS and the MOS-HIV were presented as oral presentation at the ISOQOL conference, Portugal 2006, by Medina Lara *et al.* Only Mast and colleagues have published an article in 2004 (Mast et al, 2004).

**Table 3.4 Search B**

| # | Key word(s) | Results |
|---|---|---|
| 1 | Health status | 33225 |
| 2 | Africa, Western/ or Africa South of the Saharan/ or Africa Central/or Africa, Northern/OR Africa/ or Africa/ or South Africa/or Africa, Eastern/ or Africa Southern | 44557 |
| 3 | HIV infections/or acquired immunodeficiency syndrome/ or AIDS-related opportunistic infections/ or HIV seropositivity | 161102 |
| **4** | **Combine searches 1 and 2 and 3** | **11** |

**Figure 3.2 Abstracts retrieved and reasons for rejection**




### *3.3.3.1 Data extraction*

Tables 3.5 and 3.6 below present the data that were extracted from the studies reviewed.

| General information | Study design | Outcomes |
|---|---|---|
| • Author<br>• Journal<br>• Year of publication<br>• Country | • Population<br>• Intervention<br>• Name of HRQoL instrument<br>• Type of HRQoL instrument<br>• Cross-cultural adaptation | • Clinical outcomes<br>• HRQoL outcomes<br>• Utility values |

**Table 3.5 Articles retrieved**

| General information | Study design | Outcomes |
|---|---|---|
| O'Keefe and Wood, 1996<br>Quality of life Research<br>South Africa | HIV infected individuals and healthy non-medical participants<br>Medical Outcomes Survey (MOS) Afrikaans and Xhosa versions of SF-36<br>Generic instrument | Clinical outcomes not included<br>HIV-infection impacts early on all aspects of quality of life<br>Utility values were not derived from the SF-36 |
| Hughes *et al*, 2004<br>Disability and Rehabilitation<br>South Africa | HIV infected beneficiaries from Medecins Sans Frontieres ART programme<br>Xhosa version of the EQ-5D (using Visual Analogue Scale)<br>Generic instrument | Clinical outcomes not included<br>The HRQoL of PLWA was reported compromised for those individuals in WHO stages 3 and 4<br>Utility values were not obtained since the study reported the proportion of levels within each dimension |
| Mast *et al*, 2004<br>AIDS Care<br>Uganda | HIV infected and HIV- women<br>Medical Outcomes Study Health Survey for HIV (MOS-HIV)<br>HIV/AIDS specific instrument | Clinical outcomes not included<br>There was significant difference in functional status and well-being in HIV-infected mothers compared to those mothers that were HIV un-infected<br>Utility values can not be obtained from the MOS-HIV |
| Jelsma *et al*, 2005<br>AIDS Care<br>South Africa | HIV infected individuals (WHO stages 3 and 4) n=117<br>Individuals were recruited in an ART programme<br>Xhosa version of the EQ-5D (using the Visual Analogue Scale)<br>Generic instrument | HAART can greatly improved the HRQoL of individuals<br>All domains reported as problematic were greater at baseline than at 12 months<br>The global rating of health status increased from 61.7 at baseline to 76.1 at 12 months<br>Utility values were not obtained since the study reported the proportion of levels within each dimension |
| Badri *et al*, 2006<br>Antiviral therapy<br>South Africa | HIV infected patients receiving ART enrolled at the Cape Town AIDS Cohort<br>Cost-effectiveness analysis estimating life-expectancy, lifetime costs, quality adjusted-life years, cost per QALY gained for initiating HAART at three CD4 cell count thresholds*<br>HRQoL instrument was not used<br>Type of HRQoL instrument **not applicable**<br>Cross-cultural adaptation **not applicable** | Mean life expectancy was 6.2, 18.8, 21.0 and 23.3 years; clinical benefits increased significantly with early therapy i.e., >350/microl<br>Discounted QALYs at 8% were 3.1, 6.2, 6.7 and 7.4 Clinical outcomes<br>HRQoL outcomes were not reported<br>Utility values were obtained from the UK population |

* The results presented in the outcome column related to the CD4 cell thresholds these are: <200/microl; 200-350/microl; and >350/microl.

Five studies in total were reviewed. All except one were conducted in South Africa. Two generic HRQoL instruments (Xhosa EQ-5D; Afrikaans and Xhosa SF-36) and one disease specific (MOS-HIV) were used. Three papers (Hughes *et al,* 2004, Jelsma *et al,* 2005 and Badri *et al,* 2006) included individuals receiving ART. O'Keefe and Wood, and Mast and colleagues included HIV+ not receiving ART and HIV- individuals; the authors aimed to assess the potential effect of race on HIV disease presentation (O'Keefe and Wood, 1996) and to assess the reliability, validity and feasibility of the MOS-HIV (Mast *et al,* 2004).

O'Keefe and Wood used the SF-36 and test-retested its reliability seven days after the interview in a control group of 16 healthy Afrikaans and 14 healthy Xhosa participants; where the dimensions of vitality, mental and general health performed poorly. Feasibility and internal consistency reliability were not reported. The SF-36 was able to discriminate between healthy and HIV infected individuals. The authors concluded that HIV-infection has an impact on all aspects of quality of life even at early stages of the disease. The authors also found that the impact of race and gender on the quality of life of HIV infected individuals is negligible but that it plays an important role on that of healthy individuals (O'Keefe and Wood, 1996).

Hughes and colleagues used the Xhosa EQ-5D, previously validated by Jelsma and colleagues for individuals undergoing rehabilitation and those from a community control group (Jelsma *et al,* 2004)[9]. The authors reported good responsiveness but no further details were provided in terms of its ease to administer or missing answers. The Xhosa EQ-5D was able to discriminate between healthy and HIV infected individuals, with those from the latter group reporting lower values for all the dimensions in the Xhosa EQ-5D (Hughes *et al,* 2004).

Mast and colleagues used standard methods to culturally adjust the MOS-HIV[10]. The instrument took approximately 20 minutes to administer and was found to be feasible with less than 1% (5 answers to questions) missing. Internal consistency reliability was acceptable i.e., Cronbach's $\alpha$ of > 0.70 for five out of eight multi-item scales. The multi-item scales that were found unreliable were

[9] The EQ-5D was forward and backward translated by Xhosa speakers and presented to a lay panel for testing. Not surprising the authors found that some concepts included in the EQ-5D were difficult to transfer to Xhosa. They cautioned researchers about using questionnaires that have not undergone this type of adaptation process (Mkoka et al, 2003).

[10] For standard methods, Mast and colleagues referred to the process recommended by Bullinger and colleagues that allows retaining conceptual equivalence of questions instead of performing literal translations (Bullinger *et al,* 1998).

Cognitive functioning (0.69); Vitality (0.66) and Role functioning (0.51). The MOS-HIV was able to discriminate between mothers that were HIV-infected from those that were HIV-uninfected.

Jelsma and colleagues aimed to assess if HAART was an effective intervention for improving the HRQoL of HIV-infected individuals in WHO stages 3 and 4 by comparing the HRQoL values at baseline and at 12 months of receiving HAART. The results showed that the ranking for pain and discomfort, self-care, usual activities and anxiety/depression were better after 12 months of receiving HAART. The authors compared these HRQoL results with those from a community sample. This demonstrated that even after 12 months, the HRQoL of HIV-infected individuals remained lower than in community controls, although HIV infected individuals reported fewer problems than at baseline. Jelsma and colleagues concluded that it is important to assess the HRQoL of HIV infected individuals. The authors acknowledged that the EQ-5D might not be sensitive enough to capture changes in domains that are particularly important for HIV infected individuals such as sleep, stigma, sexual functioning and others (Jelsma *et al,* 2005).

The study of Badri and colleagues was not a HRQoL study but a Markov modelling for a cost-effectiveness analysis. The original data from O'Keefe and Wood obtained from the SF-36 was transformed into the SF-6D; this is a reduced version of the SF-36 constructed by Brazier and colleagues. The SF-6D has an associated tariff system from valuations of its health states profiles by a sample of the UK population using SG in order to transform these health states into QALYs (Brazier *et al,* 2002). Badri *et al,* used the transformed health states from South Africa but applied the valuation of the UK population based on the Standard Gamble (Badri *et al,* 2006).

**Table 3.6 Translation, cross-cultural adaptation and psychometric properties of HRQoL instruments used in Africa**

| Study | Translation and back translation | Cross-cultural adaptation through qualitative methods | Psychometric properties | |
|---|---|---|---|---|
| O'Keefe and Wood, 1996 | *Not reported* | *Not reported* | Feasibility | *Not reported* |
| | | | Internal consistency reliability | *Not reported* |
| | | | Test-retest reliability | *Reported* |
| | | | Validity | *Not reported* |
| | | | Responsiveness | *Reported* |
| Hughes *et al*, 2004 | *Reported* | *Not reported* | Feasibility | *Not reported* |
| | | | Internal consistency reliability | *Not reported* |
| | | | Test-retest reliability | *Not reported* |
| | | | Validity | *Not reported* |
| | | | Responsiveness | *Reported* |
| Mast *et al*, 2004 | *Reported* | *Reported* | Feasibility | *Reported* |
| | | | Internal consistency reliability | *Reported* |
| | | | Test-retest reliability | *Not reported* |
| | | | Validity | *Not reported* |
| | | | Responsiveness | *Reported* |
| Jelsma *et al*, 2005 | *Not reported* | *Not reported* | Feasibility | *Not reported* |
| | | | Internal consistency reliability | *Not reported* |
| | | | Test-retest reliability | *Not reported* |
| | | | Validity | *Not reported* |
| | | | Responsiveness | *Reported* |
| Badri *et al*, 2006 | *Not applicable* | *Not applicable* | Feasibility | *Not applicable* |
| | | | Internal consistency reliability | *Not applicable* |
| | | | Test-retest reliability | *Not applicable* |
| | | | Validity | *Not applicable* |
| | | | Responsiveness | *Not applicable* |

## 3.4 DISCUSSION

The conclusions of the reviews all highlight the same problem i.e., the lack of a gold standard in either generic or HIV/AIDS disease specific HRQoL instruments for using in routine HIV/AIDS assessment. Some of the authors support the idea of having a battery of HRQoL tools instead of using only one HRQoL questionnaire (Tsasis, 2000; Rofail *et al,* 2006). In addition, any choice should be guided by the psychometric properties of the tool (de Boer *et al,* 1995). Shumaker and Naughton also pointed out that any instrument used should be sensitive enough to capture HRQoL changes that are related to the effect of opportunistic infections (Shumaker *et al,* 1997).

The generic instruments favoured by the most recent reviews are the EQ-5D and the SF-36 *but in conjunction with* a disease specific HRQoL instrument (Clayson *et al,* 2006; Rofail *et al,* 2006). The disadvantages from using EQ-5D, is that it suffers from pronounced ceiling effect in relative healthy populations and would not be the best choice for trials involving asymptomatic HIV infected individuals. However, if used with a HIV/AIDS specific HRQoL instrument, EQ-5D might provide useful information when used in HIV-infected individuals with more advanced disease (Clayson *et al,* 2006). In comparison the SF-36 has been used more widely in HIV/AIDS than the EQ-5D and this may be the preferred option for some researchers (Clayson *et al,* 2006). However, both HRQoL instruments still lack of sexual and sleep scales that have been found to directly affect HIV-infected individuals (Vanhems *et al,* 1996).

In comparison Skevington and O'Connell argued that a generic instrument was only necessary if comparing the HRQoL of HIV-infected individuals with that of the general population (Skevington and O'Connell, 2003).

The MOS-HIV or the FAHI questionnaires appear to be the most suitable HIV/AIDS specific instruments, due to their brevity and psychometric properties (Clayson *et al,* 2006; Rofail *et al,* 2006). However, Clayson and colleagues were concerned with the current relevance of using the MOS-HIV since it was designed before the ART era and might not capture all the relevant dimensions that are affected by treatment, including among others sleep and sex (Clayson *et al,* 2006).

It is clear that no consensus exists and one might be unlikely to exist regarding the optimal HRQoL instrument. New HIV/AIDS specific instruments are being

currently developed that attempt to address the deficiencies of existing instruments (Personal communication Dr. Murri and Dr. Duracinsky[11]).

The review of the studies conducted in Africa has shown that there is a tendency to underestimate the usefulness of qualitative methods for cross-culturally adjusting HRQoL tools that have been designed in industrialised countries for their administration in resource poor settings. This is supported by Herdman and colleagues: "*Much of the research adopts an absolutist stance, whereby it is assumed that culture has only a negligible influence on the conception and expression of HRQoL*" (Herdman et al, 1997; p. 238). Only the article reported cross-cultural adaptation of the MOS-HIV although no further information was given (Mast *et al*, 2004).

The use of the Xhosa EQ-5D may not be appropriate for HIV infected individuals since potential deficiencies have been highlighted. Hughes et al, 2004 stated that the EQ-5D was chosen since it was available in Xhosa but stated that "*it is recognised that a more HIV specific instrument might be preferable as aspects of HRQoL which are specifically affected by HIV might be included. However, the translation and validation of such an instrument would take considerable time and, as the Medicines Sans Frontières (MSF) programme was already underway, there was an urgent need to initiate the study*" (Hughes *et al*, 2004; p. 372). Jelsma *et al*, 2005 also conclude that "*the EQ-5D has not been validated for use in people living with HIV/AIDS specifically*" (Jelsma *et al*, 2005; p. 586). So although the EQ-5D has been used with HIV infected individuals robust psychometric performance of this instrument has not been demonstrated for supporting its use.

The article by O'Keefe and Wood does not evaluate the SF-36 with respect to its psychometric properties and no further comment could be drawn from it. Also no further evidence was found in this or other settings in Africa that have used the SF-36 with HIV infected individuals.

## 3.5 CONCLUSIONS

This literature review aimed to identify appropriate instrument(s) for use with HIV infected individuals living in Uganda. Only three instruments have been used

[11] Both investigators have constructed disease specific questionnaires for HIV-infected individuals that consider those sub-scales and items that have been ignored in previous questionnaires. In addition, both claim that these questionnaires would be easy to use even in resource poor settings. The drawback is that these questionnaires have not been psychometrically tested and that it would be difficult to test their validity. Nevertheless, it is a promising and interesting route to pursue.

in Africa the SF-36, the Xhosa version of the EQ-5D and the Luganda version of the MOS-HIV (O'Keefe and Wood, 1996; Hughes et al, 2004; Jelsma *et al,* 2005 and Mast *et al,* 2004). However, only the SF-36 and the Luganda version of the MOS-HIV[12] were available at the start of the empirical study.

The evidence provided from O'Keefe and Wood was not sufficient to favour the SF-36 over the MOS-HIV and since the SF-36 and the MOS-HIV had both derived from the Medical Outcome Study (MOS) and share common subscales and items it would have been unwise to use the SF-36 and MOS-HIV questionnaires together. In the light of these issues the use of the Luganda version of the MOS-HIV was chosen as the preferred option.

Using the MOS-HIV alone would have provided limited information about the impact of ART in HIV infected individuals. The article by Bayoumi and Redelmeier proved influential in choosing to use the SG, TTO and VAS used in cost-utility analysis for obtaining 'utilities', as explained in Chapter two, as an alternative way for assessing the impact of ART in HIV infected individuals in Uganda (Bayoumi and Redelmeier, 1999). Since HIV infected individuals in the study are both receiving and not receiving ART, the Health States (HS) description for evaluation in the study included three predetermined HS for HIV/AIDS (symptomatic HIV infection, minor AIDS defining illness, and major AIDS defining illness) instead of generic ones.

The third instrument, the WHOQOL-HIV, was selected on the basis that it is an instrument that has been designed, modified and tested simultaneously in several different countries; that it proposes an iterative process for validation and recognises that cultural issues are context specific. It also "*takes the view that it is important to know how satisfied or bothered people are by important aspects of their life, and this interpretation will be a highly individual matter*" *(*Skevington *et al,* 2003; p.299*)*. This decision was also influenced by the fact that the author had the opportunity to meet with individuals from the Department of Mental Health and Substance Dependence of the World Health Organization in a WHO/UNAIDS workshop on strategic information for anti-retroviral therapy programmes in Geneva in 2003, in which the importance of HRQoL assessment was drawn to the attention of policy makers and the opportunity to use this instrument in Uganda was found suitable.

[12] The work by Mast and colleagues was identified through searching the abstracts of the International AIDS conference.

# CHAPTER 4

# METHODOLOGY

*"The source of all problems is poverty. Poverty! You look for men because you do not have food to feed your children or money to send them to school...you might desire to change your ways but poverty will push you to do wrong things. This happens when you cannot meet your needs and you are left with no alternatives". Female participant.*

## 4.1. INTRODUCTION

This chapter describes the methodology used for: 1) cross-cultural adaptation the Health-related quality of life (HRQoL) instruments; 2) the construction of Health States (HS) used with the Preference Elicitation Methods (PEM); 3) the pilot study; and 4) the construction and analysis of the asset index of living standards. It also describes how the longitudinal study was conducted.

## 4.2. STUDY SETTING

As mentioned in Chapter one, in order to test the research hypotheses on pages 8 & 9, a longitudinal study was set up in Entebbe, Uganda. A protocol was developed and ethical approval obtained from the Uganda Virus Research Institute Science and Ethics Committee (Reference No GC/127; approved 28th November 2003); the Uganda National Council for Science and Technology (Reference No MV842; approved 27th March 2004) and the Research Ethics Committee of the Liverpool School of Tropical Medicine (Reference No 03.60; Approved 4th December 2003)[1]. The study was then accepted as a sub-study by the DART trial Steering Group Committee and it was then integrated into the research activities of the Medical Research Council Unit on AIDS in Uganda.

The sub-study was implemented as a collaborative research activity under the direction of the Principal Investigator an author of this thesis Antonieta Medina Lara, who wrote the protocol, obtained the ethical approvals, designed the socio-economic and the asset of living standards questionnaires, initially designed the predetermined HIV/AIDS Health States, the Focus Group Discussions (FGDs) guidelines and the data collection forms and electronic entry databases and, managed the study and the staff involved in it. Barbara Nyanzi – Ugandan study coordinator - was responsible for translating and back-translating the survey tools, conducting the Focus Group Discussions and summarising the findings, conducting interviews, making alterations to tools by consensus with the author. Other staff from the MRC also conducted interviews, double entered the data, merged databases, transferred them into STATA 9 and sent them to Liverpool. The author of this thesis cleaned the databases and did all the analysis of the data. This study was funded by the HIV/AIDS & STI Knowledge Programme and Imperial College, London. The analyses and interpretation in Chapters five, six, seven and eight are strictly the author's and do not reflect the views of the MRC,

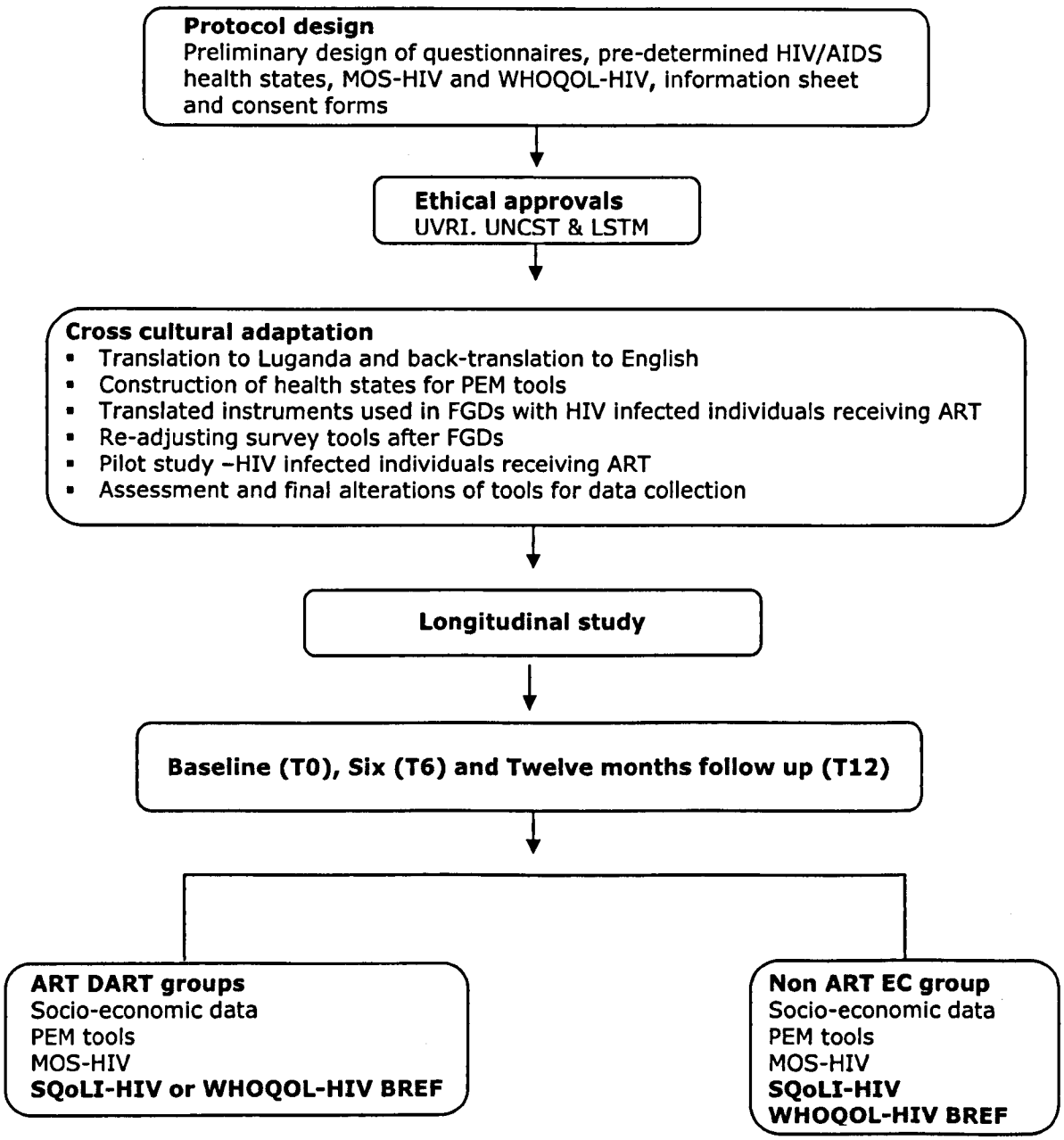
[1] The ethical approval letters were scanned and are provided in Appendix I.

the Entebbe Cohort, the DART trial nor the HIV/AIDS & STI Knowledge Programme.

The cross-cultural adaptation and the data collection for the study were conducted in Entebbe, Uganda, a town belonging to Mpigi district. According to the results from the 2002 census 613,081 inhabitants were living in this district; agriculture, and a low scale dairy farming and fishing are the main economic activities of the district.

Figure 4.1 below presents as a guide for the next sub-sections.

**Figure 4.1 HRQoL study structure**



## 4.3 PRELIMINARY SURVEY TOOLS

The conceptual and theoretical underpinnings of the HRQoL instruments used in the empirical research have already been described and explained in Chapters two and three. Here, the construction of the "asset of living standards index" (AOLS Index) and the socio-economic questionnaire will be explained in more detail.

### 4.3.1 Socio-economic questionnaire[2]

This questionnaire was designed to capture information on age, marital status, level of education, income, consumption and out of pocket costs. However, since the use of snapshots of reported income and consumption by participants in surveys for measuring individual's socio-economic status has been widely criticised (Montgomery *et al,* 2000), the socio-economic questionnaire also includes questions related to durable items owned by the individual. This had the objective of creating an AOLS Index that would allow comparison with the variable consumption reported by participants. The AOLS Index was constructed using the proxy method (ingredients approach) that relies on items possessed by the household as well as access to electricity, water, etc. The methodology used is the one proposed by the World Bank and is described in their series of technical notes for health equity analysis[3].

The construction of the asset index of living standards used principal component analysis which defines the asset index for individual *i* as:

$$A_i = \sum_k \left[ \frac{f_k (a_{ik} - a_k)}{s_k} \right]$$

where $a_{ik}$ is the value of asset k for household *i*, $a_k$ is the sample mean, and $s_k$ is the sample standard deviation.

Principal component analysis identifies the first component i.e., the component with the largest (Eigenvalue) the linear combination of variables (assets) that displays the highest variance within the sample. When principal component analysis is used to estimate the asset index of living standards the first component provides an adequate measure of welfare (Grosh and Glewwe, 1996). So the index is estimated by the sum of the included variables, weighted by the elements of the first eigenvector, the relative magnitudes of which provide insight

[2] Appendix IIa presents the complete socio-economic questionnaire.
[3] World Bank; Quantitative techniques for health equity analysis. Technical note #4

into those variables (assets) with the highest factor loadings (importance) for explaining welfare status within the household.

In addition, inequality between individuals in each group will be measured through the Gini coefficient for consumption and for the asset of living standards which is defined as:

$$G = \frac{2}{\mu n^2} \sum_{i=1}^{n} \left( r_i - \frac{n+1}{2} \right) c_i$$

Where *n* are the individuals indexed by *i*, household equivalent consumption is given by $c_i$ (in this case family expenditure), $\mu$ is the mean household equivalent consumption, $r_i$ is household *i*'s rank in the equivalent consumption ranking. The Gini coefficient is bound between 0 and 1, with 0 indicating absolute equality and 1 indicating absolute inequality (World Bank, 1993).

### 4.3.2 The Medical Outcome Study Health Survey for HIV (MOS-HIV)[4]

The MOS-HIV evaluates the different stages of health deterioration due to HIV. It consists of 35 items in which general health perceptions (5 items), physical functioning (6 items), role functioning (2 items), pain (2 items), social functioning (1 item), mental health (5 items), energy (4 items), health distress (4 items), cognitive functioning (4 items), quality of life (1 item) and health transition (1 item) are evaluated.

### 4.3.3 The World Health Organization Quality of Life Survey for HIV (WHOQOL-HIV)[5]

The WHOQOL-HIV questionnaire is based on the WHOQOL generic instrument in which the domains of physical and psychological health, level of independence, personal beliefs, and social relations are assessed. This instrument identifies integrative items and profiles specifically suitable for the assessment of QoL in HIV-infected patients; it goes a step further than the MOS-HIV by including the individual's perception of their position in life, in the context of the culture and values systems in which they live in relation to their goals (WHOQOL Group, 1995).

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[4] Written consent to use the MOS-HIV was obtained from Dr. Albert Wu at John Hopkins University, and Mr. T.C. Mast provided the Luganda version of the MOS-HIV. Both versions are presented in Appendix IIb.

[5] Formal permission to use the instrument was obtained from the WHOQOL Mental Health Department. This version is not presented in an appendix since this questionnaire was latter replaced by the WHOQOL-HIV BREF –For further details see section 4.4.3.

### 4.3.4 Preference elicitation methods (PEM)

The objective of using the preference elicitation tools was for obtaining direct valuation of health states and potential outcomes of the intervention according to the relative values that individuals place on morbidity (quality of life) and mortality (quantity of life). In order to obtain this index direct measurement was done through the administration of the Time Trade-Off (TTO), Standard Gamble (SG) and Visual Analogue Scale (VAS) for the three pre-determined HIV/AIDS health states. Direct measurement avoids potential subjective bias and is regarded as the most appropriate when empirical evidence is non-existent, as it is in this case (Torrance, 1986).

TTO evaluates respondent's willingness to trade-off time for an improved health state (Torrance, *et al;* 1972) while the SG assesses the level of risk that an individual is willing to incur in return for a better health state (Torrance, 1976; Furlong, *et al;* 1990). Visual Analogue Scale (VAS) is used so participants indicate how they were feeling at the time of the interview. In this study, it was also used for ordering and rating the predetermined health states for HIV/AIDS and as a warming up tool.

## 4.4 CROSS-CULTURAL ADAPTATION METHODOLOGY

The process of cross-cultural adaptation not only refers to the translation and back-translation of the questionnaires but how the translated instrument reflects idioms, social, cultural and day life activities and settings. A cross-cultural adapted questionnaire is also expected to have some equivalence with the original version in order to consider the results as valid (Guillemin, *et al*, 1993). The validity of the results obtained from the HRQoL tools would be tested by comparing the results presented in this thesis with those studies in developed countries; this is covered in Chapter six and seven.

The cross-cultural adaptation consisted of:

a. Translating the questionnaires to Luganda and then back-translating to English.
b. Constructing three predetermined health states for HIV/AIDS and an improved health state (IH).
c. Using the translated instruments in Focus Group Discussions (FGDs) to assess potential barriers to questions.

d. Re-adjusting the survey tools after the FGDs and testing them in a pilot study with HIV infected individuals enrolled in the DART trial that were already receiving antiretroviral therapy.
e. Evaluating the results and making final alterations to the tools for data collection purposes.

### 4.4.1 Translation and back-translation process

All survey tools were translated to Luganda and back translated to English. This was done first by an experienced social scientist that has worked previously in HIV/AIDS. The Luganda and English versions were then reviewed by two nurses and a counsellor working in the DART trial and by two lay individuals, who were asked to replace technical words by lay terms and to evaluate whether patients would be able to understand the questions. Only one of the nurses knew the objective of the study, since this was considered a way for obtaining more reliable substitution of words and comparison of wording. The social scientist took into consideration comments and the next version of the questionnaires was prepared.

The second Luganda - translated versions of the questionnaires were given to a professional translator to back translate them into English. Disagreements with words, idioms and cultural issues were resolved between the social scientist, the professional translator and the author of this thesis. These changes were shown again only to the nurses and the counsellor for their last comments and the final version of the HRQoL questionnaires was prepared for use in the FGDs.

### 4.4.2 Predetermined Health States for HIV/AIDS construction

Since study participants were recruited from the population of HIV infected individuals, three predetermined health states (HS) for HIV/AIDS were constructed for the study. The health states were not based on clinical diagnosis but on how well or poorly a person in the health state was able to function (Torrance, 1986).

The initial description of HS was derived from the article by Bayoumi and Redelmeier that considered HIV/AIDS progression and opportunistic infections that an HIV infected individual could face through their deteriorating condition (Bayoumi and Redelmeier, 1999). Three health states were constructed based on WHO stages 2, 3 and 4 for HIV infected individuals. These were named for data collection purposes as Symptomatic HIV (SHI); Minor AIDS defining illness

(MIADI) and Major AIDS defining illness (MAADI)[6]. Although ART may positively impact on an individual's quality of life, it does not cure, and, therefore, the reference for comparison of HS was 'improved health' state and not 'perfect health'. The improved health state was constructed to describe the major benefits as a consequence of individuals receiving antiretroviral therapy; this was used to compare with the pre-determined HIV/AIDS health states. All health states were assumed to last for 10 years only, after which the individual would die.

The HSs were intended to be as comprehensive as possible, including the level of physical functioning, the level of emotional functioning and the level of social functioning. Once constructed, the HSs were presented to clinicians working in the HIV/AIDS field at the Medical Research Unit for AIDS in Uganda and the Liverpool School of Tropical Medicine. Their comments were included and the final HS were prepared for the FGDs.

### 4.4.3 Focus Group Discussions (FGDs)[7] process

FGDs were used to assess the cultural barriers and problematic questions for each one of the survey tools and the health states; also they were used to address issues related to death, living with HIV/AIDS, knowledge of HIV/AIDS and antiretroviral therapy, perceptions of well-being and quality of life, etc. The qualitative research is not the subject of this thesis. Nevertheless the qualitative component helped to identify, design, refine and adapt the tools and the health states that were used for the longitudinal study. The qualitative research involved in the FGDs, was conducted by a social scientist and results are presented in a separate academic paper (Nyanzi Wakholi *et al,* forthcoming).

### 4.4.4 The pilot study and FGDs participants

Individuals who participated in the FGDs and pilot study were patients who had been enrolled in the DART trial and who had received ART for at least 10 weeks. The study was explained to patients and information sheets provided to all those that consented to participate in the FGDs and pilot study. Written consent was obtained from literate. For illiterate participants the consent was obtained through verbal consent and thumbprint (Consent and information sheets are provided in Appendix IV).

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[6] The formal definition of WHO staging is presented in Appendix IIIa, while the predetermined health states as used in the data collection are presented in Appendix IIIb and IIIc.
[7] The information sheet and consent form in English and Luganda for the FGDs and the Pilot study are presented in Appendix IV.

Over a period of one week, patients attending the DART clinic for follow up visits were invited to participate in a pilot study to calibrate the culturally adjusted HRQoL and the socio-economic questionnaires, and the HSs. The pilot study was used to pre-test the instruments and to probe if the individuals understood the questions. The instruments were then modified in the light of the pilot study results.

#### *4.4.4.1 Health States and PEM tools*

Individuals went through each one of the health states, the dimensions and the tools. Participants were prompted to ask as many questions as necessary and were asked if any of the tools were not understandable. For the VAS measure, participants were asked to rate how they were feeling at the time of interview by using a pointer against a yellow ruler of 100 cm (VAS) and the indicated value was transformed to a 0 to 1 value. Also participants ordered and ranked the three predetermined HIV/AIDS health states.

SG and TTO boards were used to facilitate the understanding of probability and trade off of time concepts to the participants for obtaining utilities. The SG board simultaneously displays the probabilities of two uncertain outcomes and one certain outcome associated with the two options presented to respondents. The board uses diagrams of common gambling-type wheels with colour coded pie-shaped segments representing the probabilities. While the TTO board also simultaneously presents two certain outcomes but one of them (the improved health state) with a pointer for changing the number of years[8].

## 4.5 LONGITUDINAL STUDY METHODOLOGY

### 4.5.1 Study population

Two groups of HIV infected individuals were recruited in the HRQoL sub-study. The first group was recruited from the Development of AntiRetroviral Therapy in Africa (DART) trial (ART DART group). The second group, were ART naïve HIV infected individuals from the Entebbe Cohort (comparator group, Non ART EC Group)[9].

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[8] Dr. Paul Kind, from the University of York provided TTO board as a loan. The chance board for SG was bought through the Centre for Health Economic and Policy Analysis from McMaster University in Canada and a wooden yellow ruler of one metre was utilized for VAS.

[9] The participants from the comparator group cannot be regarded as a genuine control group since they are likely to differ from the DART group with respect to disease stage and CD-4 cell counts at enrolment. Nevertheless, it is important to document the HRQoL changes overtime of these individuals since unexpected changes in the perception of HRQoL may occur that are not necessarily related to the use of ART.

DART is an open-label randomised trial evaluating the management of ART in symptomatic HIV infected adults in Uganda and Zimbabwe. The trial compares clinical monitoring only (CMO) with laboratory plus clinical monitoring (LCM). This trial is being conducted in three centres and one thousand patients have been recruited in each site; patients will be followed up for up to four years and will initially receive zidovudine (ZDV) and lamivudine (3TC) in combination (combivir) plus Tenofovir (TDF) or nevirapine (NPV). Second line therapies will be available for those who develop resistance.

The Entebbe Cohort[10] was established in 1995 in Entebbe, Uganda, as part of collaborative work of The AIDS Support Organisation (TASO) and the Medical Research Council (MRC) Unit on AIDS in Uganda. HIV infected individuals enrolled in the Entebbe cohort received general health examinations that include confirmatory HIV serology tests, CD4 counts, full blood count, blood slide for malaria, and Purified Protein Derivative test (PPD) on participants who have no past history or present diagnosis of TB, and are staged according to the WHO clinical staging system. Participants attend scheduled visits every six months and are encouraged to seek health care from TASO clinics between scheduled visits (interim visits) whenever ill.

The clinical endpoint of the trial will be progression to WHO HIV stage 4 or death (DART Protocol, 2002). However, the assessment of clinical efficacy alone disregards the intervention's impact on the quality of life of patients. The research in this thesis evaluates how the patient perceives the changes in his or her quality of life when receiving ART[11] and how their HRQoL differs from that of HIV infected individuals not receiving ART.

### 4.5.2 Recruitment process and data collection

Recruitment was conducted in Luganda (local language) by an experienced social scientist and a trained interviewer. To all participants, the study objectives were explained and written consent was sought (see Appendix V for information sheet and consent forms).

A total of 150 patients waiting to be seen by a counsellor, nurse or doctor at the DART clinic were invited to participate in the HRQoL study once enrolled in DART.

[10] Individuals from the Entebbe Cohort who had CD-4 cell counts below 200 and who fulfilled a set of other clinical eligibility criteria were recruited to the DART trial; although the DART trial population comprises also eligible patients from other sources.
[11] A sub-sample of DART patients from the Entebbe site only were recruited in this sub-study.

Once the ART DART group was recruited and its baseline HRQoL assessment was completed, 150 randomly selected patients who were registered at the TASO clinic were invited to participate in the study.

### 4.5.3 Changes in the study design

Although this is a methodological chapter it is important to clarify that the study design changed after the FGDs. The changes consisted of substituting the WHOQOL-HIV BREF for the WHOQOL-HIV from the battery of instruments and recruiting additional DART patients in order to answer the WHOQOL-HIV BREF[12].

The WHOQOL-HIV was an extremely difficult questionnaire to translate and to work with. It is 120 questions long and requires that individuals are asked in different ways about specific dimensions. This created confusion and frustration for the participants since they found the questions repetitive and intrusive. In some cases, English words did not have a synonym in Luganda; thus, the subtleties of the questionnaire were lost in the translation. For instance, 'Do you have any difficulties with sleeping?' was understood as being very similar to 'How much do any sleep problems worry you?', 'How satisfied are you with your sleep?', 'How important to you is a restful sleep?' and 'How well do you sleep?'.

However, some of the questions of the WHOQOL-HIV[13] were identified to be essential for a comprehensive assessment of HRQoL in HIV infected individuals. In order to avoid repetition, these questions were checked against the MOS-HIV. Those questions that were not covered by the MOS-HIV were included in a separate questionnaire that is named for data collection purposes as Specific Quality of Life Questionnaire for HIV (SQoLI-HIV)[14].

In the pilot study the SQoLI-HIV questionnaire was used to probe if the individuals understood the questions. This was achieved by randomly asking participants to explain what they meant with their answers.

Unfortunately, once data collection had almost finished for the DART participants, the WHOQOL group made available a brief version of the WHOQOL-HIV called the WHOQOL-HIV BREF. Although this version has overcome the problem of length it

[12] The English and Luganda versions are presented in Appendix VI.
[13] These included items such as social support, stigma, and uncertainties about dying and breaking generational lines, shame and blame, sleeping, among others.
[14] This questionnaire is presented in Appendix VII.

included only five questions related to HIV and left out important issues for individuals suffering from HIV/AIDS.

It was decided to recruit additional DART patients from which answers to the WHOQOL-HIV BREF were sought. Since the DART trial was at the last stages of recruitment only one-hundred and twenty one patients were recruited. This group answered the socio-economic questionnaire, the PEM tools, and the MOS-HIV and instead of answering the SQoLI-HIV these participants were administered the WHOQOL-HIV BREF. This was done in order to assess the performance of the WHOQOL-HIV BREF with respect to the SQOLI-HIV. From now on these groups will be differentiated as DART I and DART II groups. The Non ART EC group answered to both the WHOQOL-HIV BREF and SQOLI-HIV, in addition to the PEM tools, the MOS-HIV and the socio-economic questionnaire. For analysis purposes the data from ART DART I and ART DART II were analysed as one group except for the SQoLI-HIV and the WHOQOL-HIV BREF.

Since the WHOQOL-HIV BREF questionnaire was included after baseline data collection and was not piloted as the other instruments. Feedback on each one of the questions was gathered from the FGDs with respect to the WHOQOL-HIV, none of which was recognised as a problem.

### 4.5.4 Follow up

All interviews were conducted face-to-face in Luganda at baseline (before DART patients received ART) (T0), at six months (T6) and at twelve months (T12). Follow up interviews took place at the time the patients returned for follow-up visits at DART and TASO clinics. This was in coordination with nurses and counsellors at both clinics. The data collection started in February 2005 and lasted until end of May 2006.

### 4.5.5 Data entry

Data collection forms were standardised and double entered into ACCESS databases by trained data entry clerks at the MRC statistics unit in Entebbe. A statistician from the MRC was in charge of cleaning the databases and transferring them into STATA 9 before sending them to Antonieta Medina Lara at Liverpool for analysis. None of the questionnaires carried names of participants; instead, study numbers were used as personal identifiers. Data records were treated confidentially and only available to the staff directly concerned with this research.

### 4.5.6 Data analysis

Data analysis was performed using STATA 9. Statistical differences between groups were tested with:

a) T-test, for continuous variables

b) Fisher's exact test, for discrete (dichotomous) variables with relatively low or high proportions of positive observations

c) Chi-squared tests, for discrete variables, in multi-comparison analysis

The variability of continuous variables with a non-normal or skewed distribution, e.g. income, was described using inter-quartile ranges.

# CHAPTER 5

# RESULTS

*"Most employers are no longer interested in using HIV infected people. I have been working for a company that employs casual labourers. Once they discover that you are infected they chase you". Male participant.*

## 5.1 INTRODUCTION

This chapter presents the results from the FGDs, the pilot study, the main socio-demographic characteristics and the asset index of living standards results for those individuals that agreed to participate in the study

## 5.2 Focus Group Discussions (FGDs)[1]

The summary of the FGDs presented here only reflects the issues related to the perceived benefits and challenges of ART and those issues related to each one of the survey tools used in the study. A total of six FGDs were conducted in Luganda, three were with males (n=28), mean age 36 and three with females (n=26), mean age 35.

The benefits that participants reported with respect to ART were:

- Reduces disease symptoms
- Restores physical strength thus enhancing their mobility
- Enables them to resume usual activities
- Allows them to care for themselves
- Restores their self-esteem and hope
- Relieves them of depression and thoughts of death

Nevertheless the positive effect of ART on the participants was limited by stigma, taking pills and socio-economic constraints such as the lack of employment and inability to provide for basic needs like food and clothing for their families. Table 5.1 below presents the perceived changes and challenges of taking ART as perceived by the FGDs participants.

**Table 5.1 General Focus Group Discussions Findings**

| Positive changes | Perceived challenges |
|---|---|
| Improvement in physical health and appearance | Exposure to HIV status |
| Ability to embrace HIV status | Swallowing pills on empty tummy |
| Increased life expectancy | Coping with misconceptions about ART |
| Reliable treatment option | Uncertainty after DART trial ends |

*The medicine has done no harm to me, except for the hunger pangs that force me going to the kitchen every night to find something to eat. At one time, my brother in whose house I live found difficult (expensive) to cope with the situation so an uncle offered to bring food on a weekly basis.* **Female participant DART Trial**

[1] Barbara Nyanzi Wakholi conducted the qualitative part of this research. The information presented here has been discussed in great detail with her.

Interviewees felt that the socio-economic questionnaire was both easy to understand and easy to administer, no further comments were provided with respect to this questionnaire by the participants. However a number of issues need to be discussed concerning the HS and PEM tools, the MOS-HIV and the WHOQOL-HIV.

### 5.2.1 Health States

Three strategies were used for presenting the HSs to the participants:

1) Reading a description of the HS to the FGDs participants.
2) Use of photos to clarify the descriptions of HS read to FGDs participants.
3) Replacing photos by cartoons to clarify the descriptions of HS and reading each part of the HS to the participant.

Interviewers felt that using words alone did not allow them to engage with the participants. On the other hand, photos distressed participants and made them reluctant to answer. Cartoon aids were easy to understand and also helped to retain participant's attention, hence this was the final strategy for measuring HSs.

### 5.2.2 MOS-HIV

Even though the MOS-HIV was well accepted by participants, some issues with respect to specific questions came out in the FGDs. These are summarised below.

**Question 1:** "In general, how would you say your health is?"

The answer to this question did not only depend on the presence or absence of any clinical symptom but related also to the financial resources available to face any economic need, their physical appearance and the rejection suffered by their relatives and community. So if an individual was worried about monetary problems or felt rejected, this would have a negative impact on their health or at least would not allow them to be impartial with respect to reporting the absence of pain or any other physical discomfort.

**Question 3:** "During the past thirty days, how much did pain interfere with your normal work (or your normal activities, including work outside the home and housework)?"

Most of the patients reported suffering pain in the last 30 days. However, they learnt to deal with the pain and to carry on with their normal activities even if in pain. This appeared to be more common among female participants.

**Question 4:** "Does your health now limit you in the following activities? For example, the kinds or amounts of vigorous activities you can do like, digging, fetching water from a well, carrying a big bunch of matooke (bananas) ***or*** splitting firewood."

To this question some individuals answered that although they were able to fetch water from a well because it was within a short walking distance and they took a small pan, they were unable to split firewood. The questionnaire was designed for single answers eliminating the possibility of partial or multiple answers.

An additional finding throughout the questionnaires was that individuals from the Baganda background are uncomfortable talking about their emotions, in particular about sadness and depression. To express openly that you are feeling upset or depressed is to be considered within the tribes as emotionally weak, and singles out individuals as sick.

These problematic questions were modified and a culturally adjusted HRQoL questionnaire was tested in HIV infected individuals enrolled in DART; results were then used to finalise the HRQoL questionnaires. See below for results of the pilot study

## 5.3 PILOT STUDY RESULTS

A total of sixteen individuals between 31 and 42 years old participated in the pilot study; 56% of which were women, 40% were married, 50% stated that their highest level of education was primary school, 44% lived in urban areas and 38% lived in rural areas. Individuals were asked to state in which activity they spend most of their time: 'farming own garden', 'labouring and in business' and 'selling vegetables in the market' each had a 25% equal share.

### 5.3.1 Health States and PEM tools

VAS and TTO did not present any difficulty for the participants. SG proved more difficult to understand and for this, SG requires a careful explanation and

awareness from the interviewer. No further comments or revisions were added to this part of the study.

On average participants rated their own health as 0.45 (within a 0-1 range) using VAS. In 99% of the cases participants rated Major AIDS Defining Illness (MAADI) as the worst health state and Symptomatic HIV Infection (SHI) as the best health state. Minor AIDS Defining Illness (MIADI) was rated as intermediate.

### 5.3.2 MOS-HIV results

The administration of the MOS-HIV questionnaire lasted between 15 and 20 minutes, only one missing answer was recorded. Issues related to the MOS-HIV were with respect to: *large category response* (e.g., excellent, very good, good, fair and poor). Although this attempted to measure the severity of each limitation, it proved difficult to understand by the participants. For example, some questions had five to six ranks of severity: 'All of the time', 'Most of the time', 'A good bit of the time', 'Some of the time', 'A little of the time' and 'None of the time'. Participants understood the extreme values and the intermediate ones; however, 'a good bit of the time' and 'a little of the time', were difficult to understand for them. When the social scientist probed them to clarify this issue it was evident that the difficulty was an issue of language. There are no superlatives in Luganda and if an individual wants to refer to a superlative they would be adding the word more. For example, to the question: 'In general, would you say your health is: excellent, very good, good, fair or poor?' the Luganda answers are 'nungi nyo nyo', 'nungi nyo', 'nungi', 'bwetyo bwetyo' or 'mbi'.

The mental health dimension in the MOS-HIV questionnaire contains 5 questions and these were found difficult to answer by the individuals. This may be explained by the Buganda background which socially constricts the individual to appear to be well even if suffering physically, mentally or spiritually.

Another two questions that were found difficult to understand related to the cognitive functioning. Participants were concerned about the necessity of having to keep their attention in an activity (question 12c) and when asked if they had difficulties in concentrating and thinking (question 12d).

It was brought to the interviewer's attention that question 4 (see page 92) was often difficult to respond with a single answer since for example some of the participants reported that although they could bend they were unable to kneel, while other participants reported being able to kneel but not to bend.

## 5.4 LONGITUDINAL ANALYSIS OF SOCIO-DEMOGRAPHIC DATA

The socio-economic questionnaire was administered at baseline, six and twelve months[2]. The administration of this questionnaire lasted on average less than 10 minutes. An overview of the main socio-demographic characteristics for all the groups over the period of analysis is presented in Tables 5.2 to 5.8.

### 5.4.1 Socio-demographic data results at baseline

A total of 276 individuals were recruited from the DART trial and 159 from the Entebbe Cohort. The majority of the participants from both groups were females, 64% in the ART DART group and 76% in the Non ART EC group; this difference was statistically significant at conventional levels (Pr = 0.009).

The mean age of the participants was similar 36.5 and 36.6 for ART DART and Non ART EC groups. One participant from DART trial did not know her age.

Although lower levels of education were observed in the Non ART EC participants compared to the ART DART group participants, this was not statistically significant.

The groups differ with respect to marital status; ART DART participants were more likely to be married than the Non ART EC participants, and Non ART EC participants were more likely to be widowed than those in the ART DART group. This difference was statistically significant (Pr = 0.000). None of the groups reported any divorcee.

The average household size between the groups was similar i.e., 4.8 and 5.2 for ART DART and Non ART EC participants. Both groups reported a mean of four children that were currently economically dependent on them.

At baseline, ART DART had a higher proportion of individuals living in peri-urban areas whilst the majority of Non ART EC participants lived in rural areas; the

[2] The questionnaires are presented in Appendix IIa.

observed difference in terms of reported place of residence was statistically significant (Pr = 0.000). This might be a reflection on the recruitment criteria of the DART trial[3], which stipulated that those enrolled in the trial lived within a certain radius from Entebbe.

**Table 5.2 Baseline socio-demographic data**

| Variable | ART DART group | Non ART EC Group |
|---|---|---|
| Number of participants | 276 | 159 |
| Female (%) | 177 (64) | 122 (76) |
| Mean age (SD) | 36.5 (7.5) | 36.7 (9.1) |
| Level of education at primary or above (%) | 90 | 87 |
| *Marital status* (%) | | |
| Single | 10 | 9 |
| Married* | 35 | 18 |
| Living as married** | 1 | 13 |
| Separated | 28 | 23 |
| Widowed | 26 | 37 |
| Household size | 4.8 | 5.2 |
| *Place of residence* (%) | | |
| Rural | 10 | 65 |
| Peri-urban | 65 | 31 |
| Urban | 25 | 4 |

IQR Inter-quartile range.
*In this context married refers to a relationship established on the basis of a traditional, religious or government act that entitle the individuals to legal recognition and responsibilities.
**"Living as married" within the Ugandan society refers to a co-habiting relationship with no legal bond, this situation is recognised as less committed compared to that of married couples with the implicit idea that the two parties involved are not obliged to stick to one partner and can end the relationship allowing for polygamy and separation. Also either party can claim under legal grounds for requisition of care or maintenance from the other (Mukiza-Gapere, 1995).

Selling perishable goods at the local market was reported as the main activity by participants from both groups. Individuals were asked to report family expenditure and personal income in the last month; the ART DART and Non ART EC participants reported median family expenditure of 80,000 and 70,000 Uganda Shillings, i.e., $45 and $39[4], respectively. This implies a difference between ART DART participants and Non ART EC participants of 10,000 Uganda Shillings ($5.5).

[3] Although formal definitions of place of residence in Entebbe were sought in the Uganda Bureau of Statistics (UBOS) none was found. For study purposes 'urban areas' refers to planned and developed areas with road networks and infrastructure; 'peri-urban' describes areas occupied by shanty and temporary structures, with poor road, water and sanitation networks, often characterized by over populated households; finally, rural areas are sparsely settled places away from cities. The peri-urban areas within Entebbe are identified as slums Abaita ababiri and Kitoro, since these can not be defined as rural or urban areas.
[4] Uganda shillings were transformed to US$, using an exchange rate of 1798.89 Uganda Shillings per 1US$, applicable for 2005 and 1812.15 Ugandan Shillings for January to May 2006, obtained from the Bank of Uganda.

The median monthly income reported for ART DART and Non ART EC participants was 100,000 and 50,000 Uganda Shillings, i.e., $56 and $28, respectively. The difference between groups was 50,000 Uganda Shillings ($28); this difference was found to be statistically significant (P= 0.002).

The per capita family expenditure was estimated by dividing family expenditure by the number of people that lived in the household. The median monthly per capita family expenditure for ART DART participants was approximately 22,000 Uganda Shillings ($12) and 15,000 Uganda Shillings ($8) for Non ART EC participants (P = 0.002). In total 84% of the ART DART and 90% of the Non ART EC participants were under the official international poverty line defined by the World Bank in 1990 of $1 per capita per day (Ravallion *et al,* 1991; World Bank 1990).

Participants were asked about their job situation twelve months before their date of enrolment in the HRQoL study. In total, 58% of the ART DART group reported not having a paid job while only 29% did so among Non ART EC participants. The main reason for not having a job for both groups, was non-availability of employment in 109(67%) and in 32(70%) of the cases for ART DART and Non ART EC participants, respectively. Ill health was reported as the second reason in 20(13%) and 13(30%) of the cases for ART DART and Non ART EC participants, respectively. Other reasons reported by ART DART participants were attending Church, reading the Bible, resting at home but not ill.

Those that had a paid job twelve months before study entry reported mean monthly income of 80,000 Uganda Shillings ($45), and 60,000 Uganda Shillings ($33) for ART DART and Non ART EC participants, respectively.

**Table 5.3 Employment and income status at baseline**

| | ART DART Group n (%) | Non ART EC Group n (%) | Difference between ART DART & Non ART EC |
|---|---|---|---|
| Selling perishable goods as a main type of occupation | 57 (21) | 45 (28) | 0.07% |
| Working full-time No. (%) | 166 (60) | 112 (70) | 0.10% |
| Family expenditure Median (IQR) | n = 174<br>80,000<br>(40,000 - 180,000) | n = 115<br>70,000<br>(40,000 - 150,000) | 10,000 |
| Personal income last month Median (IQR) | n = 215<br>40,000<br>(0 - 157,000) | n =105<br>50,000<br>(20,000 - 120,000) | -10,000 |
| Per capita family expenditure per month Median (IQR) | 22,000<br>(10,000 - 40,000) | 15,000<br>(8,333 - 33,333) | 7,000* |
| Paid job twelve months ago No. (%) | 116 (42) | 114 (71) | 0.29% |
| Personal income twelve months ago Median (IQR) | n = 108<br>80,000<br>(40,000 - 150,000) | n = 98<br>60,000<br>(30,000 - 120,000) | 20,000 |

**P = 0.002

Participants received transport reimbursement but were asked to provide the amount of money spent on transport in order to attend their scheduled appointments at DART and TASO clinics; they were also asked to report missed work, lost wages, accompanying persons for clinic attendance, and the main occupation of their companion. This information is presented in Table 5.4 below.

The majority of DART and Entebbe participants (83% and 77%) used taxi[5] as a form of transportation. It took most participants between 10 minutes and less than an hour to reach the clinics. ART DART and Non ART participants spent on average $0.44 and $0.30 respectively for that purpose.

Almost 50% of the ART DART participants reported missing work in order to attend their appointment at the clinic from those reported as being in full-time employment, in comparison with 25% from those of the Non ART EC group. Less than 8% of both groups reported losing wages. Although the majority of

[5] Taxi which is also referred to as Matutu is a van that seats a maximum of fourteen people offering charged public transport, with charges depending on the length of the journey.

participants came on their own (90% ART DART and 97% Non ART EC), among those that were accompanied, the accompanying persons were the spouse, the participant's own children or friends that otherwise would have been primarily farming their own subsistence garden.

**Table 5.4 Out-of-pocket costs at baseline**

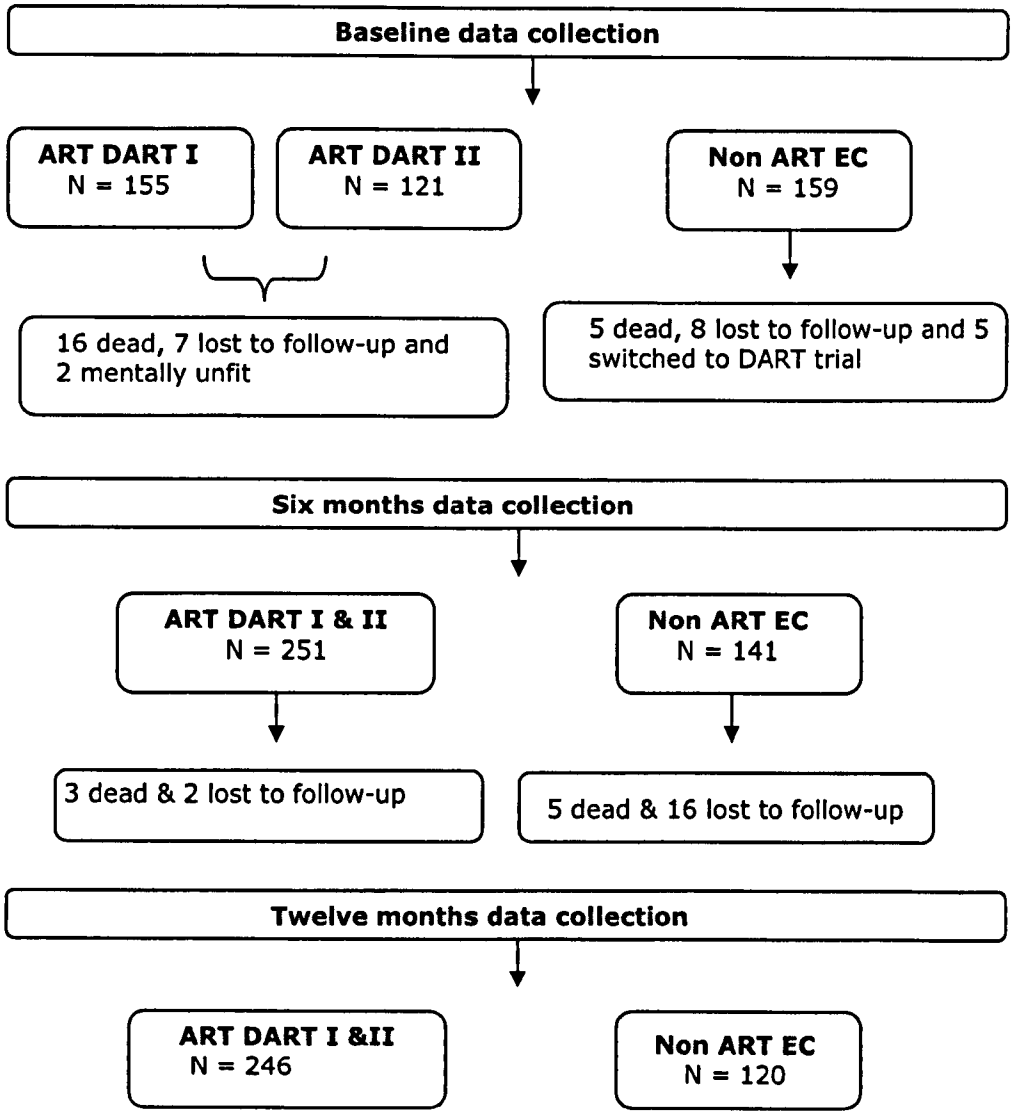
| | ART DART Group | Non ART EC Group |
|---|---|---|
| Taxi as a main mode of transport No. (%) | 229 (83) | 122 (77) |
| Median out-of-pocket costs for transport (IQR) | n = 250<br>800<br>(500 - 1,500) | n = 136<br>500<br>(500 - 1,100) |
| Mean length of trip > 10 min ≤ 1 hr (%) | 74 | 67 |
| Percentage of people missing work | 42 | 25 |
| Percentage of people losing wages for attending appointments | 9 | 6 |

### 5.4.2 Socio-demographic data results at six and twelve months

Over the period of one year, ART DART group had an overall death rate of 7% and a rate of loss to follow up of 5%. The overall Entebbe death rate was 6% and had a 15% rate of loss to follow up. Defaulters from the Non ART EC group were contacted and reasons for missing their appointment obtained. Reasons include: living outside Entebbe, feeling unwell, and considered unnecessary to attend their scheduled visit at TASO since they were feeling well. See Figure 5.1 provided below.

In the following pages results for six and twelve-month data will be presented with respect to those variables that changed relative to baseline. Family expenditure and personal income are analysed only for those individuals that have completed data at baseline, six and twelve months.

**Figure 5.1 Consort diagram**




### *5.4.2.1 Marital status*

Marital status was analysed for those participants with complete data for all the three interviews. Complete data were available for 245 participants from the ART DART group; of these 15(6%) participants lost their wives/husband and 54(22%) individuals had a new sexual partner. In comparison, complete data (n=117) for the Non ART EC group were available; of these 11(9%) lost their wives/husbands and 13(11%) changed their sexual partners.

### *5.4.2.2 Place of residence*

The proportion of individuals living in urban, peri-urban and rural areas changed over time and the difference between groups was statistically significant at baseline and six months (Table 5.2 only includes data for those individuals that

attended the three interviews). However, it is unclear whether the place of residence reported by participants was considered as temporary or permanent see Table 5.5 below.

**Table 5.5 Place of residence** - *at baseline, six and twelve months*

| Variable | ART DART Group N = 245 | Non ART EC Group N = 117 |
|---|---|---|
| **Baseline (%)*** | | |
| Rural | 9 | 63 |
| Peri-urban | 64 | 33 |
| Urban | 27 | 3 |
| **Six months (%)**** | | |
| Rural | 37 | 14 |
| Peri-urban | 44 | 36 |
| Urban | 19 | 50 |
| **Twelve months (%)** | | |
| Rural | 26 | 17 |
| Peri-urban | 17 | 21 |
| Urban | 57 | 62 |

*P = 0.0000; **P = 0.000

### *5.4.2.3 Family expenditure*

The data reported in Table 5.6 is for those participants that have completed data for the three periods. It appears that family expenditure remains constant over the period of one year for both groups.

**Table 5.6 Family expenditure** – *at baseline, six and twelve months*

| | ART DART Group N = 133 | Non ART EC Group N = 73 | Difference between groups |
|---|---|---|---|
| Baseline Median (IQR) | 84,000 (45,000 - 200,000) | 70,000 (49,000 - 150,000) | 14,000 |
| Six months Median (IQR) | 90,000 (40,000 - 150,000) | 70,000 (35,000 - 150,000) | 20,000 |
| Twelve months Median (IQR) | 80,000 (30,000 - 150,000) | 70,000 (30,000 - 150,000) | 10,000 |

### *5.4.2.4 Personal income*

Only those participants that reported completed data for the three interviews were reported in Table 5.7. At baseline the median personal income was 40,000 and 90,000 Uganda Shillings ($22 and $50) for ART DART and Non ART EC participants, respectively. The difference in median personal income between participants was 50,000 Uganda Shillings ($28) (P = 0.044). At six and twelve

months personal income except for Non ART EC participants at six months changed slightly ($20 and $28 and, $28 and $45 for six and twelve months for ART DART and Non ART EC participants, respectively) but no statistical difference was found between the groups or within groups over time.

**Table 5.7 Personal income** – *at baseline, six and twelve months*

| | ART DART Group N = 163 | Non ART EC Group N = 50 | Difference Between groups |
|---|---|---|---|
| Baseline Mean (IQR) | 40,000 (0 - 140,000) | 90,000 (30,000 - 150,000) | -50,000* |
| Six months Mean (IQR) | 35,000 (0 - 120,000) | 50,000 (30,000 - 148,000) | -15,000 |
| Twelve months Median (IQR) | 50,000 (0 - 140,000) | 80,000 (30,000 - 150,000) | -30,000 |

P = 0.044

Individuals were also asked to record the number of days that they were unable to work due to ill health in the last month. For those that were on paid employment, the average missed work days were 4 for ART DART participants and 5 for Non EC participants. ART DART and Non ART EC participants worked 26 hrs and 45.5 hrs in a week, respectively. The mean lost wages was 9,847 and 10,635 Ugandan Shillings ($5.5 and $5.9) for ART DART (n=65) and Non ART EC (n=37) participants, respectively. The mean difference between groups was 788 Uganda Shillings ($0.43). The average missing days at work was equal for both groups at twelve months to the figure reported at six months. The mean wage loss for those that were on paid employment per group at 12 months was also higher in the DART group, 10,063 ($5.6) and 12252 ($6.8) for ART DART (n=62) and Non ART EC (n=29) participants, respectively.

#### *5.4.2.5 Out- of- pocket costs*

At six months the percentage of participants attending appointments using Matutu as a transport increased; it also increased the length of time that it took to reach the clinic, an observation that might be related to the changes in place of residence occurring in the intervening period. The median out-of-pocket costs for transport were 800 and 850 Uganda Shillings ($0.44 and $0.50) for ART DART and Non ART EC groups, respectively. The median lost wages was equal 5,000 ($3). See Table 5.8 below for data at six months.

At twelve months the proportion of individuals using Matutu and the length of the trip were similar to those reported at six months. The median cost for transport at twelve months increased to 1000 Ugandan Shillings ($0.56) for both groups.

**Table 5.8 Out-of-pocket costs at six months**

| | ART DART Group | Non ART EC Group |
|---|---|---|
| Taxi as a main mode of transport No. (%) | 216 (87) | 102 (72) |
| Median out-of-pocket costs for transport (IQR) | N = 238<br>800<br>(500 - 1500) | N= 104<br>850<br>(500 - 1500) |
| Length of trip more than 10 min but less than 2 hrs (%) | 96 | 92 |
| Percentage of people missing work | 65 | 68 |
| Percentage of people losing wages for attending appointments | 40 | 34 |
| Median lost wages (IQR) | 5,000<br>(3,000 - 10,000) | 5,000<br>(3,000 - 10,000) |

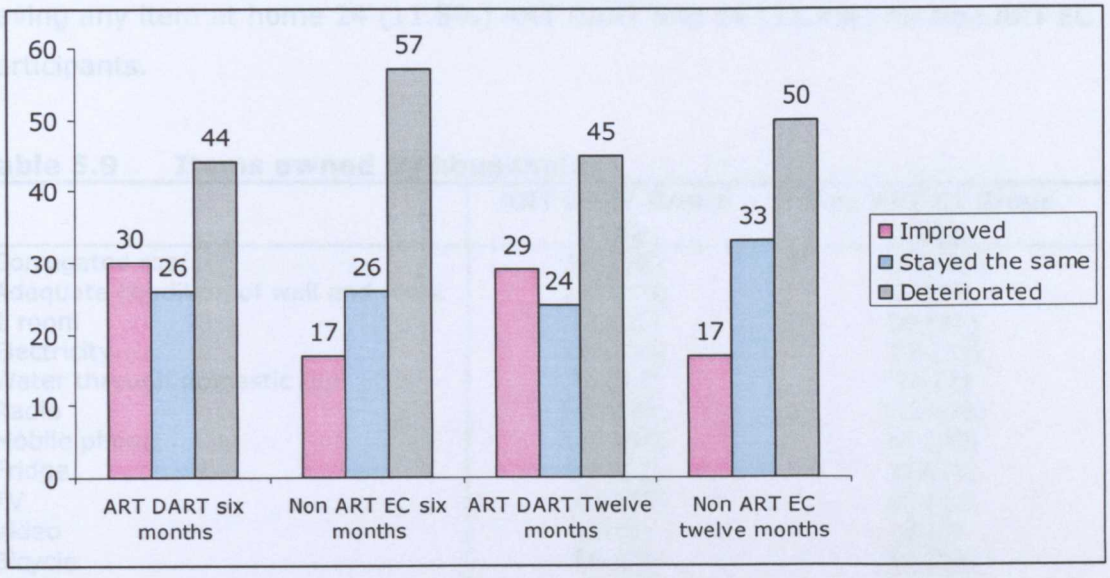
In addition, participants were asked to compare their perceived overall economic situation and perceived quality of life with baseline. Only participants with complete data for six and twelve months were analysed for both groups (n= 245 for ART DART group and n=117[6] for Non ART EC Group) in Graph 5.1 and 5.2 below. The majority, 44% and 57% for ART DART and Non ART EC participants, reported that their economic situation had deteriorated by six months, although in both groups quality of life had improved (86% and 84% for ART DART and Non ART participants). At twelve months participants were asked to compare their current overall economic situation with six months ago. There was deterioration in their overall economic situation in 45% and 50% of the cases, for ART and Non ART EC participants. By comparison, their quality of life further improved in 84% and 51% of the cases for ART DART and Non ART EC participants, respectively.

A test for association between perceived overall economic situation and quality of life reveals that quality of life is significantly associated with improved perceived overall economic situation in the ART DART group at both follow-up

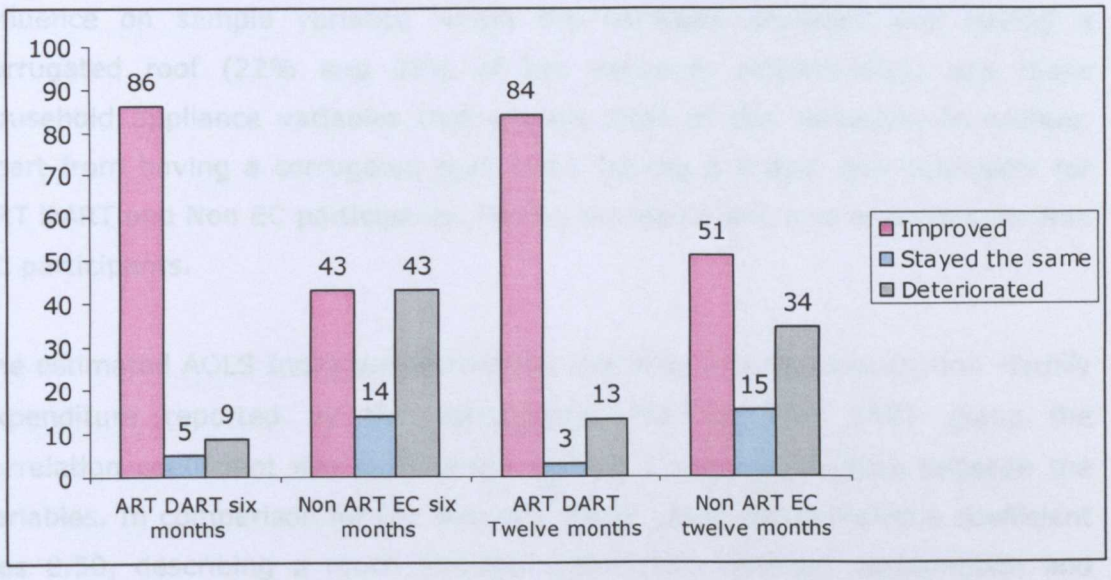
[6] Although 120 Non ART participants returned for twelve months follow up, three of those did not have six months data and were excluded for this analysis.

points. In the Non ART EC group a statistically significant positive trend was found only at six months[7].

**Graph 5.1 Overall economic situation** - at six and twelve months both groups




**Graph 5.2 Overall perceived quality of life** - at six and twelve months both groups




[7] A likelihood ratio test on the coefficient of the perceived quality of life variable in an ordered logit regression of perceived overall economic situation as a function of the former variable was used to test for this association, separately for each group and follow-up –see Tables 1 and 2 for ART DART Group and Table 3 and 4 for Non ART EC group in Appendix VIIIa for details.

### 5.4.3 Asset of living standards Index (AOLS Index)[8]

Table 5.9 presents the proportion of items owned by ART DART and Non ART EC participants. Non ART EC participants reported fewer items than those in the ART DART group (1.5 (IQR, 1 – 3) and 2.9 (IQR, 1 - 4)), respectively. This difference was statistical significant (p = 0.000). In both groups participants reported not having any item at home 24 (11.5%) ART DART and 14 (11.4%) for Non ART EC participants.

**Table 5.9 Items owned by households**

| | ART DART Group (%) | Non ART EC Group (%) |
|---|---|---|
| Corrugated roof | 261(95) | 147 (92) |
| Adequate condition of wall and roofs | 193 (70) | 72(47) |
| 1 room | 90 (33) | 60 (37) |
| Electricity | 150 (54) | 57 (36) |
| Water through domestic tap | 36 (13) | 11 (7) |
| Radio | 235 (85) | 125 (78) |
| Mobile phone | 127 (46) | 47 (29) |
| Fridge | 61 (22) | 18 (11) |
| TV | 106 (38) | 35 (22) |
| Video | 15 (5) | 8 (5) |
| Bicycle | 52 (19) | 32 (20) |
| Motorbike | 11 (4) | 3 (2) |
| Car | 20 (7) | 8 (5) |

For ART DART and Non ART EC participants the variable that has the highest influence on sample variance within the variables analysed was having a corrugated roof (22% and 29% of the variance, respectively); and those household appliance variables that explain most of the variability in welfare, apart from having a corrugated roof, were 'having a fridge' and 'television' for ART DART and Non EC participants. Having tap water was also important for Non EC participants.

The estimated AOLS Index was correlated with the variable consumption –family expenditure reported by the participants. For the ART DART group the correlation coefficient was 0.28 which reflects a weak correlation between the variables. In comparison for the Non ART DART group the correlation coefficient was 0.50, describing a much stronger association between consumption and wealth variables.

[8] Appendix VIIIb presents the principal component results for baseline (ART DART group p 228-230; Non ART EC group p. 230-234); six months (ART DART group p 235-236; Non ART EC group p. 237-238), and twelve months (ART DART group p 239-240; Non ART EC group p. 241-224), as well as gini coefficient estimations and Lorenz curves –although the curves were not illustrative of the differences between groups and are not discussed in this section.

The gini coefficient was calculated in order to describe the level of inequality in the groups. Then it was used to compare inequality across groups using as a measure of welfare family expenditure or, alternatively, the asset index of living standards. Both family expenditure and the asset index of living standards suggested a higher degree of inequality in the ART DART group than the Non ART EC Group; this difference was found significant at the 5% level (See Table 5.10 below).

**Table 5.10 Gini coefficients of inequality for the welfare measures**

| | ART DART Group | Non ART EC Group |
|---|---|---|
| Asset index of living standards<br>95% CI | 0.15<br>[0.1321, 0.1647] | 0.11<br>[0.0831, 0.1202] |
| Family expenditure<br>95% CI | 0.59<br>[0.5198, 0.6575] | 0.52<br>[0.4627, 0.5761] |

Note: Higher values denote greater inequality

#### *5.4.3.1 Results at six and twelve months*

There was no change in terms of 'having corrugated roof' as the variable that showed greatest effect on socio-economic variance for both groups at six and twelve months[9].

The correlation between the asset index of living standards and family expenditure continued to have a weak relationship (0.37 at six months; 0.34 at twelve months) for the ART DART group and also for the for Non ART EC group for which the relationship decreased over time to 0.40 (six months) and 0.34 (twelve months).

## 5.5 CONCLUSIONS

In summary the results of the pilot study showed that:

- The socio-economic questionnaire was well received, easy to understand and easy to administer.

- Individuals preferred cartoon aids to photos or text only for the predetermined HIV/AIDS health states.

[9] At twelve months individuals were asked if they own the mobile phone that they reported as an item within the household and also the type of radio that they had in the house.

- None of the preference elicitation methods (VAS, TTO and SG) present a major obstacle for data collection. No further problems were identified at this stage that would impede the use of these tools in the empirical study.

- The MOS-HIV was easy to understand and to administer.

- In terms of sample characteristics and behaviour:
  - Sexual partnership formation increased among patients on ART in the 12 month period of follow-up after enrolment.
  - The majority of participants in both groups reported an overall perceived improvement in QoL over 12 months.
  - However, participants in both groups perceived deterioration on their overall economic situation.

- The AOLS Index was constructed which may help in describing the welfare of participants particularly in the light of the proportion of cases with missing family expenditure data.

# CHAPTER 6

# PREFERENCE ELICITATION METHODS AND RESULTS

*"I was very sick and was taken back to the village. Believe me I was gone! All that was left to do was my burial. But when they see me today, they ask me what drugs I am taking and said to other people...have you not seen how good Kayibinji's daughter looks and yet she was once returned to the village to be buried." Female participant*

## 6.1 INTRODUCTION

This chapter has the objective of describing the results obtained from using preference elicitation methods in individuals receiving and not receiving antiretroviral therapy (ART DART and Non ART EC participants). Since utility values were not available for Uganda, direct measurement was used to assess the psychometric properties (see Chapter 2; section 2.2.7; p. 30) of using preference elicitation methods in a resource constrained setting and specifically with HIV-infected individuals.

The subsequent sections explain how the tools were used, the interview process, the methods for analysis; the last section presents the conclusions.

## 6.2 THE PREFERENCE ELICITATION TOOLS

Each one of the tools was explained in great detail before asking individuals to respond to the questions.

The extreme values used in this study were 0, for worst health state attainable, and 1, for best health state attainable. These were selected on the basis that a cure for HIV/AIDS has not been discovered so even when individuals receiving antiretroviral therapy benefit from the drugs they will not be cured and therefore will not recover their full health. Both the predetermined HIV/AIDS health states (Symptomatic HIV Infection (SHI); Minor AIDS Defining Illness (MIADI) and Major AIDS Defining Illness (MAADI)) and the pre-defined improved health state were assumed to last 10 years followed by death.

Participants were interviewed face-to-face in the local language (Luganda) and were asked to:

a. Rate his/her own health state using VAS;
b. Rank and evaluate three pre-determined HIV/AIDS hypothetical health states (SHI, MIADI and MAADI) with VAS;
c. Consider whether they would like to change their initial valuation and if so to provide their new valuation for own health state using VAS;
d. Evaluate the HIV/AIDS predetermined health states using TTO and SG relative to a pre-defined Improved Health State (IHS) using cartoon aids.

This interview process is explained in more detail below.

### 6.2.1 Visual Analogue Scale (VAS)

The interviewers used a yellow ruler of 100 cm and the description of the predetermined health states for HIV/AIDS with cartoon aids and text. Once the VAS was explained and time was given to the participants to ask for clarification, the participants were asked: 'how are you feeling today?' *(question 1)* and to give a value within the 100 cm range. Then the interviewer explained each one of the predetermined health states and participants were asked to rank from worst to best the hypothetical health states *(questions 2-4)*. Participants were then asked to value each health state according to their own valuation against the ruler and they were asked for the specific figure that they had in mind (*questions 5-7*). After this exercise, individuals were asked if they wanted to change their ranking for how they were feeling today, (*question 8*), for those that responded yes they were asked to provide their new value (*question 9*). Finally they were asked to provide a value to death (*question 10*)[1].

### 6.2.2 Time Trade-Off (TTO)

Individuals were asked to express the amount of time that they were willing to give up in order to have a pre-defined improved health state instead of being in each one of the predetermined HIV/AIDS health states. TTO values were obtained once the participant was indifferent between living in each predetermined HIV/AIDS health state for ten years and living in the pre-determined improved health state[2] for a reduced number of years.

### 6.2.3 Standard Gamble (SG)

The aim of the SG was to assess the level of risk that an individual was willing to incur in return for a better health state. The participants were faced with the choice between staying at a predetermined HIV/AIDS health state or taking a gamble (a hypothetical drug) with two possible outcomes: an improved health state with probability p or immediate painless death with probability 1-p (see Chapter 2; section 2.2.4; p. 25-27). The utility weight is then obtained by varying the level of risk (from extremes i.e., 95% then varied to 5%, 90% then varied to 10%, etc.) until the participant sees no difference in benefit to either option. Note that for both options the number of prospective life years was the same (10 years), after which the individual would die.

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[1] See Appendix IX for PEM response sheets in English and Luganda.
[2] Interviewer guidelines are presented in Appendix X. The guidelines were developed using as reference the Standard Gamble and TTO user manuals developed in 1994 by the Centre of Health Economics at the University of York.

By using TTO and SG, the greater the risk/time that the person is willing to take/give up in return for the better prospect offered by the treatment, the lower the value that the person attaches to the predetermined HIV/AIDS health state.

## 6.3 PSYCHOMETRIC PROPERTIES PERFORMANCE

Each instrument was evaluated with respect to its psychometric properties, i.e.:

### 6.3.1 Practicality or feasibility

This was assessed through the mean time of administration, the percentage of missing responses and ease of administration for interviewers and interviewees.

### 6.3.2 Reliability

An instrument is reliable if it produces consistent results on repeated administrations for the same subject population and under similar conditions. A sub-group of 20 individuals for each group were invited to return for a repeated interview after two weeks of their first interview[3]. Test-retest reliability was tested using Spearman's rank correlation coefficient.

### 6.3.3 Empirical validity

Also known as convergent validity, this assesses if different instruments yield similar results; this was tested through estimating the Spearman's rank correlation coefficient (ordinal data) between the instruments.

Construct validity was assessed through linear regression analysis to determine whether there was any relationship between the PEM values and: gender, age, CD4 cell counts or self-assessed health[4] (measured with VAS).

The psychometric performance was only analysed at baseline. However, an analysis of validity of the instruments, including baseline, six and twelve months assessments, is also presented. The analysis used a hierarchical two-level model with Gaussian normal distribution[5] to test for construct validity, separately for

[3] See Appendix XI for the information sheet and consent forms for the test-retest groups.
[4] Since the baseline construct validity analysis pooled data for the three pre-determined HIV/AIDS health states together, the covariates were interacted by binary indicators variables (dummies) to control for the three different pre-determined HIV/AIDS health states. Standard t-tests (linear model) or Walt tests (in the Gamma models) on the coefficients of the interactions were used to test for the hypothesis that the effect of the variable in question did not differ between groups.
[5] Although the data from the PEM tools are not normally distributed the use of an alternative distribution i.e., Gamma was not feasible due to the existence of zero values in TTO and VAS which are not supported by this distribution. The model specification used may be thought of as a linear approximation to the distribution underlying the data.

each PEM tool. The model specification was that of a variance component model[6] which accounts for the clustering of individual valuations (at baseline, six and twelve months; level 1) within individuals (level 2).

## 6.4 RESULTS

Table 6.1 presents the number of participants at baseline, six and twelve months that answered the PEM tools. The reasons given to refuse answering the PEM tools were: partial blindness; lack of time; language barrier; feeling distress; feeling unwell; incomprehension of the tools; and religion.

**Table 6.1 Number of participants answering the PEM tools**

| | ART DART Group Total recruited n = 276 | | | Non ART EC Group Total recruited n = 159 | | |
|---|---|---|---|---|---|---|
| | Total | PEM | Refused | Total | PEM | Refused |
| Baseline | 276 | 267 (97%) | 9 (3%) | 159 | 150 (94%) | 9 (6%) |
| Six months | 251 | 241 (96%) | 10 (4%) | 141 | 132 (94%) | 9 (6%) |
| Twelve months | 246 | 238 (97%) | 8 (3%) | 120 | 112 (93%) | 8 (7%) |

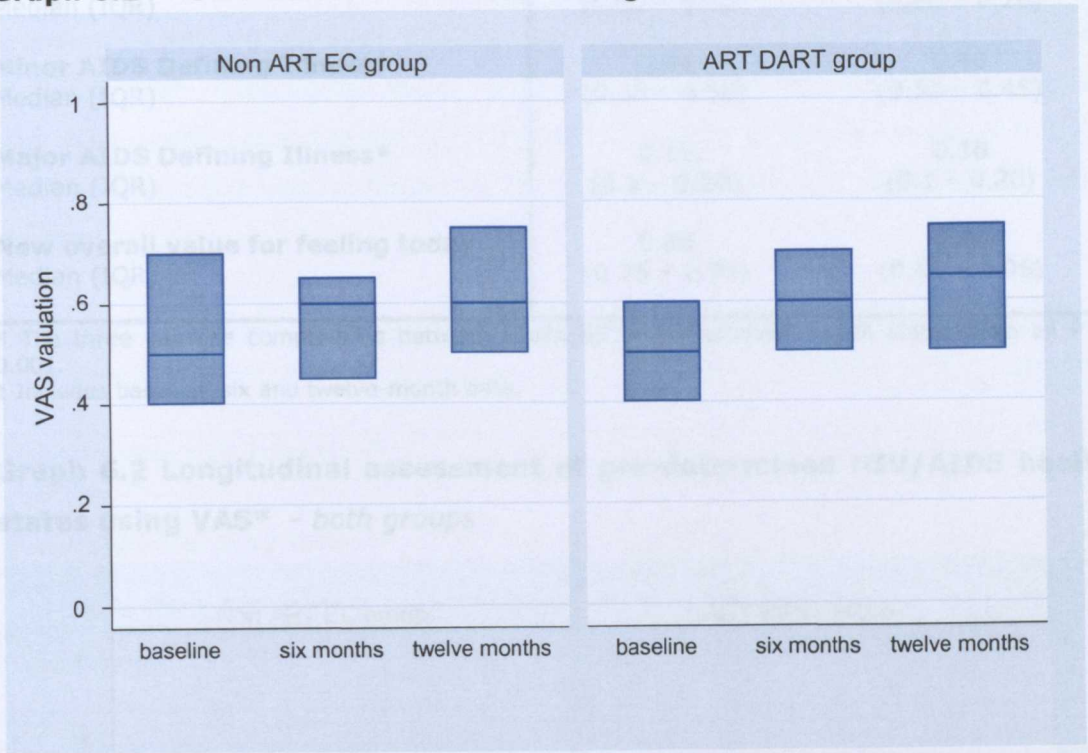
### 6.4.1 VAS results

For comparability with TTO and SG values, VAS scores were transformed to 0 to 1 scale, instead of the original 0 to 100 metric. Graph 6.1 presents the median own health assessment reported by participants by group and by follow-up (see below). In contrast to the non ART group, ART DART participants increased their own health assessment evaluation during the twelve month period. The difference between baseline and six months valuations was 0.10 and this was found not statistically significant ($p = 0.081$). However, the difference between six and twelve months was 0.15 and was statistically significant ($p = 0.013$). In comparison, Non ART EC participants increased their valuation from baseline to six months but it remained the same between six and twelve months. None of the comparisons were statistically significant at $p = 0.05$.

[6] The variance component model is an extension of the standard linear regression model where the error term is now constituted by two random components: a random term that varies across individuals but that it is constant for observation within a given individual and a second term which varies across all observations as in the standard model. The first term is used to account for the lack of independence between observations for the same individual.

The majority of participants from both groups identified and ranked Major AIDS as the worst health state (99%), Symptomatic HIV (99%) as the best health state and the Minor AIDS as the intermediate health state (99%).

**Graph 6.1 Own health assessment using VAS*** -whole period both groups



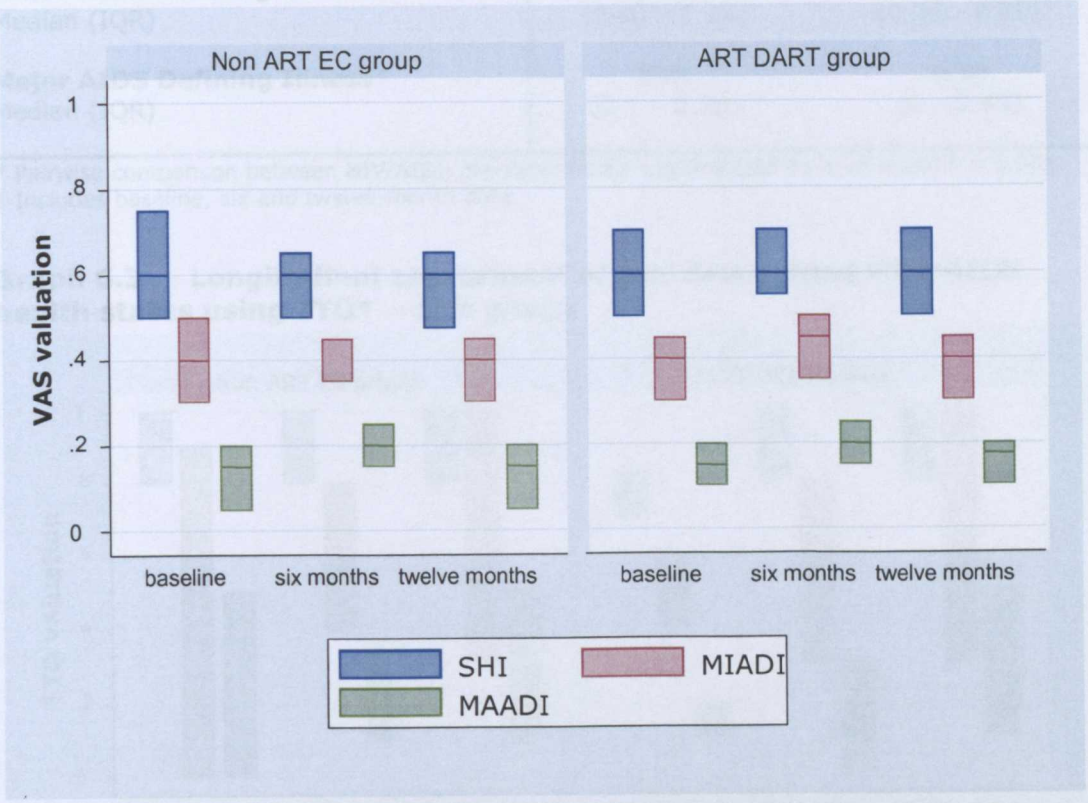

* The top and bottom of the boxes represent interquartile range. The line inside the box represents the median.

Using VAS, participants for both groups were able to discriminate between the best, intermediate and worst predetermined HIV/AIDS states as it is shown by their successively decreasing valuation. These differences were statistically significant ($P \leq 0.001$). Once the pre-determined HIV/AIDS health states were valued participants increased their own health assessment evaluation; the new figures are presented in the last row of Table 6.2 below. Graph 6.2 below shows the longitudinal assessment using VAS for both groups. Death was scored zero for the majority of participants in both groups (ART DART 96% and Non ART EC 99%).

| | n = 746 | n = 394 |
|---|---|---|
| **Feeling today**<br>Median (IQR) | 0.60<br>(0.45 - 0.70) | 0.60<br>(0.45 - 0.70) |
| **Symptomatic HIV Infection***<br>Median (IQR) | 0.60<br>(0.50 - 0.70) | 0.60<br>(0.50 - 0.70) |
| **Minor AIDS Defining Illness***<br>Median (IQR) | 0.40<br>(0.30 - 0.50) | 0.40<br>(0.30 - 0.45) |
| **Major AIDS Defining Illness***<br>Median (IQR) | 0.15<br>(0.1 - 0.20) | 0.18<br>(0.1 - 0.20) |
| **New overall value for feeling today**<br>Median (IQR) | 0.85<br>(0.75 - 0.95) | 0.80<br>(0.65 - 0.95) |

* The three pairwise comparisons between HIV/AIDS pre-determined health states have all $P \leq 0.001$.
1 Includes baseline, six and twelve-month data.

**Graph 6.2 Longitudinal assessment of pre-determined HIV/AIDS health states using VAS*** *- both groups*




* The top and bottom of the boxes represent interquartile range. The line inside the box represents the median. The median value for SHI at six months for the Non ART EC group was equal to the 75 percentile.

### 6.4.2 TTO results

The results from TTO are consistent with those from VAS as participants were also able to discriminate between the HIV/AIDS states. These differences were

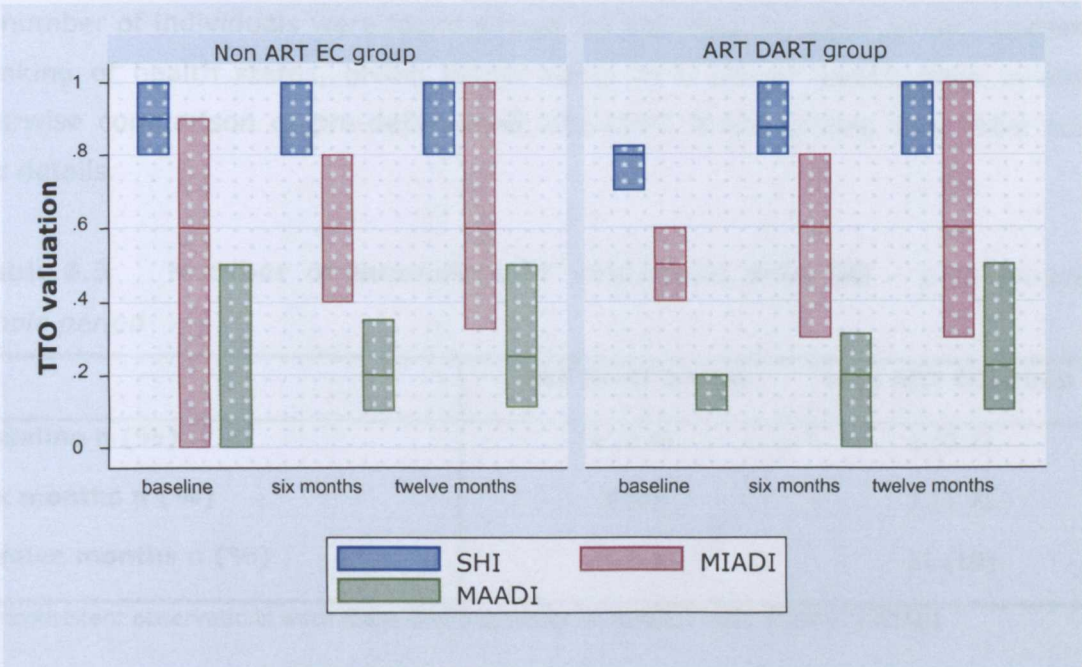
statistically significant (P < 0.001). Table 6.3 presents the results from the valuation of predetermined HIV/AIDS states by TTO. According to results presented in Table 6.3, a representative individual from ART DART group would be willing to give up 2 out of 10 years of life in order to improve his/her health status from SHI. In comparison, the typical Non ART EC respondent was unwilling to give up any time to do so. At the other extreme the median number of years that respondents would consider giving up in order to achieve an improved health state instead of remaining at MAADI for 10 years was 8 in both groups. Graph 6.3 below shows the longitudinal assessment using TTO for both groups.

**Table 6.3 Overall[1] results from TTO**

| | ART DART Group | Non ART EC Group |
|---|---|---|
| **Symptomatic HIV Infection*** Median (IQR) | 0.8 (0.70 - 1) | 1 (0.80 - 1) |
| **Minor AIDS Defining Illness*** Median (IQR) | 0.55 (0.40 - 0.70) | 0.60 (0.30 - 0.90) |
| **Major AIDS Defining Illness*** Median (IQR) | 0.20 (0.1 - 0.30) | 0.20 (0 - 0.45) |

* Pairwise comparison between HIV/AIDS pre-determined health states have all equal P < 0.001.
1 Includes baseline, six and twelve-month data.

**Graph 6.3 Longitudinal assessment of pre-determined HIV/AIDS health states using TTO*** *- both groups*




* The top and bottom of the boxes represent interquartile range and the line inside represents the median. The median value for SHI at six and twelve months for the Non ART EC group was equal to the 75 percentile. This was also for MAADI at baseline for both groups and for SHI at twelve months for ART DART participants.

### 6.4.3 SG results

Although, as mentioned before, SG did not present any problem in the pilot study, in the data collection it became clear that some individuals were unwilling to take the gamble if it had an attached positive probability of immediate painless death. At baseline the majority of ART DART participants were willing to take the gamble. Although the majority of Non ART EC participants took the gamble a higher proportion refused to do so in this than the previous group. However, this result reverses at six months and at twelve months both groups appear to be equally reluctant to take the gamble for any of the pre-determined health states. See Table 6.4 for details.

**Table 6.4 Individuals that would only take the drug if no probability of death was attached to it** – *both groups whole period*

| | Baseline | Six months | Twelve months |
|---|---|---|---|
| **Symptomatic HIV Infection n(%)** | | | |
| ART DART (n = 265) | 7 (3) | 52 (22) | 34 (14) |
| Non ART EC (n = 150) | 42 (28) | 3 (2) | 15 (13) |
| **Minor AIDS Defining Illness n(%)** | | | |
| ART DART (n = 241) | 6 (2) | 36 (15) | 31 (13) |
| Non ART EC (n = 132) | 29 (19) | 3 (2) | 16 (14) |
| **Major AIDS Defining Illness n(%)** | | | |
| ART DART (n = 238) | 6 (2) | 25 (10) | 50 (21) |
| Non ART EC (n = 112) | 19 (13) | 9 (7) | 23 (21) |

A number of individuals were found whose SG valuations implied an inconsistent ranking of health states, giving higher value to a poorer health state in any pairwise comparison of pre-determined HIV/AIDS health states. See Table 6.5 for details.

**Table 6.5 Number of inconsistent* valuations with SG** – *both groups whole period*

| | ART DART group | Non ART EC group |
|---|---|---|
| **Baseline n (%)** | 1 (0.4) | 1 (0.7) |
| **Six months n (%)** | 4 (5) | 7 (1.7) |
| **Twelve months n (%)** | 28 (12) | 11 (10) |

* Inconsistent observations were those that had either of MIADI > SHI, MAADI > MIADI.

Table 6.6 presents the results from the valuation of predetermined HIV/AIDS states by SG. Using SG, participants from both groups were able to discriminate

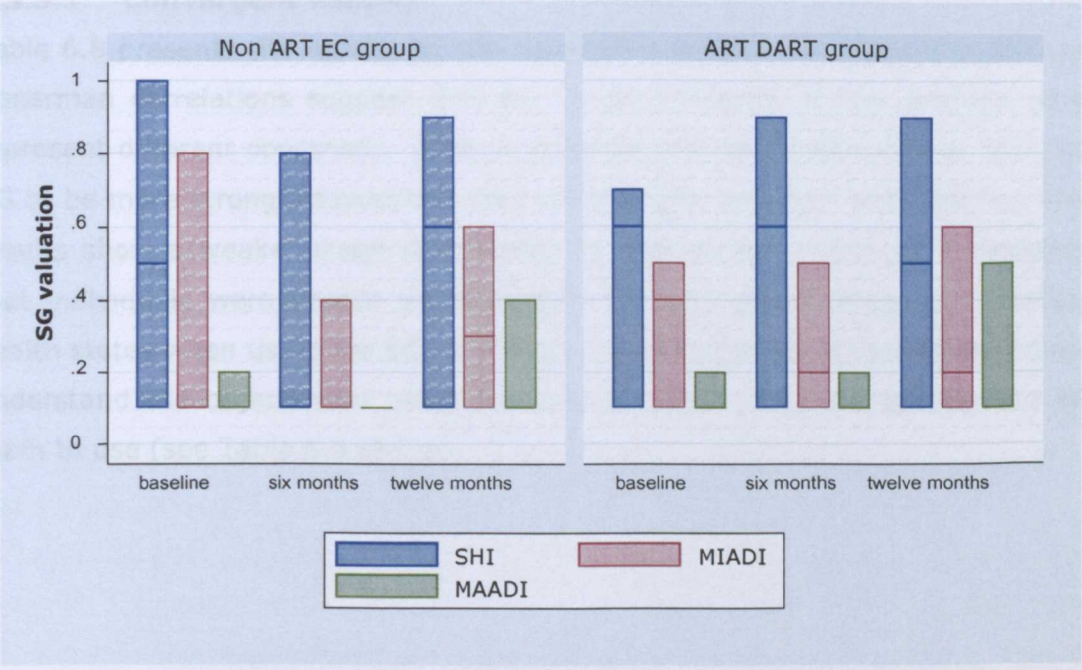
between SHI and MIADI, and between SHI and MAADI. Although ART DART participants were able to discriminate between MIADI and MAADI the difference was not statistically significant (P = 0.31). Non ART EC participants were unable to discriminate between MIADI and MAADI. The typical value given by an ART DART participant implies a willingness to take a gamble with a 40% (i.e., 1 – 0.6) chance of immediate death instead of facing a certain prospect of living for 10 years in SHI. The respective value for Non ART EC participant was 50%. At the other end MAADI would prompt the willingness to take up a gamble with 90% chance of sudden death for both groups. Graph 6.4 below shows the longitudinal assessment using SG for both groups.

**Table 6.6 Overall[1] results from SG**

| | ART DART Group | Non ART EC Group |
|---|---|---|
| **Symptomatic HIV Infection*** Median (IQR) | 0.60 (0.10 – 0.80) | 0.50 (0.1 – 0.90) |
| **Minor AIDS Defining Illness**** Median (IQR) | 0.20 (0.10 – 0.50) | 0.10 (0.10 – 0.50) |
| **Major AIDS Defining Illness**** Median (IQR) | 0.10 (0.1 – 0.20) | 0.10 (0.10 – 0.20) |

* Pairwise comparison between SHI and MIADI and between SHI and MAADI have P ≤ 0.001.
** Pairwise comparison between MIADI and MAADI had a P = 1 and P = 0.31 for the Non ART EC group and ART DART group respectively.
1 Includes baseline, six and twelve-month data.

**Graph 6.4 Longitudinal assessment of pre-determined HIV/AIDS health states using SG*** - *both groups*




* * The top and bottom of the boxes represent interquartile range and the line inside represents the median. The median value for MAADI at six months for the Non ART EC group was equal to the 75 percentile.

## 6.5 PSYCHOMETRIC PERFORMANCE RESULTS

### 6.5.1 Feasibility results

It took less than 10 minutes to explain and administer VAS. TTO and SG took between 12 and 15 minutes. VAS was found the easiest tool to explain and administer, followed by TTO and SG. No missing values or problems were reported at baseline when using VAS or TTO and only 2 missing values for the three pre-determined health states for the ART DART group were recorded with SG.

### 6.5.2 Reliability results

Only 12(66.6%) individuals from the Non ART EC group that were invited for test-retest came back after two weeks of the first interview. All the ART DART participants returned. The Spearman's rank correlation coefficients per instrument for both groups are shown in Table 6.7 below. From the results it appears that SG is less reliable than the TTO and VAS for both groups.

**Table 6.7 Test-retest reliability**

| | **ART DART group** n = 20 Spearman coefficient | **Non ART EC group** n = 12 Spearman coefficient |
|---|---|---|
| **VAS** | 0.71 | 0.83 |
| **TTO** | 0.72 | 0.77 |
| **SG** | 0.41 | 0.42 |

### 6.5.3 Empirical validity results

#### *6.5.3.1 Convergent validity*

Table 6.8 presents the results for the correlation between instruments. The low Spearman correlations suggest that the values obtained by the different tools represent different constructs. While in principle one would expect that TTO and SG to be more strongly associated than either of the two with VAS, the fact that results show a weaker linear relationship for the former might be a reflection that individuals were unable to distinguish between pre-determined HIV/AIDS health states when using the SG. It may be argued that individuals either did not understand the objective of using this tool or that it was too complicated for them to use (see Table 6.6 above).

**Table 6.8 Spearman correlation coefficients**

| | VAS | TTO | SG |
|---|---|---|---|
| **VAS** | | | |
| ART DART group | 1 | 0.61 | 0.34 |
| Non ART EC group | | 0.45 | 0.26 |
| **TTO** | | | |
| ART DART group | 0.61 | 1 | 0.39 |
| Non ART EC group | 0.45 | | 0.21 |
| **SG** | | | |
| ART DART group | 0.34 | 0.39 | 1 |
| Non ART EC group | 0.26 | 0.21 | |

#### *6.5.3.2 Construct validity*

In this analysis valuations were modelled as a function of the covariates interacted with indicators used to distinguish between pre-determined HIV/AIDS health states in a single regression. Differences in the effect of covariates on valuations across health states were therefore tested by conducting standard t tests on the coefficients of interactions. The results of regression analyses are presented in Appendix XIIa.

Age, CD4 cell counts and gender showed no systematic influence on the VAS and SG valuations of both groups and on TTO valuations in the ART DART participants. Gender was associated with TTO valuations of the three pre-determined HIV/AIDS health states for the Non EC ART participants; male participants were less willing to trade off time in exchange for an improved health state (see Tables 29, 30 and 31 in Appendix XIIa). No other covariates had any apparent effect on valuations of this group. The interactions were found insignificant in all cases suggesting that the same observed effect applied across the pre-determined health states for HIV/AIDS.

Own health assessment was positively associated with TTO and VAS valuations of the hypothetical health states for both groups (DART ART group Tables 4 to 6 for VAS and 14 for TTO; and for the Non ART EC group Tables 25 to 28 for VAS and 30 to 35 in Appendix XIIa) and negatively associated with SG for ART DART participants (see Tables 18 to 21 in Appendix XIIa) and so too for the first pre-determined HIV/AIDS health state (Symptomatic HIV Infection) for Non ART EC participants but positive for the other two pre-determined HIV/AIDS health states in SG (see Tables 38 to 41 in Appendix XIIa). These associations were found statistically significant at $p = 0.05$.

#### *6.5.3.3 Multi – level model*[7]

This model showed that VAS valuations were positively associated with own health in both groups (see Tables 1 to 6 for both groups in Appendix XIIb). Other covariates had no influence on the results except that age was positively associated with the values given in VAS MAADI health state in the ART DART group (i.e., older individuals provided higher values with VAS) (see Table 5 in Appendix XIIb).

In TTO no covariates were found to have an effect on the valuations of the ART DART group. In the Non ART EC group however, own health assessment appears to have a positive effect only on the MAADI health state; in other words healthier individuals were less willing to hypothetically give up years of their lives (see Table 12 in Appendix XIIb). Being female had a negative relationship with the valuations for the SHI and MIADI, implying less willingness from males to trade-off years of life for improved health (see Tables 8 and 10, in Appendix XIIb).

In SG results varied by pre-determined HIV/AIDS health states; own health is negatively associated with SHI health state in both groups without any apparent effect by other covariates (see Table 13 and 14 in Appendix XIIb); valuations of MIADI health state are independent of all covariates in both groups; valuations of MAADI health state are positively associated with own health while independent from other covariates in both groups (see Table 17 and 18 in Appendix XIIb).

## 6.6 CONCLUSIONS

- The use of TTO and VAS in HIV infected individuals was feasible and produced reliable results.

- Convergent validity between TTO and VAS valuations was low, although this should be expected since these two instruments relate to different constructs. VAS is a choice-less measure, individuals identify the point in a thermometer-like scale that represent the relative health status in question; TTO requires the individual to undertake a comparative assessment to determine the value of the health state with reference to an improved health state.

[7] The results of this analysis are presented in Appendix XIIb.

- The analyses of construct validity appear to be acceptable and in line with other studies (Dolan *et al,* 1996) for TTO and VAS valuations. In general, these valuations are independent of age and gender while being (positively or negatively) associated with self-assessed health but not with CD4 count.

- Participants were able to discriminate between the three pre-determined HIV/AIDS health states using TTO and VAS as shown by their valuations.

- It appears that participants from the Non ART EC group are unable to distinguish the quality of life differences between MIADI and MAADI when SG is used, showing that SG is insensitive in this patient population. Also the fact that a proportion of individuals are unwilling to take the gamble makes the results difficult to analyse and interpret. A small number of individuals appear not to have understood the assessment as suggested by the incongruent ranking of states implied by their valuations. In addition, the results from the psychometric tests show low reliability and convergent validity and mixed results from construct validity.

# CHAPTER 7

# RESULTS FROM DISEASE SPECIFIC HRQoL QUESTIONNAIRES

*"I visit my friends, it is a very good way of avoiding worrying...the presence of a friend is like medicine it makes you feel good" Male participant.*

## 7.1 INTRODUCTION

This chapter describes the methods and the results of using the MOS-HIV, the WHOQOL-HIV BREF and the SQoLI-HIV questionnaires in HIV infected individuals receiving and not receiving ART.

## 7.2 HIV/AIDS SPECIFIC HRQoL QUESTIONNAIRES

### 7.2.1 Medical Outcomes Health Study Survey for HIV (MOS-HIV)

The MOS-HIV questionnaire is an adaptation from the Medical Outcome Study (MOS), a four-year observational study that aimed to develop a user-friendly tool for monitoring patient outcomes in medical practice. The study identified 116 items as core indicators of quality of life, including physical limitations due to physical health problems, cognitive functioning, depression, anxiety, positive affect, feeling of belonging, role limitations due to emotional problems, energy/fatigue, sleep problems, symptoms, social activity limitations due to health, social functioning, role functioning, health distress and general health problems (Bozzette, 1995). The MOS-HIV consists of eleven dimensions, these are: General health perceptions (5 items); Physical functioning (6 items); Role functioning (2 items); Social functioning (1 item); Cognitive functioning (4 items); Bodily Pain (2 items); Mental health (5 items); Vitality (4 items); Health distress (4 items); Quality of life (1 item) and Health transition (1 item). In the MOS-HIV higher values represent better health. The MOS-HIV hypothesizes the different stages of health deterioration due to HIV using a four week recall period. The higher the score obtained the better the health state that the individual is in.

### 7.2.2 World Health Organization Health Survey for HIV reduced version (WHOQOLI-HIV BREF)

The WHOQOL-HIV BREF is based on the WHOQOL-HIV, which attempts to assess an individual's subjective perception of quality of life and identifies integrative items and profiles specifically suitable for the assessment of QoL in HIV-infected patients. This reduced version evaluates 31 items of the following domains: physical, psychological health, level of independence, social relationships, environment and spirituality. This questionnaire is scored with higher values representing better quality of life.

### 7.2.3 Specific Quality of Life Instrument for HIV (SQOLI-HIV)

This instrument was compiled only for the purpose of this research study. Its aim was to assess if those questions omitted in the WHOQOL-HIV BREF from the original WHOQOL-HIV were irrelevant for the population under study (see Chapter four; section 4.5.3; page 86). This questionnaire consists of 25 questions. For convenience the same recall period as the MOS-HIV, that is 30 days, was used.

The allocation of items to dimensions followed a two-step process. The first one was to assign the items following the original WHOQOL-HIV constitution of dimensions. Using the WHOQOL-HIV item allocation to dimensions the questions from the SQoLI-HIV questionnaire were distributed in six dimensions of health-related quality of life including (see Table 7.1 below):

- ***Physical*** (3 items, pain and discomfort, sleep and rest and symptoms of People Living with HIV/AIDS (PLWHA));
- ***Psychological*** (4 items, positive feelings and self-esteem);
- ***Social relationships*** (5 items, personal relationships, social support, social exclusion and sexual activity);
- ***Spirituality*** (8 items, forgiveness and blame, death and dying, concerns about the future and spiritual);
- ***Level of independence*** (1 item, medications and treatment);
- ***Environment*** (4 items, physical safety and security, financial resources and physical environment) (see Table 7.1 below).

**Table 7.1 Summary of concepts for SQOLI-HIV using the WHOQOL-HIV classification**

| Concepts | No. of items | Meaning of scores | |
|---|---|---|---|
| | | Low | High |
| **Physical** | 3 | An extreme amount of problems with sleeping, unpleasant physical problems related to HIV and pain | No problems with sleeping, no unpleasant physical problems related HIV and no pain at all |
| **Psychological** | 4 | Very pessimistic, unhappy, unsure and feeling completely alone | Hopeful, content, confident and not feeling alone |
| **Social relationships** | 5 | Unsupported by family and friends, unable to support others, rejected by people and unhappy with actual sexual life | Totally supported from family and friends, able to support others, accepted by people and fully contented with actual sexual life |
| **Spirituality** | 8 | Extremely concerned with death or breaking family line; extremely guilty about HIV status and feeling that suffering comes from fate. Personal beliefs not providing strength | Not at all concerned with death or breaking family line; no feelings of guilt due to HIV status or suffering from fate. Strength coming from personal beliefs |
| **Level of independence** | 1 | Extremely important not to depend on medications or treatments | Not important at all to depend on medications and treatments |
| **Environment** | 4 | Extremely insecure, unsafe and not comfortable with physical environment, extreme financial difficulties and unable to meet needs | Totally secure, safe and comfortable with physical environment; no financial difficulties and extremely able to meet needs |

The second involved re-assigning items using the multidimensional conceptualization of health-related quality of life as described by Testa and Nackley – see Table 7.2 below (Testa and Nackley, 1994).

**Table 7.2 Multidimensional conceptualization of health-related quality of life**

| | Dimensions | Indicators (Indices, scales and subscales) | SQoLI-HIV question number[1] |
|---|---|---|---|
| Opportunity | Social or cultural | Access to care, social stigma, support | q6, q7, q14, q15, q19, q20, q21, q22 |
| | Coping | Ability to withstand stress, psychological or physical | q8, q23, q24, q25, q26 |
| Health Perceptions | General health perceptions | Self-rating, worry, concern | q8, q17, q18 |
| | Satisfaction | Satisfaction with functioning | |
| Functional | Social | Work and daily life | Covered by MOS-HIV |
| | Psychological | Distress (anxiety, depression, loss of behavioral and emotional control); well-being (positive affect, emotional ties, life satisfaction) | q4, q5, q12, q16, q27 |
| | Cognitive | Memory, alertness, reasoning | Covered by MOS-HIV |
| Morbidity | Physical | Activity restrictions, fitness, objective clinical findings directly observable | q3, q10, q11 |
| | Signs | Laboratory measures, pathology | Not applicable |
| | Symptoms self-reports physiologic | Patient self-reports of symptoms and conditions | Not applicable |
| | Diagnosis and severity | | |

1 The numbering of questions of the SQOLI-HIV goes from 3 to 27 since questions 1 and 2 are age and sex.

## 7.3 ANALYSIS OF DATA

Some of the items within dimensions were recoded to allow homogeneity in scale among all answers to items across dimensions. Raw dimension scores were obtained by summing up the items within each dimension. Raw scores were then transformed to a 0 – 100 scale in order to compare with the scores of other questionnaires. If values were missing, these were replaced by mean substitution for only those multi-item scales (two or more items) where no more than 50% of the items were missing (see p. 126 - overall feasibility of the tools for further details).

***Feasibility:*** It was evaluated by examining the percentage of missing item responses, interviewer feedback acceptability, and the time and ease of administration.

***Reliability:*** It was assessed only on multi-scales by estimating the Cronbach's α

coefficient. This coefficient obtains the average inter-correlation among the items belonging to the same domain in a given survey. Intuitively, if the Cronbach's α coefficient is high we may say that there is evidence that the items are measuring the same underlying construct or that the domain is measured more reliably on the generated scale combining the items than by individual items separately.

***Construct validity:*** For the MOS-HIV questionnaire construct validity was tested by principal component analysis[1]. Raw scores were transformed into a 0 to 100 scale; where 0 representing the lowest possible score and 100 the highest score. The linear transformation allows comparisons between the dimensions that have different response categories. These scores were then normalized and used to estimate the principal component analysis. Mental and Physical Health Summary Scores were then computed by multiplying the individual sub-scales scores (transformed into a z score) by the score coefficients for the sub-scales generated by the principal component analysis (Revicki *et al,* 1998). In addition, for the MOS-HIV and WHOQOL-HIV BREF the results obtained for the sub-scales were controlled by age and sex.

## 7.4 RESULTS

### 7.4.1 Overall feasibility

The average time for administration was between 10 and 15 minutes per questionnaire. The questionnaires were well received by participants. Only with the MOS-HIV did participants query two issues: why there were questions about having to learn new things and making decisions. With both MOS-HIV and the SQOLI-HIV less than one percent had missing values for any item (3 answers missing). The WHOQOL-HIV BREF did not present any problem and it had 100% response rate with no missing values.

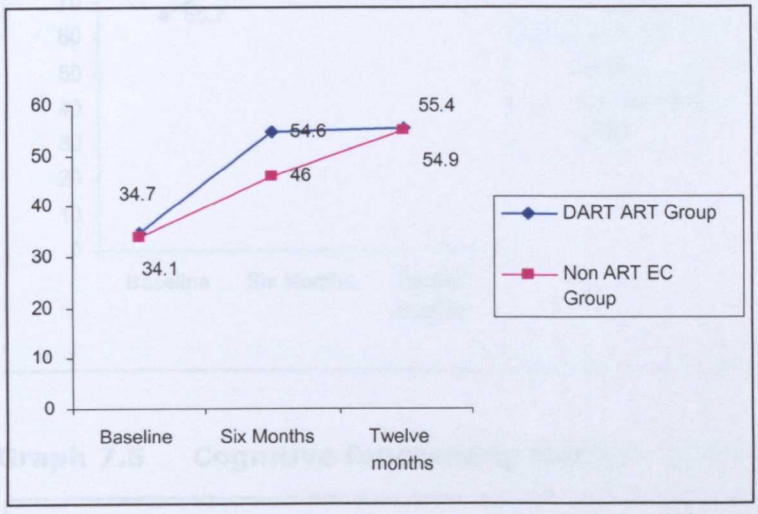
### 7.4.2 MOS-HIV results

Graphs 7.1 to 7.11, present the mean[2] values of the 11 domains for both groups at baseline, six and twelve months. All the scores for both groups over time are in the high end of the scales. ART DART participants appeared to have improved in all the domains at six months and only two domains are worse at twelve

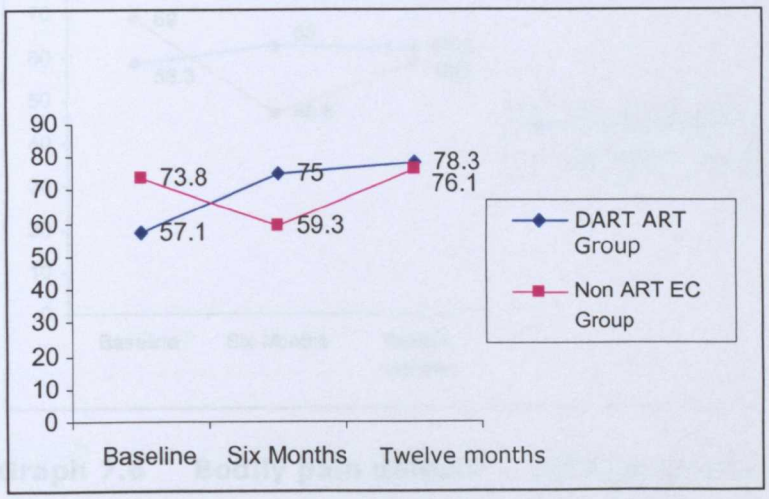
[1] Using unrotated principal components in order to maintain the axes uncorrelated and to provide the maximum variance.
[2] Mean values and standard deviations for both groups over time for the MOS-HIV, the WHOQOL-HIV BREF and the SQOLI-HIV are presented in Appendix XIII.

months (cognitive functioning and quality of life). In comparison, Non ART EC participant's scores decline at six months (physical, cognitive functioning and bodily pain) but all their dimensions are improved at twelve months.

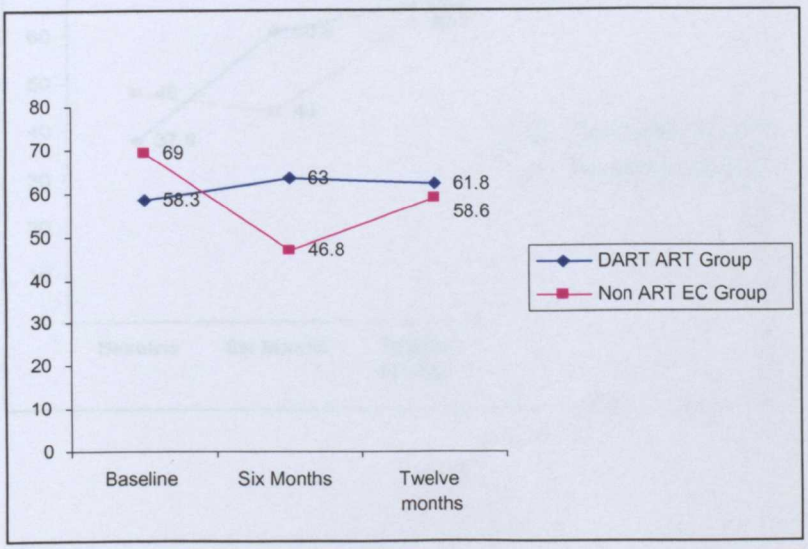
**Graph 7.1 General Health perception domain** – *both groups whole period*



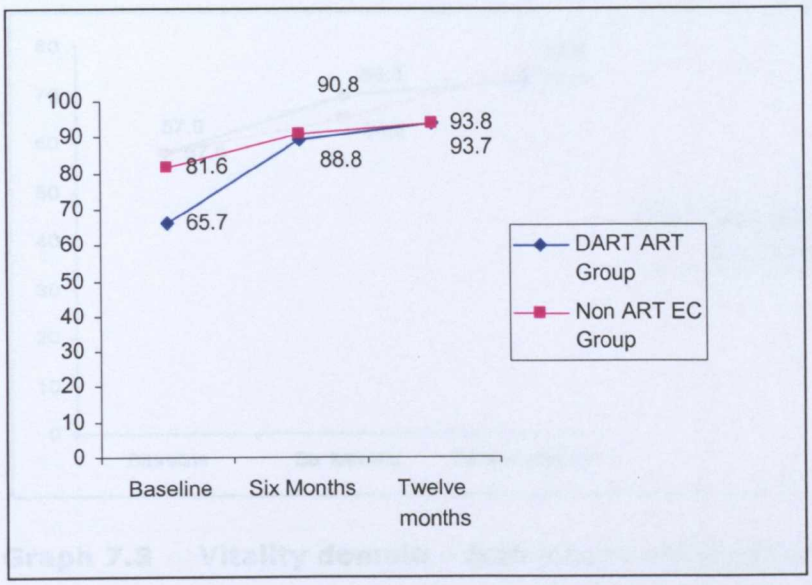

**Graph 7.2 Physical functioning domain** – *both groups whole period*



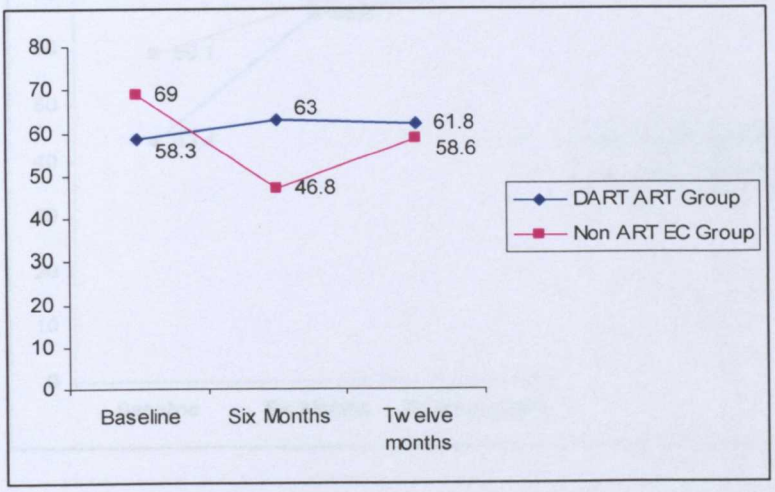

**Graph 7.3 Role functioning domain** – *both groups whole period*



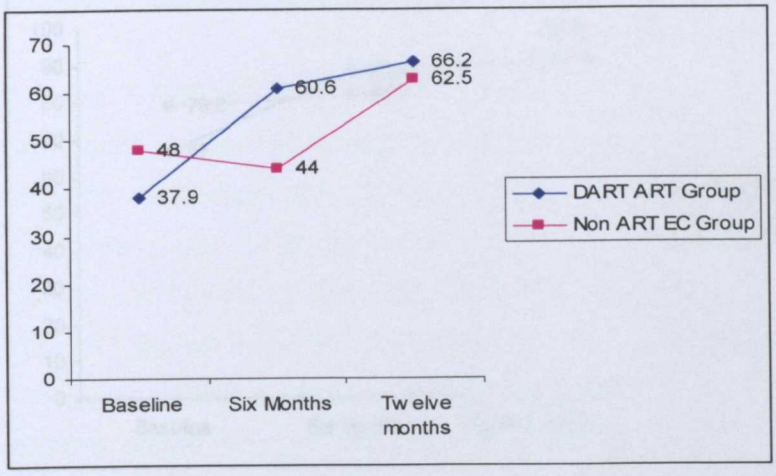
**Graph 7.4 Social functioning domain** – *both groups whole period*



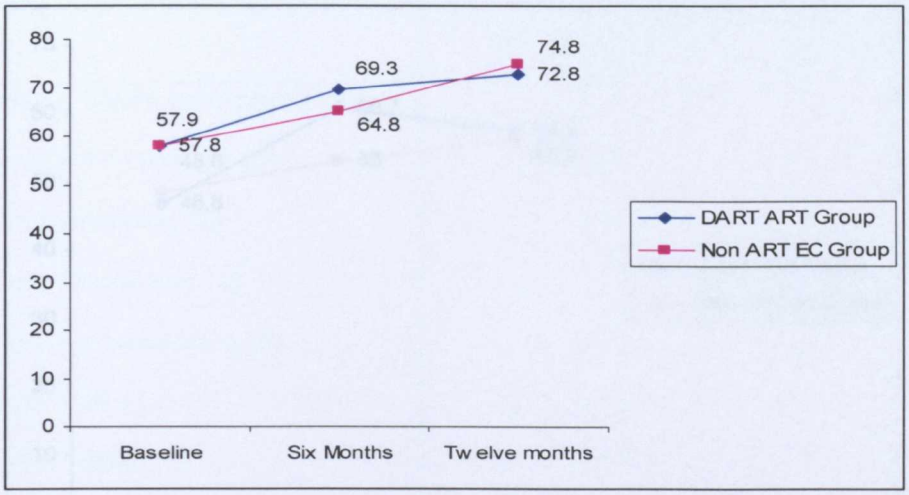

**Graph 7.5 Cognitive functioning domain** – *both groups whole period*



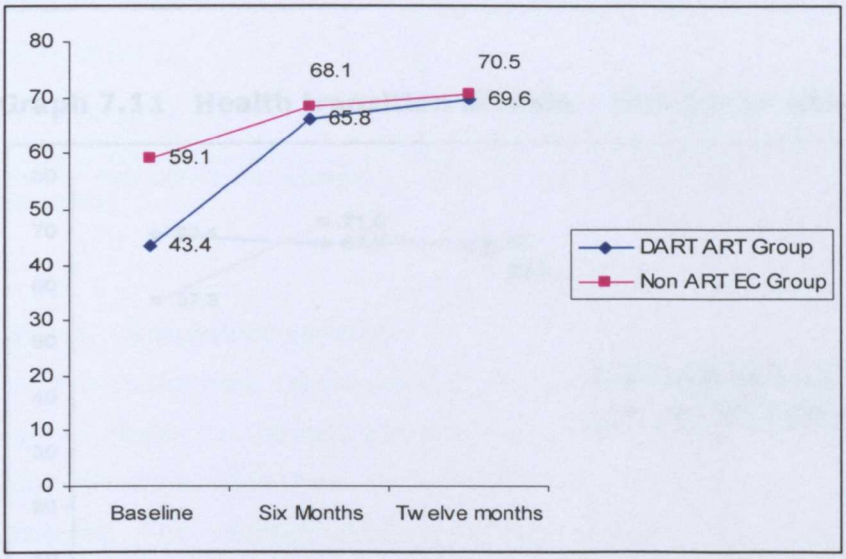

**Graph 7.6 Bodily pain domain** – *both groups whole period*



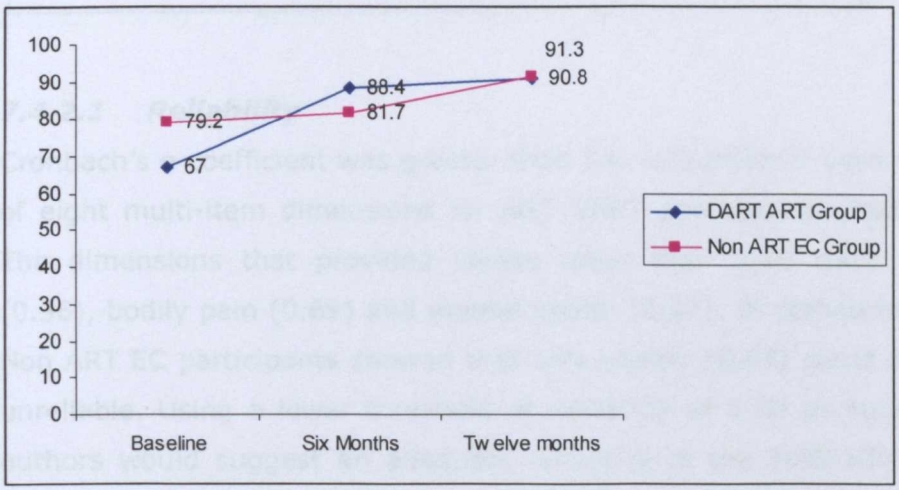
**Graph 7.7 Mental health domain** – *both groups whole period*



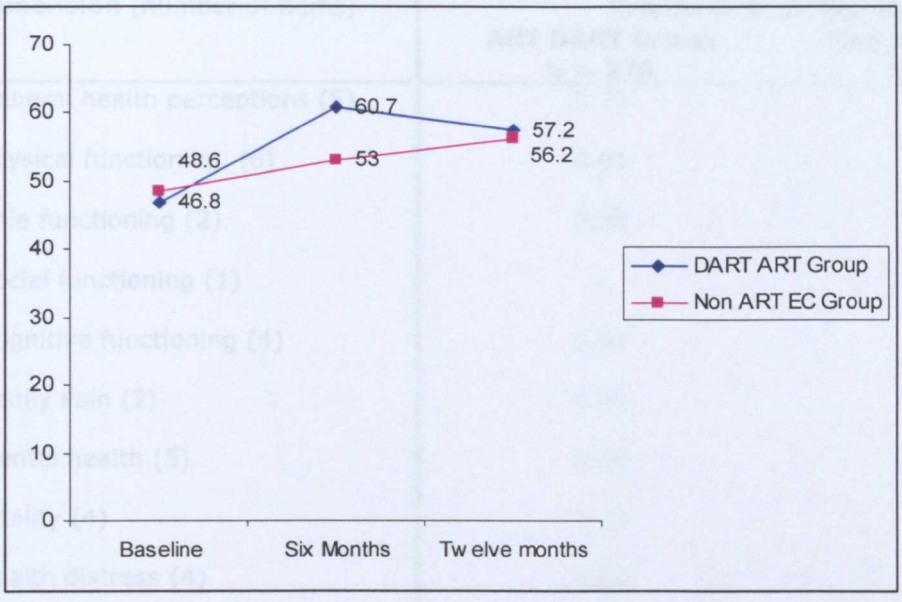

**Graph 7.8 Vitality domain** – *both groups whole period*



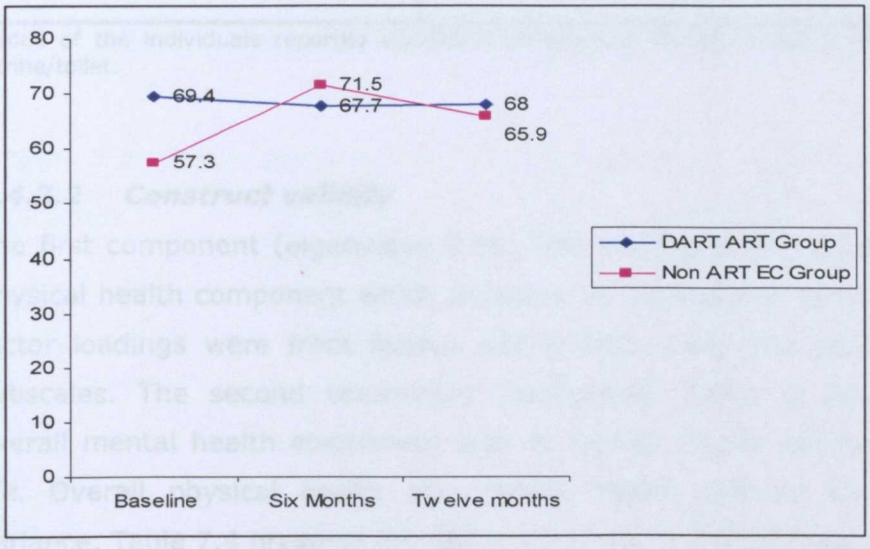

**Graph 7.9 Health distress domain** – *both groups whole period*



**Graph 7.10 Quality of life domain** – *both groups whole period*




**Graph 7.11 Health transition domain** – *both groups whole period*




### *7.4.2.1 Reliability*

Cronbach's α coefficient was greater than the conventional used 0.70 for five out of eight multi-item dimensions for ART DART participants (Paton *et al,* 2002). The dimensions that provided values lower than 0.70 were role functioning (0.36), bodily pain (0.69) and mental health (0.67). In comparison, results from Non ART EC participants showed that only vitality (0.65) could be considered as unreliable. Using a lower threshold of reliability of 0.50 as suggested by some authors would suggest an adequate reliability of the MOS-HIV since only role functioning for ART DART participants had a Cronbach's α less than 0.50 (Helmstadter, 1964). See Table 7.3 below for details.

**Table 7.3 MOS-HIV Cronbach's coefficients for baseline both groups**

| **Dimension** (number of items) | **Cronbach's coefficients** | |
|---|---|---|
| | **ART DART Group n = 276** | **Non ART EC Group n = 159** |
| General health perceptions (5) | 0.75 | 0.88 |
| Physical functioning (6) | 0.81 | 0.78 |
| Role functioning (2) | 0.36 | 0.88 |
| Social functioning (1) | - | - |
| Cognitive functioning (4) | 0.84 | 0.81 |
| Bodily Pain (2) | 0.69 | 0.76 |
| Mental health (5) | 0.68 | 0.79 |
| Vitality (4) | 0.76 | 0.65 |
| Health distress (4) | 0.82 | 0.96 |
| Quality of life (1) | - | - |
| Health transition (1) | - | - |

*None of the individuals reported significant limitation in eating, dressing, bathing or using the latrine/toilet.

#### *7.4.2.2 Construct validity*

The first component (eigenvalue 3.96) was considered to represent the overall physical health component which accounts for 36% of the variance. The highest factor loadings were from fatigue and energy, pain and physical functioning subscales. The second component (eigenvalue 1.94), is interpreted as the overall mental health component with its highest factor weight from quality of life. Overall physical health and mental health account for 57.1% of the variance. Table 7.4 presents the factor structure of the principal components.

**Graph 7.12 MOS-HIV Eigen values**

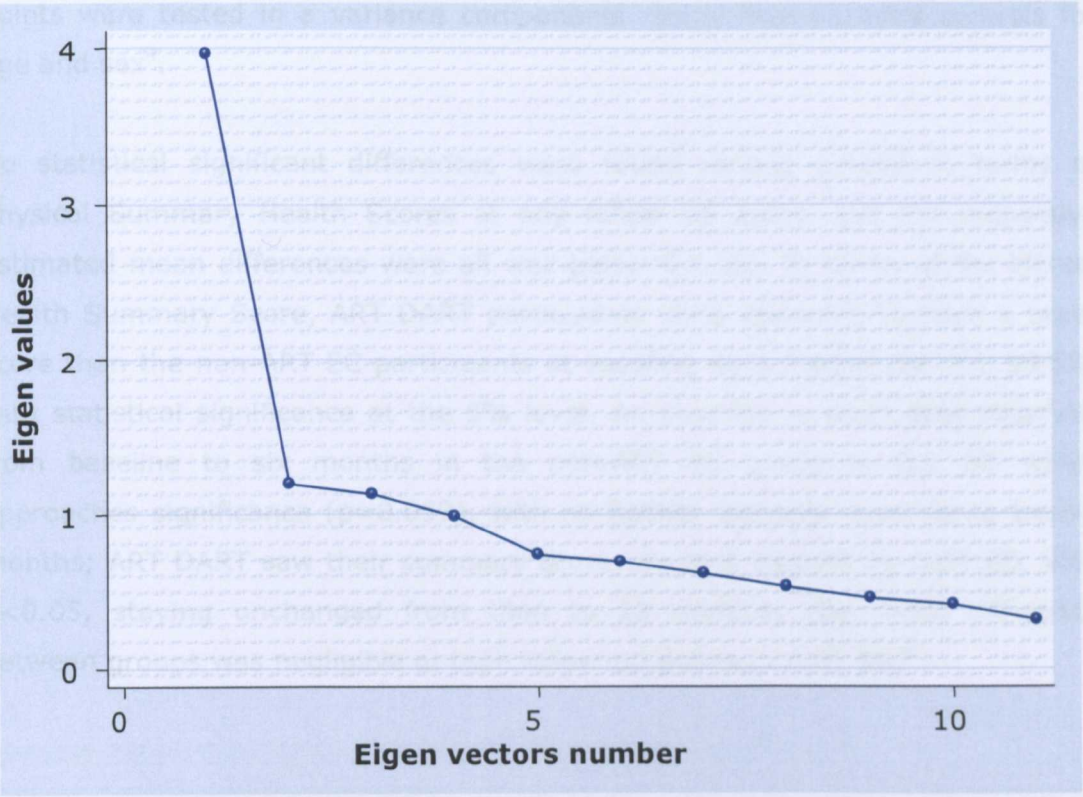



**Table 7.4 Factor structure for the two principal components**

| Subscale | Factor 1 Physical Health | Factor 2 Mental Health |
|---|---|---|
| **PF_Z** | **0.36194** | 0.28005 |
| **GH_Z** | 0.31198 | -0.45426 |
| **PN_Z** | **0.37749** | -0.23047 |
| **RP_Z** | 0.35908 | 0.14897 |
| **SF_Z** | 0.28595 | 0.23555 |
| **MH_Z** | 0.27818 | -0.24434 |
| **VT_Z** | **0.40619** | 0.12066 |
| **HD_Z** | 0.34902 | -0.04832 |
| **CF_Z** | 0.23059 | 0.11669 |
| **QL_Z** | 0.03101 | **0.62213** |
| **HT_Z** | 0.01181 | -0.32737 |

2 PF =Physical functioning; GH=General Health; PN= Pain; RP= Role Functioning; SF=Social Functioning; MH=Mental Health; VT=Vitality; HD=Health distress; CF=cognitive functioning; QL=Quality of life and HT=Health Transition.

Factor analysis was also estimated for six and twelve-month data[3]; this was done primarily to estimate the Physical and Mental Health Summary Scores for

[3] The results for the principal component analysis are available from the author upon request.

each group at each follow up. The differences between groups by follow-up points were tested in a variance components model that included controls for age and sex[4].

No statistical significant differences were found among groups in terms of Physical Summary Health Scores at any follow up point, and the respective estimated mean differences were all well below 0.1 SD. In terms of the Mental Health Summary Score, ART DART participants were observed to have a lower score than the non-ART EC participants at baseline by a magnitude of 0.39 SD, with statistical significance at the 5% level. An increase in score was observed from baseline to six months in the non-ART EC group of 0.2 SD which approaches significance ($p=0.057$), with no further increase from six to twelve months; ART DART saw their summary score rise at 6 months by 0.59 SD, with $p<0.05$, staying unchanged from then to 12 months; the initial difference between groups was negligible at both follow-up points (<0.01 SD)[5].

### 7.4.3 WHOQOL-HIV BREF

The answers obtained from the WHOQOL-HIV BREF were scored following the guidelines provided by Mental Health Department at WHO. As mentioned before the WHOQOL-HIV BREF evaluates six domains of quality of life; the domains values go from 4 to 20, with higher values representing better quality of life; Graphs 7.13 to 7.18 present scores at baseline, six and twelve months for Non ART EC and for a sub-group of the DART ART participants. In addition Table 7.5 presents the Cronbach's α for all the domains for both groups at baseline, six and twelve months.

The same pattern emerged as the one seen with the MOS-HIV for physical domain. For the psychological domain Non ART EC participants remain in the same position whilst ART DART increased their psychological well-being at six months but dropped at twelve months. Level of independence, social relationships and environmental domains appeared to have improved for ART DART participants at six and twelve months, but for Non ART EC participants these domains deteriorated at six and improved at twelve months. Environmental domain further deteriorated at twelve months for Non ART EC

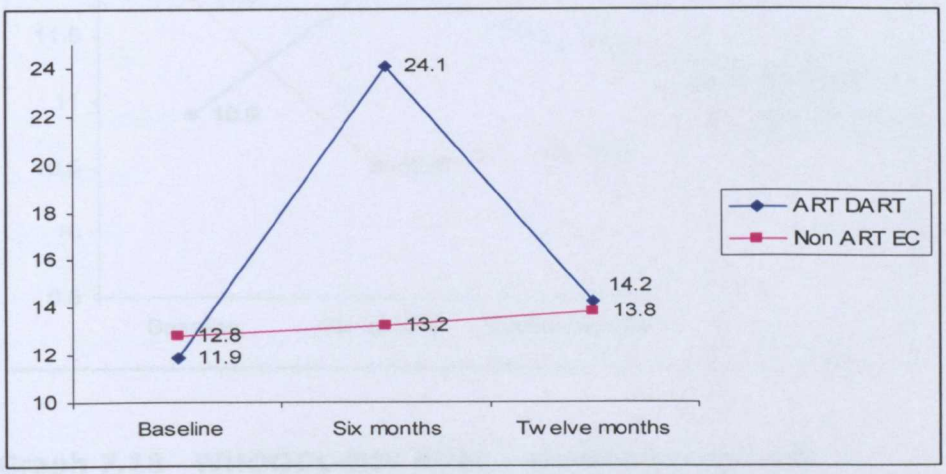
[4] Both Mental and Physical Summary Scores were analysed in the same model using an item response specification. This estimates factor loadings that applied to the random term in the random component model thereby allowing for different impact of the random effect on the values on the dependent variable for each construct.

[5] The results of the modelling analysis for the MOS-HIV are presented in Appendix XIV.

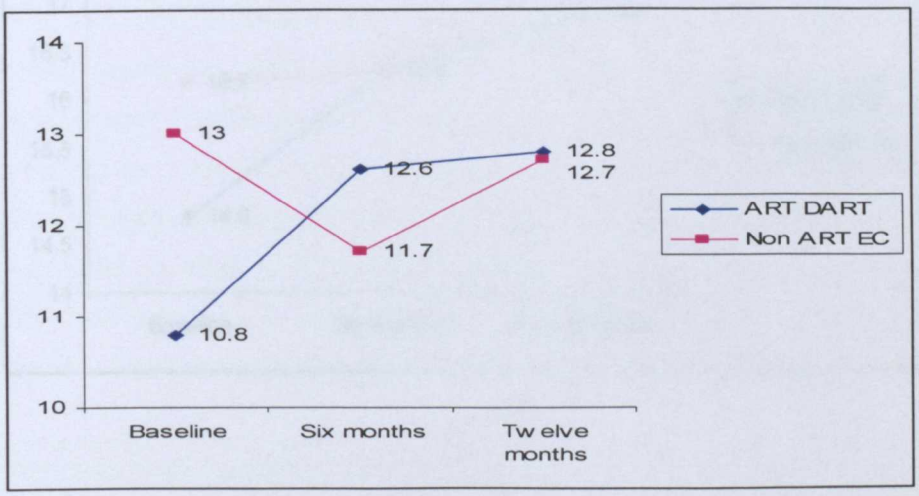
participants. Spirituality domain improved for the two groups at the two follow-ups.

**Graph 7.13 WHOQOL-HIV BREF - physical domain**

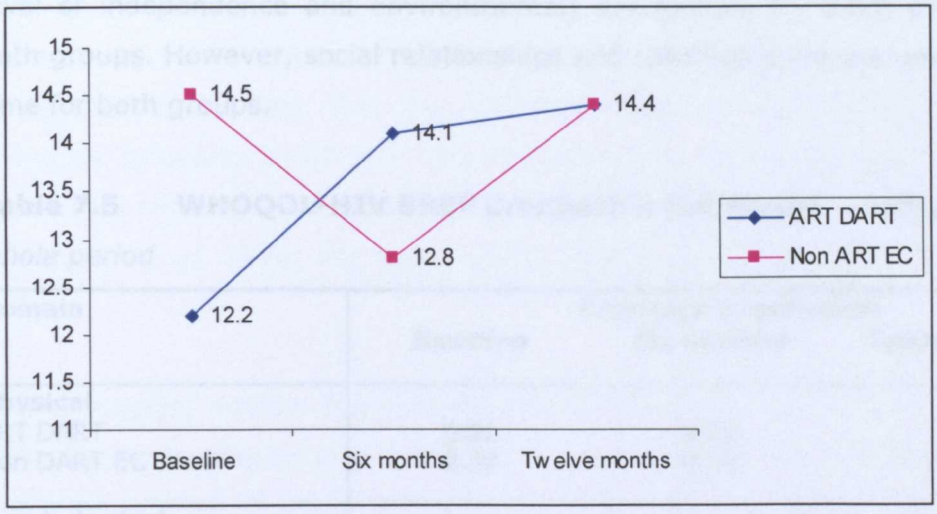

**Graph 7.14 WHOQOL-HIV BREF - psychological domain**



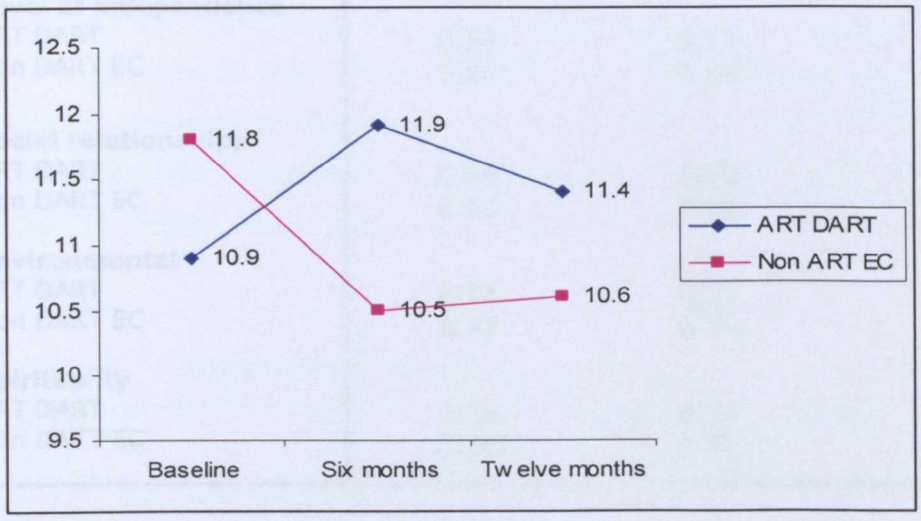

**Graph 7.15 WHOQOL-HIV BREF - level of independence domain**



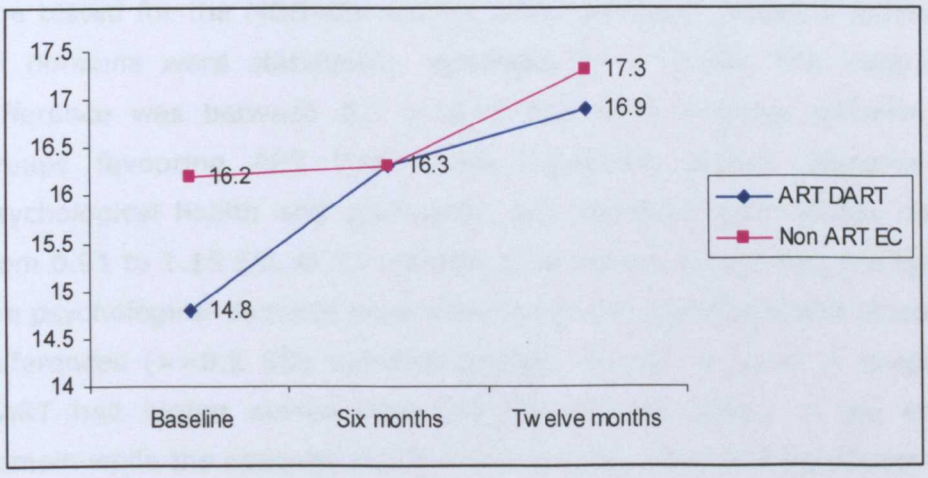
**Graph 7.16 WHOQOL-HIV BREF - social relationships domain**




**Graph 7.17 WHOQOL-HIV BREF - environmental domain**




**Graph 7.18 WHOQOL-HIV BREF - spirituality domain**



As shown in Table 7.5 below four out of six domains (physical, psychological, level of independence and environmental) are reliable (> 0.50) over time for both groups. However, social relationships and spirituality remain unreliable over time for both groups.

**Table 7.5 WHOQOL-HIV BREF Cronbach's coefficient** – *both groups whole period*

| Domain | Cronbach's coefficient | | |
|---|---|---|---|
| | Baseline | Six months | Twelve months |
| **Physical** | | | |
| ART DART | 0.61 | 0.72 | 0.71 |
| Non DART EC | 0.72 | 0.55 | 0.72 |
| **Psychological** | | | |
| ART DART | 0.44 | 0.52 | 0.71 |
| Non DART EC | 0.58 | 0.55 | 0.61 |
| **Level of independence** | | | |
| ART DART | 0.54 | 0.72 | 0.75 |
| Non DART EC | 0.60 | 0.64 | 0.65 |
| **Social relationships** | | | |
| ART DART | 0.64 | 0.35 | 0.41 |
| Non DART EC | 0.51 | 0.36 | 0.56 |
| **Environmental** | | | |
| ART DART | 0.74 | 0.71 | 0.72 |
| Non DART EC | 0.57 | 0.70 | 0.73 |
| **Spirituality** | | | |
| ART DART | 0.26 | 0.52 | 0.49 |
| Non DART EC | 0.48 | 0.42 | 0.42 |

In order to test for differences between groups over time, a similar model to the one tested for the MOS-HIV results, was estimated. Baseline differences across all domains were statistically significant ($p < 0.05$). The magnitude of the difference was between 0.3 to 0.95 SD. At 6 months, differences between groups favouring ART DART were significant across domains except for psychological health and spirituality, and significant differences ranged in size from 0.91 to 1.15 SD. At 12 months, only the environmental, the spirituality and the psychological domains were associated with significant and at least moderate differences (>=0.2 SD) between groups; as can be seen in Graph 7.17, ART DART had higher scores than the non-ART EC group in the environmental domain while the opposite was the case for the other two significant domains[6].

[6] The results of the modelling analysis for the WHOQOL-HIV BREF are presented in Appendix XV.

### 7.4.4 SQOLI-HIV results

The results from the SQOLI-HIV questionnaire as shown on Graphs 7.19 to 7.23 are contrary to those found with the WHOQOL-HIV BREF. A possible explanation about this is the fact that the questions included in the SQOLI-HIV were primarily targeting items that are believed to be important for HIV infected individuals and that were omitted in the WHOQOL-HIV BREF and in the MOS-HIV (Vanhems *et al,* 1996; Wu *et al,* 1997; Jelsma *et al,* 2005 and Clayson *et al,* 2006).

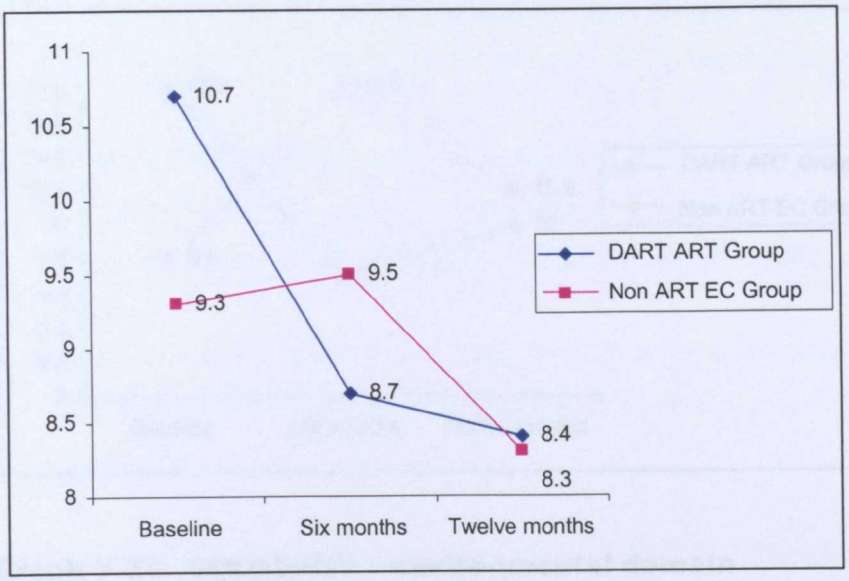
In the physical domain these items included: whether the individual have any difficulty in sleeping?; How much are you bothered by any unpleasant physical problems related to your HIV infection?; and How important is to be free of pain?. Another clear example relates to social relationships domain, where the emphasis was on assessing: if the individuals felt accepted by the people they know; if they count on family and friends; how much they felt discriminated against because of their health condition; how important was their sexual life; and how comfortable they were with their ability to provide for and support others. However, Cronbach's reliability tests for the SQOLI-HIV domains appear to be unreliable[7] (see Table 7.6). Further analysis is needed to clarify these findings.

**Table 7.6 SQOLI-HIV Cronbach's coefficient** – *both groups whole period*

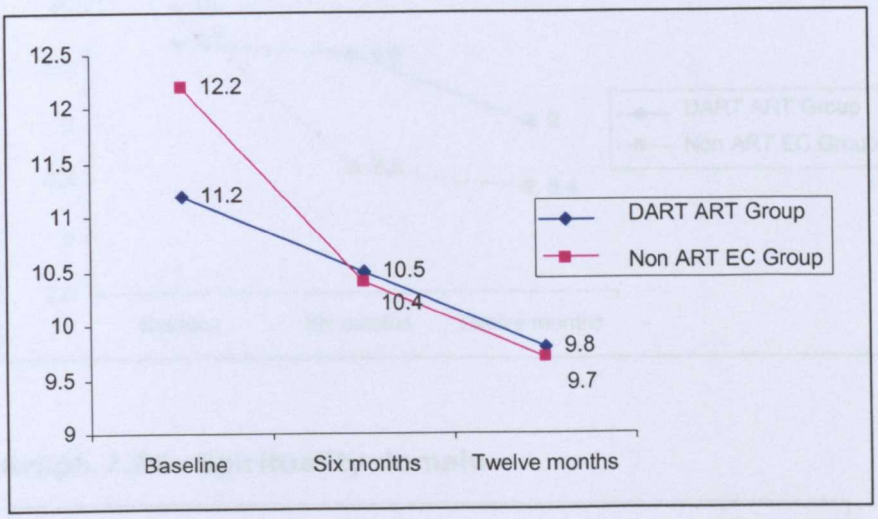
| Domain | Cronbach's coefficient | | |
|---|---|---|---|
| | Baseline | Six months | Twelve months |
| **Physical** | | | |
| ART DART | 0.20 | 0.11 | 0.48 |
| Non DART EC | 0.29 | 0.37 | 0.16 |
| **Psychological** | | | |
| ART DART | 0.61 | 0.38 | 0.32 |
| Non DART EC | 0.53 | 0.25 | 0.31 |
| **Social relationships** | | | |
| ART DART | 0.42 | 0.55 | 0.51 |
| Non DART EC | 0.40 | 0.52 | 0.41 |
| **Environmental** | | | |
| ART DART | 0.44 | 0.42 | 0.44 |
| Non DART EC | 0.42 | 0.36 | 0.28 |
| **Spirituality** | | | |
| ART DART | 0.56 | 0.48 | 0.44 |
| Non DART EC | 0.58 | 0.32 | 0.46 |

[7] Level of independence only contained one question: How important to you is to be free of dependence on medications and treatment.

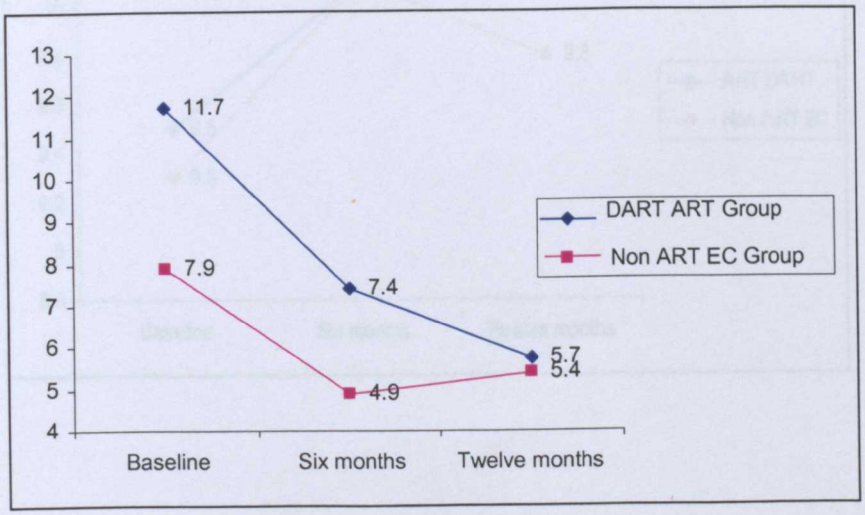
**Graph 7.19 SQOLI-HIV - physical domain**



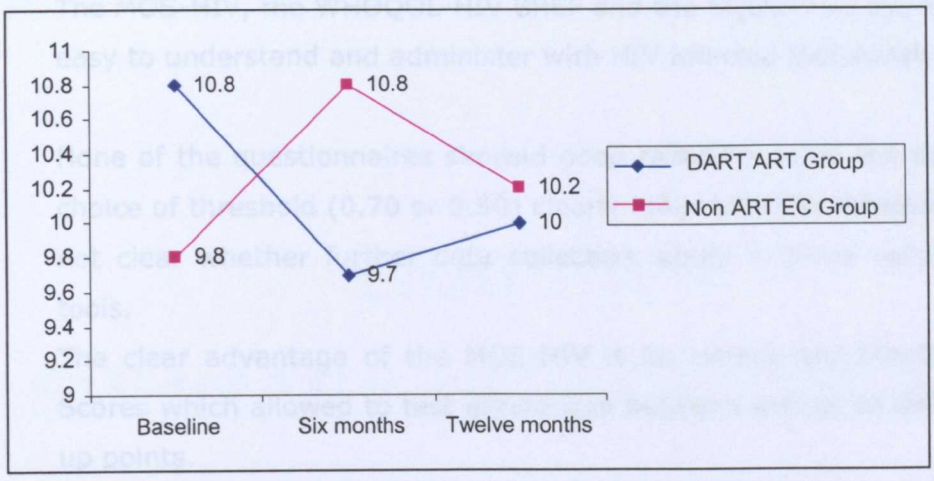

**Graph 7.20 SQOLI-HIV - psychological domain**



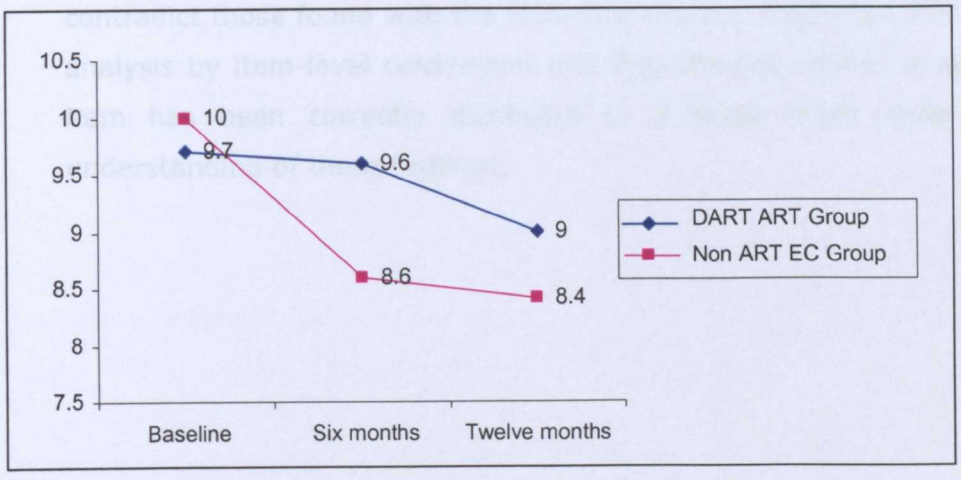

**Graph 7.21 SQOLI-HIV - level of independence domain**



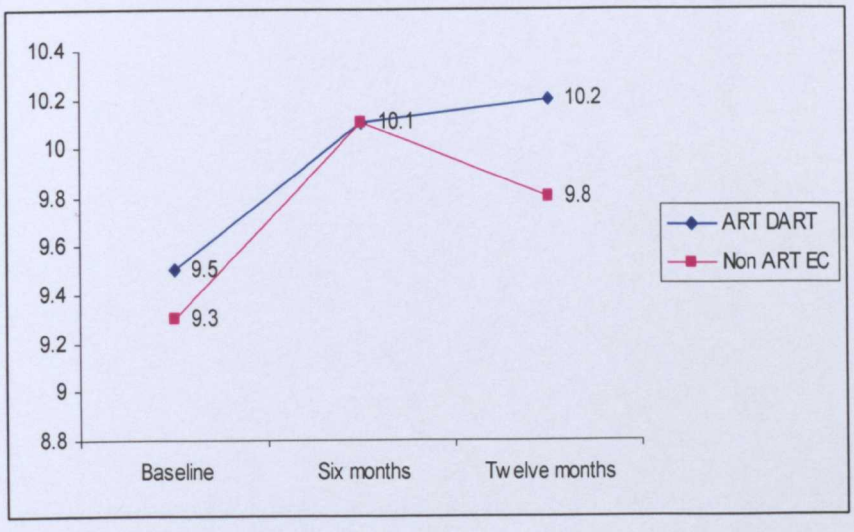
**Graph 7.22 SQOLI-HIV - social relationships domain**




**Graph 7.23 SQOLI-HIV - environmental domain**




**Graph 7.24 Spirituality domain**



## 7.5 CONCLUSIONS

- The MOS-HIV, the WHOQOL-HIV BREF and the SQOLI-HIV appeared to be easy to understand and administer with HIV infected individuals.

- None of the questionnaires showed good reliability in all the domains. The choice of threshold (0.70 or 0.50) clearly influences this interpretation. It is not clear whether further data collection would improve reliability of the tools.
- The clear advantage of the MOS-HIV is its Health and Mental Summary Scores which allowed to test differences between groups at different follow up points.

- As mentioned before the results from the SQOLI-HIV appeared to contradict those found with the MOS-HIV and the WHOQOLI-HIV BREF. Re-analysis by item-level convergent and discriminant validity to assess if an item has been correctly attributed to a scale might show a clearer understanding of these findings.

# CHAPTER 8

# SUMMARY OF RESULTS AND CONCLUSIONS

*"Some men think that their wives will abandon them when they discover that they are infected...men often have money so they buy the medicine and take it secretly... so they keep on lying to their wives" Female participant.*

## 8.1 INTRODUCTION

This chapter presents the summary of findings, discusses the results of the literature review, the Preference Elicitation and HRQoL assessments in Chapters six and seven with reference to the hypotheses presented in Chapter one. The caveats of the study and insights for further research in HIV/AIDS and HRQoL in Africa are also discussed.

## 8.2 SUMMARY OF FINDINGS

Previous studies of HRQoL in HIV/AIDS are concentrated in industrialised countries, only a handful of studies have been conducted in developing countries populations and only four have studied an African population. This is undoubtedly related to the, until recently, almost complete lack of access to ART; the availability of the treatment has converted the disease from a fatal terminal condition into a chronic one, raising the profile of quality of life outcomes as an aim of therapy.

### 8.2.1 Literature review

As shown in Chapter three, the lack of consensus with respect to a gold standard or superior instrument, disease specific and/or generic, for assessing the HRQoL of HIV infected individuals does not facilitate the choice of tool for researchers. This problem is exacerbated when the research is to be undertaken in a resource constrained setting where cross-cultural adaptation would be necessary before using any instrument.

An additional concern is the fact that the generic HRQoL results from O'Keefe and Wood (O'Keefe and Wood, 1996) have been used to convert health states into QALYs, using relative values (utilities) elicited from the UK general population by TTO[1] and SG, and then used in a cost-effectiveness analysis of a Markov model of patient survival (Pitt *et al.*, 2004; Badri *et al.*, 2006). Although the absence of utility values for African populations might tempt analysts into considering the use of utility values derived from, say, the UK or USA general population as acceptable, cost-effectiveness analyses used to inform resource allocation decisions in resource poor settings should reflect the specific preferences of the population in each country. Moreover, the same generic item may refer to completely different constructs in a developed setting from that

[1] The study by Pitt *et al.*, was not included in the review since this was an abstract presented at the International AIDS Conference in Thailand and has not been published. Nevertheless, this study reinforces the concern presented in this paragraph.

applicable to a resource poor setting. Taking mobility for example, to be bedridden in Africa i.e., without running water, no electricity in some cases and no means by which to fetch firewood is not equivalent to being bedridden in Liverpool where HIV infected individuals are supported by the NHS and the social services to keep distress to the minimum.

One way of dealing with these issues would be to develop a HRQoL questionnaire for HIV infected individuals and to test the questionnaire in several African populations. However, this exercise would be time consuming and costly.

The three disease specific instruments that have been used in this thesis are the MOS-HIV and the WHOQOL-HIV BREF and the specifically compiled SQOLI-HIV questionnaire. In addition pre-determined health states for HIV/AIDS were constructed in order to assess the performance of VAS, TTO and SG. These were chosen due to their documented psychometric properties, feasibility and relevance to the African situation.

### 8.2.2 Pilot Study

The results from the FGDs showed that ART has a positive impact on different domains of HIV-infected individuals' daily life, including reduced disease symptoms, and restored physical strength, thus enhancing their mobility and enabling them to resume their usual activities and care for themselves. It also had a positive impact on their self-esteem, giving hope and relieving them of depression and thoughts of death. Nevertheless, the positive effects of ART on the participants were limited by factors that were not related to the drug such as lack of employment and means to take care of their families. These findings confirm the multidimensional nature of *quality of life* as an outcome measure for HIV infected individuals in Uganda.

The number of participants' partners who died over this period is cause for concern. Unfortunately it is impossible to assess whether these deaths were also due to AIDS. Partner notification and, when possible, ART enrolment and care for offspring remain a challenge for ART programmes and organisations such as TASO.

The pilot study also demonstrated that asking individuals about their sexual activities tended to be intrusive and uncomfortable for both the interviewee and the interviewer. However, it is necessary to understand shifts in partnership

formation and in detecting potential areas of intervention such as further educative programmes, counselling, des-stigmatisation, etc., that programme managers may be able to strengthen in prevention, treatment or care.

### 8.2.3 Socio-demographic characteristics

An unexpected finding was the proportion of individuals from both groups that had new sexual partners. Further research with relation to the changes in sexual behaviour resulting from increased ART availability might help to address the importance of understanding the dynamics within the societies and communities affected by HIV and aid the disentanglement of operational issues in order to avert further HIV infections.

Also surprising was the high level of mobility from rural to urban areas of this population. In the long-run, these movements will necessarily affect attendance to clinic appointments, undetected side-effects in ART recipients, level of adherence, and continuity of care in general. However, it is important to recognise that, in resource-poor settings, job opportunities are concentrated primarily in urban areas. Initiatives for retracing and maintenance of monitoring for these individuals in urban areas may be ideal but will also add to the pressure exerted on the already stretched health services in urban areas.

In order to characterise the socioeconomic position of participants and their households, the theoretically relevant welfare measure is actual consumption (Deaton, 1997), which was measured as family expenditure. It was clear that not all participants from both groups were able to respond to this question and if the question was answered, it was not possible to test the reliability of the data provided. An alternative wealth-related indicator is the asset index of living standards which attempted to overcome problems of measures of consumption related to recall bias and missing data. Nevertheless, when the correlation between consumption and the asset of living standards was estimated, it showed that it was weak (i.e., 0.2 - 0.4). This weak correlation has been explained in other empirical studies by the choice of asset indicators which Moser has argued should be tailored to context specific situations (Moser, 1998). In this case, the variables that were included in the questionnaire were carefully selected and, since the results from the Non ART EC group were substantially different to those from ART DART group, the reason behind this weak correlation is unclear.

Some studies have found that the choice of welfare measure influences the results of equity analysis (Wagstaff and Watanabe, 2003). In the analysis presented in Chapter five, it was found that both consumption and the asset of living standards were consistent in their identification of the ART DART group having a more unequal distribution of welfare. So in this particular sample the choice of welfare measure did not provide different responses between the groups.

### 8.2.4 PEM tools

The difficulties of measuring individuals' preferences arise in conceptualising, measuring and obtaining comparative valuations of different levels of quality of life. Firstly, who should make such valuations and on what basis? For example, who has the 'right' to specify that one year spent in a wheelchair is only 'worth' nine months spent with full mobility? On what basis are such calculations made? Secondly, no single method has been universally accepted; theoretical debates[2] around the validity of Standard Gamble (SG) being the gold standard technique, the assumption that Time Trade-Off (TTO) is based on utility theory and the use of VAS for assessing individuals preference are still taking place. However, the decision to use TTO or SG "*needs to be informed by their respective performance on empirical grounds*" (Dolan *et al.*, 1996).

On empirical grounds, the PEM tools used in this population showed that VAS is a good warming up tool and also that both VAS and TTO have good psychometric properties. The results obtained from TTO and VAS, were in line with other empirical studies in industrialised countries (Dolan *et al,* 1996; Bayoumi and Redelmeier, 1999[3]). Nevertheless, the fact that individuals were willing to change their initial valuation after evaluating the pre-determined HIV/AIDS shows clearly that VAS is affected by the context.

Contrary to the results published for SG in this area, the results of this study showed that the majority of participants did not understand the purpose of using SG. However, this is not surprising since the use of probabilities have been shown to be a difficult when trying to elicit preferences in areas such as health, transport and environment in industrialised countries (Loomes, et al, 2002; Hey, 1995).

[2] These debates were presented in Chapter 4.
[3] Although the results of this study are lower than those presented in Bayoumi and Redelmeier, 1999.

Another point for consideration is the fact that, in this study, the upper limit or normative state used for assessing the pre-determined HIV/AIDS health state was 'improved health' and not 'full health'. In the event that the utility values from TTO or a transformation of VAS were to be used in cost-effectiveness analysis, the values would have to be scaled down to re-express them relative to full-health, the standard metric that allows comparisons with interventions in HIV/AIDS and other clinical areas.

### 8.2.5 HIV/AIDS disease specific tools

On empirical grounds none of the tools can be considered a gold standard. The fact that disease specific questionnaires such as the MOS-HIV and WHOQOL-HIV only have in common two domains might imply that the questionnaires complement each other, but even using both questionnaires would leave out important items such as sleep, sexual functioning, stigma and others that are considered important for assessing the HRQoL of HIV infected individuals (Jelsma et al, 2005).

The results from the SQoLI-HIV should be considered with caution. This was a newly designed instrument with questions reflecting a narrow approach to items that are important for HIV infected individuals that were omitted in the MOS-HIV and the WHOQOL-HIV. Although this work was done by carefully considering each item and with the guidance of a social scientist with expertise in HIV/AIDS in Uganda, it is now clear that the definition of dimensions and groupings were not adequate enough to reach reliability. This is also illustrated by the selection of only one item for the dimension of level of independence from medicines; even though it allowed assessment of how important this was for the individual, it is unclear if there are other factors influencing this dimension.

Ideally, several different versions of the same questionnaire with different items included in each of the dimensions should have been tested in order to avoid mono-method biases. These biases make in this case the results restricted to this context and population and can not be generalised to the Ugandan population of HIV infected individuals.

### 8.2.6 Research hypotheses

1. At ***baseline*** participants that have just enrolled in the DART trial are assumed to be sicker than those in the comparator group and will value their HRQoL lower.

The MOS-HIV questionnaire is more illustrative than the WHOQOL-HIV to prove this hypothesis since it provides summary scores for Physical and Mental Health instead of using only dimensions. Summary scores for physical health appear to contradict this hypothesis but observed differences between groups were negligible. The opposite applies to Mental Health Summary Score: inferential statistics and the observed direction of difference are consistent with the postulated hypothesis, while the magnitude of the difference falls between what has been described as 'small' and 'moderate' (Wu, 1996).

2. At ***twelve months*** the health improvements of ART recipients are expected to correspond with an increase in their HRQoL valuation relative to that at ***baseline***, while the comparator group in absence of treatment will have a deteriorated health and reduced HRQoL valuation.

It appeared that ART DART participants improved at twelve months as shown by the increase in average values for most of the domains of the MOS-HIV and WHOQOLI-HIV BREF questionnaires. However, multi-scale role and cognitive functioning and single items quality of life and health transition for the MOS-HIV and psychological and environmental domains for WHOQOL-HIV BREF deteriorated at twelve months for the ART DART group. In contrast, Non ART EC participants improved in all domains apart from health transition (MOS-HIV) and environmental domain (WHOQOL-HIV BREF).

It was unexpected to find the improvement on perceived HRQoL by Non ART EC participants. However, it is unclear if this can be interpreted as spontaneously changing in patients who do not receive such therapy or if Non ART EC patients were receiving cotrimoxazole or any other treatment that improved their HRQoL. However, these changes remain an open question for further investigation.

3. Sicker individuals (DART participants ***at baseline*** and Entebbe Cohort participants ***at twelve months***) will have a higher willingness to give up time and accept riskier treatment prospects in order to attain a better health state.

TTO generally conforms to the hypothesis although for some states own health assessment did not influence valuations. SG showed the opposite association to that postulated a priori among ART DART participants, whereas for the Non-DART group own health did not seem to affect preference statements. While it was observed that more than 30% of individuals changed their initial own health valuation, an examination of the robustness of findings to the substitution of the revised own health assessments for the original assessments was not undertaken here. Analysis in terms of CD4 counts instead of own health assessments showed no effect of the measurements on preference statements across both groups for all pre-determined states.

4. ***Worse health states*** are expected to be equivalent to riskier treatment gambles and associated with greater willingness from individuals to give up time in order to attain a better health state.

The results for TTO confirm the hypothesis whereas those for SG suggest a qualified concordance with it. Participants seem to have had problems discriminating between Major AIDS Defining Illness and Minor AIDS Defining Illness. Some (5 - 12%) gave valuations which implied incongruent rankings of the three pre-determined health states.

5. By ***twelve months*** better health from DART participants is expected to have a positive effect in their socio-economic status, while worse health states from the comparator group will have negatively affected their socio-economic status.

Income changes were found not statistically significant over time. Further understanding on individual's economic situation was associated with their perceived overall economic situation and quality of life. For ART DART participants this association supports the idea that increased quality of life is associated with improved overall economic situation over time. Although this was true at six months for the Non ART EC participants, at twelve months no association was found.

## 8.3 CAVEATS OF THE STUDY

One of the main limitations of this study is that the performance of PEM tools was analysed in relation to pre-determined HIV/AIDS health states and it is

unclear if this has introduced biases that would underestimate the use these tools in a resource constrained setting.

In analysing the valuations implicit in the responses to HRQoL and PEM tools, the analysis has assumed that missing data can be ignored. It remains to be explored whether the patterns of evolution in valuations over the twelve month period of follow-up is indeed a valid reflection of the course of disease in the two patient populations or whether the results are influenced by the non-response rates at 6 and 12 months, of 5% and 12%.

A strength and weakness of this study is the use of disease specific and not generic HRQoL instruments. The strength is that this study concentrates on HIV infected individuals; however, given the impact of HIV/AIDS in Africa, it would be important to know how healthy individuals perceive their quality of life and compare their statements to those of individuals that are HIV infected. Although this follows the recommendation of Skevington and O'Connell (see Chapter three; Section 3.4; p. 73) (Skevington and O'Connell, 2003).

It was not possible to capture the role that the Baganda culture played in influencing individual's answers for both disease specific and PEM tools. In addition to use surveys and in-depth interviews with study participants might allow a better understanding of responses.

## 8.4 FURTHER RESEARCH

Health Related Quality of Life research in Africa in general and specifically in the area of HIV/AIDS, is in its infancy. However, this type of assessment provides additional information that might help to understand which domains influence individual's perceptions of HRQoL.

Understanding changes in domains such as environmental and health transition might be easier to capture at household level by including in the assessment not only HIV infected individuals but also members of their household. Further research that aims to evaluate and compare the HRQoL perceptions of healthy and sick individuals in Uganda is necessary.

Including generic health states such as the one used in the EuroQol might facilitate the evaluation of PEM tools and would allow comparisons with published studies in South Africa (Hughes *et al,* 2004 and Jelsma *et al,* 2005).

Studies conducted with similar populations in different countries assessing ART provision would be necessary to fully understand the impact of ART in different societies. An additional challenge is to assess the impact that HIV/AIDS has on the HRQoL of orphan children or children living with HIV/AIDS.

# APPENDICES

## APPENDIX I
## Ethical Approvals

LIVERPOOL
SCHOOL OF
TROPICAL
MEDICINE (Affiliated to the University of Liverpool)

Pembroke Place
Liverpool L3 5QA
Telephone: 0151-708 9393
Fax: 0151-705 3370
http://www.liv.ac.uk/lstm/lstm.html

5 December 2003

Ms Antonieta Medina Lara &
Dr D Lalloo

Dear Ms Medina Lara

The research protocol **Adaptation and assessment of Health Related Quality of Life (HRQoL) instruments for people living with HIV/AIDs in Uganda** Reference No **03.60** was considered by the Research Ethics Committee on **4 December 2003.**

The committee felt that this was much need investigation. The protocol has formal Ethical Approval from the LSTM Research Ethics Committee. It is noted that you have also received confirmation that your protocol has been approved by the ethics committee in Uganda.

**Conditions of Approval**

- The approval is for a fixed period of three years or for the duration of the grant, renewable annually thereafter.
- The committee may suspend or withdraw ethical approval where it is felt appropriate.
- In accordance with International Committee on Harmonisation of Good Clinical Practice (ICH GCP) Guidelines, annual update must be provided to the committee. Failure to do so could result in suspension of the study without further notice.
- A copy of the final report should be sent to the committee
- Any serious adverse events must be reported to the committee.

Any proposed amendments to the protocols must be notified to the LSTM Research Ethics Committee for approval before implementation. (Full application is not necessary at this stage)

The Research Support Office (RSO) maintains a Database of Local Research Committees in the countries where collaborative work is being carried out. Could you, therefore, feed back to me (via Sharda Mistry in the RSO) as much information as possible on the local Committees/Review Bodies that will review (or have reviewed) this protocol. The following details would be much appreciated:

- Name
- Address
- Contact numbers or individuals (tel / fax / e-mail)
- A copy of the appropriate form or some details on the submission mechanism (including charges)
- Any details you are able to obtain on
  a) number on the committee
  b) how many lay representatives sit on the committee?

Yours sincerely,

**Dr J B S Coulter**
**Acting - Chair, Research Ethics Committee**

Tel: (256) 41 - 320631 (Director)
(256) 41 - 320385/6 (General)
Fax: (256) 41 - 320483
E-mail: arbovir@infocom.co.ug

THE REPUBLIC OF UGANDA

UGANDA VIRUS RESEARCH INSTITUTE
P. O. BOX 49, ENTEBBE (U)

**Our Ref:** GC/127
**Your Ref:**

November 28, 2003

Dr. Antonieta Medina Lara
Liverpool School of Tropical Medicine
MRC/UVRI Programme on AIDS in Uganda
Uganda Virus Research Institute
Entebbe

Dear Dr. Lara:

The Science and Ethics Committee met regarding your protocol titled "Adaptation and assessment of health related quality of life instruments for people living with HIV/AIDS in Uganda". I am pleased to inform you that the protocol has been approved.

I wish to congratulate you on this important step in beginning your research and to convey Institute clearance to conduct the study. Please remember to also submit this proposal to the Uganda National Council for Science and Technology (UNCST) for final approval and clearance using the standard format established by the council including sending all appropriate documents relevant to the protocol and payment of fees. In addition, both the UVRI Science and Ethics Committee and the UNCST require annual updates in order for the study to continue.

I wish you and your co-investigators the best of luck.

Sincerely,

Dr. Miph Musoke
**Acting Director,**
**Uganda Virus Research Institute**

Cc: Dr. Mermin, Ms. Kalibbala, Dr. Grosskurth

# Uganda National Council For Science and Technology

*(Established by Act of Parliament of the Republic of Uganda)*

*Your Ref:*.....

*Our Ref:*.....MV 842.....

*Date:*.....15 April 04.....

Dr. Antonieta Medina Lara
C/O MRC Programme UVRI
P.O Box 49
**ENTEBBE**

Dear Dr. Medina Lara,

**RE: RESEARCH PROJECT, "ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA"**

This is to inform you that the Uganda National Council for Science and Technology (UNCST) approved the above research proposal on **March 27, 2004**. The approval will expire on **March 27, 2005**. If it is necessary to continue with the research beyond the expiry date, a request for continuation should be made in writing to the Executive Secretary, UNCST.

Any problems of a serious nature related to the execution of your research project should be brought to the attention of the UNCST, and any changes to the research protocol should not be implemented without UNCST's approval except when necessary to eliminate apparent immediate hazards to the research participant(s).

This letter also serves as proof of UNCST approval and as a reminder for you to submit to UNCST timely progress reports and a final report on completion of the research project.

Yours sincerely,

Julius Ecuru
for: Executive Secretary
**UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY**

*LOCATION/CORRESPONDENCE*
*PLOT 18, KAMPALA ROAD*
*UGANDA HOUSE, 11TH FLOOR*
*P. O. BOX 6884*
*KAMPALA, UGANDA.*

*COMMUNICATION*
TEL: (256) 41-250499
FAX: (256) 41-234579
E-MAIL: uncst@starcom.co.ug
WEBSITE: http://www.uncst.go.ug

**APPENDIX IIa**
**Baseline socio-economic questionnaire – English Version**

**Date** ☐ **HRQoL ID** ☐ **Original** ☐ **2 Weeks Follow Up** ☐

**1. Age** ☐

**2. Sex**
1 ☐ Male
2 ☐ Female

**3. What is your marital status?**
1 ☐ Single
2 ☐ Married
3 ☐ Living as married
4 ☐ Separated
5 ☐ Divorced
6 ☐ Widowed

**4. What is your highest level of education?**
1 ☐ None
2 ☐ Primary
3 ☐ Secondary
4 ☐ Technical/skilled job training
5 ☐ University

**5. Place of residence**
1 ☐ Rural
2 ☐ Peri-urban
3 ☐ Urban

**6. What is your house roof made of?**
1 ☐ Thatch
2 ☐ Corrugate
3 ☐ Tiles

**7. How would you describe the condition of your house walls/roof?**
1 ☐ Poor
2 ☐ Adequate
3 ☐ Good

**8. How many rooms are there in your house?** ☐

**9.Do you have electricity (mains or generator) in your house?**
1 ☐ Yes
2 ☐ No

**10.Where do you get water?**
1 ☐ Lake
2 ☐ Well
3 ☐ Standpipe
4 ☐ Domestic tap

**11. Which of the following items are found in your house?**
***(allow for multiple answers)***
1 ☐ Fridge 5 ☐ TV
2 ☐ Radio 6 ☐ Video
3 ☐ Mobile phone 7 ☐ Bicycle
4 ☐ Motorbike 8 ☐ Car

**12.How many people live together in the same house as you (excluding visitors)?** ☐

***(If none (0) go to question 14)***

**13.Who are they?**
(allow for multiple answers)

1 ☐ Spouse/Partner
2 ☐ Brother/Sister/Cousins
3 ☐ Parents
4 ☐ Aunt/Uncle
5 ☐ Own children
6 ☐ Other people's children
7 ☐ Friend/s
8 ☐ Lodger
9 ☐ Landlord/landlady

**14. How many children have you had (your own children)?**

**15. How many children are dependent on you? (even if they are not your own)**

**16. What do you spend most of the time doing?**

1 ☐ Farming –home garden
2 ☐ Farming -other
3 ☐ Fishing
4 ☐ Labouring
5 ☐ Office job
6 ☐ Business
7 ☐ Housework
8 ☐ Looking after children
9 ☐ Looking after sick person
10 ☐ Bed ridden
11 ☐ Other (specify)

**17.What is your current employment status?**

1 ☐ Working full-time
2 ☐ Working part-time
3 ☐ Working occasionally
4 ☐ Full-time student
5 ☐ Not working due to ill health
6 ☐ Not working due to lack of employment
7 ☐ Other (specify)

**18. Approximately how much money did your family spend last month?**

**19. What was your personal income last month?**

**20.Did you have a paid job twelve months ago?**

1 ☐ Yes
2 ☐ No (Go to question 22)

**21. What was your personal typical monthly income twelve months ago?**

☐ Declined to answer
(Go to question 23)

**22. Which is the main reason for not having a paid job twelve months ago?**

1 ☐ Ill health
2 ☐ Lack of employment
3 ☐ Other (specify)

**23. Which of the following was your main mode of transport to come here?**

1 ☐ Walking
2 ☐ By boda boda bicycle
3 ☐ By boda boda motorbike
4 ☐ By bus
5 ☐ By taxi
6 ☐ Special hire
7 ☐ Private bicycle
8 ☐ Private motorbike
9 ☐ Private car
10 ☐ Other (specify)

**24. Did you spend anything on transport to come here today?**

1 ☐ Yes
2 ☐ No (go to question 26)

**25. If yes, how much did you spend on transport to come here today?**

☐ Declined to answer

**26. How long did the trip last?**

1 ☐ Less than 10 mins
2 ☐ More than 10 mins
3 ☐ More than 30 mins
4 ☐ More than 1 hr
5 ☐ More than 2 hrs
6 ☐ Other (specify)

**27. Did you miss studies or work in coming here today?**

1 ☐ Yes
2 ☐ No

**28. Did you lose any wages in coming here today?**

1 ☐ Yes
2 ☐ No

**29. Did anyone accompany you to the clinic?**

1 ☐ Yes
2 ☐ No (thanks for your participation)

**30.Who accompanied you to the clinic?**

1 ☐ Partner/Spouse
2 ☐ Child/Children
3 ☐ Other relative
4 ☐ Other (specify)

**31.What would your companion otherwise have been doing as their main activity if they had not accompanied you to the clinic?**

1 ☐ Housework
2 ☐ Childcare
3 ☐ Caring for a relative
4 ☐ Attending school
5 ☐ On sick leave
6 ☐ Seeking work
7 ☐ Paid work
8 ☐ Other (specify)

**APPENDIX IIa**
**Baseline socio-economic questionnaire – Luganda Version**

| Date | DD/MM/YY | HRQoL ID | | Original ☐ | 2Weeks Follow Up ☐ |
|---|---|---|---|---|---|

**1. Emyaka** ☐

**2. Muntu ki?**
1 ☐ Musajja
2 ☐ Mukazi

**3. Oli mufumbo?**
1 ☐ Ndi wa bussa
2 ☐ Ndi mufumbo
3 ☐ Tubera fembi naye tetuli bafumbo
4 ☐ Twayawukana
5 ☐ Nanoba
6 ☐ Namwandu/ Semwandu

**4. Wakoma mu kibina kya kumekka?**
1 ☐ Sasoma n'akamu
2 ☐ Pulayimale
3 ☐ Siniya
4 ☐ Tekiniko/ essomero ly'eby'mikono
5 ☐ Yunivasite

**5. Obeera wa?**
1 ☐ Kyalo
2 ☐ Simukyalo ate si mu kibuga
3 ☐ Mu kibuga

**6. Enyumba yo bagiseeresa ki?**
1 ☐ Subi
2 ☐ Mabaati
3 ☐ Mategula

**7. Ebisenge ne nsereka ye nyumba yo obyogerako otya?**
1 ☐ Mbi
2 ☐ Emala
3 ☐ Nungi

**8. Enyumba yo erina ebisenge bimekka?** ☐

**9.Orina amasanyalazze (aga UEB oba jenereta) mu nyumba yo?**
1 ☐ Yee
2 ☐ Nedda

**10. Amazzi ogagya wa?**
1 ☐ Ku nyanja
2 ☐ Ku luzzi
3 ☐ Tapu eri ebweru w'enyumba
4 ☐ Tapu eri mu nyumba

**11. Ku bintu bino, biriwa ebiri mu nju yo?**
(ansa ziyinza okusuka mw'emu)

| | | | |
|---|---|---|---|
| 1 ☐ | Firigi | 5 ☐ | T.V |
| 2 ☐ | Radiyo | 6 ☐ | Vidiyo |
| 3 ☐ | Akasimu k'omungalo | 7 ☐ | Eggali |
| 4 ☐ | Pikipiki | 8 ☐ | Emotoka |

**12. Bantu bamekka ababeera mu nyumba mwosula (nga tobaliddemu abagenyi?**
*(Answer bweba TEWALI N'OMU (0), genda ku kibuuzo 14)*

☐

**13. Be bani?**
(ansa ziyinza okusuka mw'emu)
1 ☐ Mwami/Mukyala wange
2 ☐ Baganda bange
3 ☐ Bazzade
4 ☐ Senga/Kojja/mama omuto/ tata omuto
5 ☐ Abaana bange
6 ☐ Abaana bantu abalala
7 ☐ Mikwano gyange
8 ☐ Omupangisa
9 ☐ Landilodi

**14. Ozadde abaana bamekka?**

**15. Abaana bamekka bolabirira wadde si gwe abazaala?**

**16. Obudde bwo obusinga obumala okola ki?**
1 ☐ Nima ewaka
2 ☐ Nimira abantu abalala
3 ☐ Nvuba
4 ☐ Mpakasa
5 ☐ Nkola mu ofisi
6 ☐ Nsubula
7 ☐ Nkola egy'awaka
8 ☐ Ndabira baana
9 ☐ Ndabirira mulwadde
10 ☐ Nsiibba mu buliri olw'obulwadde
11 ☐ Ekirala (kiwandike wo)

**18. Amakka go gasasanya sente nga mekka omwezi oguwedde?**

**19. Wayingiza sente mekka omwezi oguwedde?**

**20. Walina omulimo omwaka gumu emabegga?**
1 ☐ Yee
2 ☐ Nedda (Genda ku 22)

**21. Wali ofuna sente mekka buli mwezi, omwaka gumu emabegga?**
☐ Yaganye okuddamu
(Genda ku kibuuzo 23)

**22. Nsonga ki enkulu lwaki tewalina mulimo omwaka gumu emabega?**
1 ☐ Bulwadde
2 ☐ Nabulwa omulimo
3 ☐ Ekirala (kiwandike wo)

**23. Kuzino, eri wa eyabadde entambula enkulu gyewakozeseza okugya wano?**
1 ☐ Kutambula
2 ☐ Boda y'akagali
3 ☐ Boda y'epiki
4 ☐ Baasi
5 ☐ Taxi
6 ☐ Specilo
7 ☐ Eggali yange
8 ☐ Epiki piki yange
9 ☐ Emotoka yange
10 ☐ Ekirala (kiwandike wo)

**24.Olina kyewasasanyiza kuntambula?**

1 ☐ Yee
2 ☐ Nedda (genda ku 26)

**25. Oba yee, wasasanyiza sente mekka kuntambula?**

☐ Yaganye okuddamu

**26. Olugendo lwa badde lwa sawa mekka?**

1 ☐ Eddakika ezitawera 10
2 ☐ Eddakika ezisuka 10
3 ☐ Eddakika ezizuka 30
4 ☐ Okusoba mu sawa emu
5 ☐ Okusoba mu sawa biiri
6 ☐ Ekirala (kiwandike wo)

**27. Ofiriddwa emirimo gyo oba okusoma bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**28. Ofiridwa omusala bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**29. Waliwo akuwerekedde ku dwaliro?**

1 ☐ Yee
2 ☐ Nedda (Webale okuddamu ebibuuzo)

**30. Ani akuwelekedde ku dwaliro?**

1 ☐ Mwami/mukyala wange
2 ☐ Omwana/abaana bange
3 ☐ Abenganda abalala
4 ☐ Ekirala (kiwandike wo)

**31. Oyo akuwelekedde yandibadde akola ki ekikulu singa takuwelekedde ku dwaliro?**

1 ☐ Akola emirimo egy'awakka
2 ☐ Alabirira abaana
3 ☐ Alabirira abenganda
4 ☐ Asoma
5 ☐ Afunye livu olw'obulwadde
6 ☐ Anonya mulimo
7 ☐ Akola mulimo nebamusasula
8 ☐ Ekirala (kiwandike wo)

**APPENDIX IIa**
**Six months follow up socio-economic questionnaire – English Version**

**Date** ☐ **HRQoL ID** ☐ **6 months FUP** ☐ **2 Weeks FUP** ☐

**1. Age:** ☐

**2. Sex:**
1 ☐ Male
2 ☐ Female

**3. What is your marital status**
1 ☐ Single
2 ☐ Married
3 ☐ Living as married
4 ☐ Separated
5 ☐ Divorced
6 ☐ Widowed

**4. Are you abstaining from having sex?**
1 ☐ Yes
2 ☐ No

**5. What is your highest level of education?**
1 ☐ None
2 ☐ Primary incomplete
3 ☐ Primary complete
4 ☐ Secondary incomplete
5 ☐ Secondary complete
6 ☐ Technical/skilled job training
7 ☐ University incomplete
8 ☐ University complete
9 ☐ Postgraduate studies

6. Place of residence.
1 ☐ Rural
2 ☐ Peri-urban
3 ☐ Urban

**7. What is your house roof made of?**
1 ☐ Thatch
2 ☐ Corrugate
3 ☐ Tiles

**8. What is your house floor made of?**
1 ☐ Mud
2 ☐ Cement
3 ☐ Tiles

**9. Do you have access to clean water?**
1 ☐ Yes
2 ☐ No
3 ☐ Don't know

**10. Where do you get water?**
1 ☐ Lake
2 ☐ Well
3 ☐ Standpipe
4 ☐ Domestic tap

**11. How long does it take you to get to the water source?**
1 ☐ Less than 10 mins
2 ☐ More than 10 mins
3 ☐ More than 30 mins
4 ☐ More than 1 hr
77 ☐ Other (specify)
☐

**12. What type of toilet does the house you are living in have?**

1 ☐ None
2 ☐ Flush to sewer
3 ☐ Flush to septic tank
4 ☐ Bucket
5 ☐ Covered pit latrine
6 ☐ Uncovered pit latrine
7 ☐ Ventilation improved pit latrine
77 ☐ Other (specify)

**13. How many rooms are there in the house you are living in?**

**14. Which of the following items are found in your house? (Allow for multiple answers)**

1 ☐ Fridge
2 ☐ Radio
3 ☐ Mobile phone
4 ☐ Motorbike
5 ☐ TV
6 ☐ Video
7 ☐ Bicycle
8 ☐ Car

**15. How many adults live together in the same house as you (excluding visitors)? (If none (0) go to question 17)**

**16. Who are they? (Allow for multiple answers)**

1 ☐ Spouse/Partner
2 ☐ Brother/Sister/Cousins
3 ☐ Parents
4 ☐ Aunt/Uncle
5 ☐ Own children
6 ☐ Other people's children
7 ☐ Friend/s
8 ☐ Lodger
9 ☐ Landlord/landlady

**17. How many children live in the house you are living in?**

**18. How many children are dependent on you? (even if they are not your Own)?**

**19. How many people living in the house you are living in contribute to the household income?**

**20. How many people not living in the house you are living in contribute in the household income?**

**21. Who contributes most to household income?**

**22. What is your current employment status?**

1 ☐ Working full-time
2 ☐ Working part-time
3 ☐ Working occasionally
4 ☐ Full-time student
5 ☐ Not working due to ill health
6 ☐ Not working due to lack of employment
77 ☐ Other (specify)

**23. What do you spend most of the time doing?**

1 ☐ Farming –home garden
2 ☐ Farming -other
3 ☐ Fishing
4 ☐ Labouring
5 ☐ Office job
6 ☐ Business
7 ☐ Housework
8 ☐ Looking after children
9 ☐ Looking after sick person
10 ☐ Bed ridden
77 ☐ Other (specify)

**24. Approximately how much money did your family spend last month?**

**25. What was your personal income last month?**

**26.Did you have a paid job six months ago?**

1 ☐ Yes
2 ☐ No (Go to question 28)

**27. What was your personal typical monthly income six months ago?**

☐ Declined to answer (Go to question 29)

**28. Which is the main reason for not having a paid job six months ago?**

1 ☐ Ill health
2 ☐ Lack of employment
77 ☐ Other (specify)

**29. Have you looked for a job in the last six months?**

1 ☐ Yes (go to question 31)
2 ☐ No

**30. What was the main reason for not looking for a job?**

1 ☐ Ill health
2 ☐ Lack of employment
77 ☐ Other (specify)

**31. Which of the following was your main mode of transport to come here?**

1 ☐ Walking
2 ☐ By boda boda bicycle
3 ☐ By boda boda motorbike
4 ☐ By bus
5 ☐ By taxi
6 ☐ Special hire
7 ☐ Private bicycle
8 ☐ Private motorbike
9 ☐ Private car
77 ☐ Other (specify)

**32. Did you spend anything on transport to come here today?**

1 ☐ Yes
2 ☐ No (go to question 34)

**33. If yes, how much did you spend on transport to come here today?**

☐ **Declined to answer**

**34. How long did the trip last?**

1 ☐ Less than 10 mins
2 ☐ More than 10 mins
3 ☐ More than 30 mins
4 ☐ More than 1 hr
5 ☐ More than 2 hrs
77 ☐ Other (specify)

**35. Did you miss studies or work in coming here today?**

1 ☐ Yes
2 ☐ No

**36. Did you lose any wages in coming here today?**

1 ☐ Yes
2 ☐ No(Go to question 38)

**37. If so, how much?**

☐ Don't know

**38. Did anyone accompany you to the clinic today?**

1 ☐ Yes
2 ☐ No (Go to question 42)

**39. Who accompanied you to the clinic today?**

1 ☐ Partner/Spouse
2 ☐ Child/Children
3 ☐ Other relative
77 ☐ Other (specify)

**40.What would your companion be doing as a main activity if he/she had not accompanied you to the clinic today?**

1 ☐ Housework
2 ☐ Childcare
3 ☐ Caring for a relative
4 ☐ Attending school
5 ☐ On sick leave
6 ☐ Seeking work
7 ☐ Paid work
77 ☐ Other (specify)

**41. Did your companion lose wages in coming here today?**

1 ☐ Yes
2 ☐ No

**42.How do you compare your overall economic situation now with six months ago?**

1 ☐ Improved
2 ☐ Stayed the same
3 ☐ Deteriorated

**43.How do you feel about your QoL since the last six months?**

1 ☐ Improved
2 ☐ Stayed the same
3 ☐ Deteriorated

**44. Why do you feel that your QoL has improved/stayed the same/deteriorated?**

**APPENDIX IIa**
**Six months follow up socio-economic questionnaire – Luganda Version**

| Date | | HRQoL ID | | 6months FUP ☐ | 2 Week FUP 6months ☐ |
|---|---|---|---|---|---|

**1. Emyaka** ☐

**2. Muntu ki?**
1 ☐ Musajja
2 ☐ Mukazi

**3. Oli mufumbo?**
1 ☐ Ndi wa bussa
2 ☐ Ndi mufumbo
3 ☐ Tubera fembi naye tetuli bafumbo
4 ☐ Twayawukana
5 ☐ Nanoba
6 ☐ Namwandu/ Semwandu

**4. Wewala ekikolwa eky'obufumbu?**
1 ☐ Yee
2 ☐ Nedda

**5. Wakoma mu kibina kya kumekka?**
1 ☐ Sasoma n'akamu
2 ☐ Samalako Pulayimale
3 ☐ Namalako Pulayimale
4 ☐ Samalako Siniya
5 ☐ Namalako Siniya
6 ☐ Tekiniko/ essomero ly'eby'mikono
7 ☐ Samalako Yunivasite
8 ☐ Namalako Yunivasite
9 ☐ Neyongerayo nga maze Yunivasite

**6. Obeera wa?**
1 ☐ Kyalo
2 ☐ Simukyalo ate si mu kibuga
3 ☐ Mu kibuga

**7. Enyumba yo bagiseeresa ki?**
1 ☐ Subi
2 ☐ Mabaati
3 ☐ Mategula

**8. Omwaliriro gwe nyumba yo gufunana gutya?**
1 ☐ Budongo
2 ☐ Sementi
3 ☐ Mategula

**9. Osobola okufuna amazzi agatukula?**
1 ☐ Yee
2 ☐ Nedda
3 ☐ Simanyi

**10. Amazzi ogagya wa?**
1 ☐ Ku nyanja
2 ☐ Ku luzzi
3 ☐ Tapu eri ebweru w'enyumba
4 ☐ Tapu eri mu nyumba

**11. Kikutwalira edakika mekka okutuka wogya amazzi?**
1 ☐ Eddakika ezitawera 10
2 ☐ Eddakika ezisuka 10
3 ☐ Eddakika ezizuka 30
4 ☐ Okusoba mu sawa emu
77 ☐ Ekirala (kiwandike wo)

**12. Enyumba mw'osula erina kabuyonjo efanana etya?**

1 ☐ Teyina kabuyonjo
2 ☐ Y'amazzi go sikka negagenda mu muffulejje
3. ☐ Y'amazzi go sikka negagenda mu muffulejje
4. ☐ Kadoli
5. ☐ Ey'ekinya erina ekibikako
6. ☐ Ey'ekinya etarina kibikako
7. ☐ Ey'ekinya enongosemu
77 ☐ Ekirala (kiwandike wo)

**13. Enyumba yo erina ebisenge bimekka?**

**14. Ku bintu bino, biriwa ebiri mu nju yo?**

1 ☐ Firigi
2 ☐ Radiyo
3 ☐ Akasimu k'omungalo
4 ☐ Pikipiki
5 ☐ T.V
6 ☐ Vidiyo
7 ☐ Eggali
8 ☐ Emotoka

**15. Bantu abakulu bamekka ababeera mu nyumba mwosula (nga tobaliddemu abagenyi?**
*(Answer bweba TEWALI N'OMU (0), genda ku kibuuzo 17)*

**16. Be bani?** (Allow for multiple answers)

1 ☐ Mwami/Mukyala wange
2 ☐ Baganda bange
3 ☐ Bazzade
4 ☐ Senga/Kojja/mama omuto/ tata omuto
5 ☐ Abaana bange
6 ☐ Abaana bantu abalala
7 ☐ Mikwano gyange
8 ☐ Omupangisa
9 ☐ Landilodi

**21. Ani asinga okuwayo eri enyingiza ye nyumba?**

**22. Olina omulimo kati?**

1 ☐ Nkola buli lunaku
2 ☐ Nkola kitunda kya lunaku
3 ☐ Nkola lumu na lumu
4 ☐ Nsoma
5 ☐ Sikola olw'obulwadde
6 ☐ Sikola kubanga sirina mulimo
77 ☐ Ekirala (kiwandike wo)

**23. Obudde bwo obusinga obumala okola ki?**

1 ☐ Nima ewaka
2 ☐ Nimira abantu abalala
3 ☐ Nvuba
4 ☐ Mpakasa
5 ☐ Nkola mu ofisi
6 ☐ Nsubula
7 ☐ Nkola egy'awaka
8 ☐ Ndabira baana
9 ☐ Ndabirira mulwadde
10 ☐ Nsiibba mu buliri olw'obulwadde
77 ☐ Ekirala (kiwandike wo)

**24. Amakka go gasasanya sente nga mekka omwezi oguwedde?**

**25. Wayingiza sente mekka omwezi oguwedde?**

**26. Walino omulimo emyezi mukagga emabegga?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 28)

**27. Wali ofuna sente mekka emyezi mukagga emabegga?**

☐ Yaganye okuddamu (Genda ku kibuuzo 29)

**28. Nsonga ki enkulu lwaki tewalina mulimo omwaka gumu emabega?**

1 ☐ Bulwadde
2 ☐ Nabulwa omulimo
77 ☐ Ekirala (kiwandike wo)

**29. Ononyeza omulimo mu myezi mukagga egiyise?**

1 ☐ Yee (Genda ku kibuuzo 31)
2 ☐ Nedda

**30. Nsonga ki enkulu lwaki tononyeza mulimo?**

1 ☐ Bulwadde
2 ☐ Nabulwa omulimo
77 ☐ Ekirala (kiwandike wo)

**31. Kuzino, eri wa eyabadde entambula enkulu gyewakozeseza okugya wano?**

1 ☐ Kutambula
2 ☐ Boda y'akagali
3 ☐ Boda y'epiki
4 ☐ Baasi
5 ☐ Taxi
6 ☐ Specilo
7 ☐ Eggali yange
8 ☐ Epiki piki yange
9 ☐ Emotoka yange
77 ☐ Ekirala (kiwandike wo)

**32. Olina kyewasasanyiza kuntambula gye wakozeseza okugya wano leero?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 34)

**33. Oba yee, wasasanyiza sente mekka kuntambula gye wakozeseza okugya wano leero?**

☐ Yaganye okuddamu

**34. Olugendo lwa badde lwa sawa mekka?**

1 ☐ Eddakika ezitawera 10
2 ☐ Eddakika ezisuka 10
3 ☐ Eddakika ezizuka 30
4 ☐ Okusoba mu sawa emu
5 ☐ Okusoba mu sawa biiri
77 ☐ Ekirala (kiwandike wo)

**35. Ofiriddwa emirimo gyo oba okusoma bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**36. Offiridwa omusala gwona bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 38)

**37. Oba yee, omusala gwenkana wa?**

☐ Simanyi

**38. Waliwo akuwerekedde ku dwaliro leero?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 42)

**39. Ani akuwelekedde ku dwaliro leero?**

1 ☐ Mwami/mukyala wange
2 ☐ Omwana/abaana bange
3 ☐ Abenganda abalala
77 ☐ Ekirala (kiwandike wo)

**40. Oyo akuwelekedde yandibadde akola ki ekikulu singa takuwelekedde ku dwaliro leero?**

1 ☐ Akola emirimo egy'awakka
2 ☐ Alabirira abaana
3 ☐ Alabirira abenganda
4 ☐ Asoma
5 ☐ Afunye livu olw'obulwadde
6 ☐ Anonya mulimo
7 ☐ Akola mulimo nebamusasula
77 ☐ Ekirala (kiwandike wo)

**41. Oyo akuwerekedde affiridwa omusala gwona bwazze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**42. Ebyensimbi byo leero obigerageranya otya ne bwebyali emyezi mukaga emabegga?**

1 ☐ Bilongose
2 ☐ Bisigadde kyekimu
3 ☐ Biyononese

**43. Embeera y'obulamu bwo ogigera geranya otya ne bweyali emyezi mukaga emabegga?**

1 ☐ Elongose
2 ☐ Esigadde kyekimu
3 ☐ Eyononese

**44. Lwaki olowoza embeera y'obulamu bwo elongose/ esigadde kyekimu/ eyononese?**

**APPENDIX IIa**
**Twelve months follow up socio-economic questionnaire – English Version**

| Date | | HRQoL ID | | 2 months FUP ☐ | 2Week FUP 12 months ☐ |
|---|---|---|---|---|---|

**1. Age** ☐

**2. Sex:**
1 ☐ Male
2 ☐ Female

**3. What is your marital status?**
1 ☐ Single
2 ☐ Married
3 ☐ Living as married
4 ☐ Separated
5 ☐ Divorced
6 ☐ Widow

**4. What is your highest level of education?**
3 ☐ Primary complete
4 ☐ Secondary incomplete
5 ☐ Secondary complete
6 ☐ Technical/skilled job training
7 ☐ University incomplete
8 ☐ University complete
9 ☐ Postgraduate studies

**5. Place of residence.**
1 ☐ Rural
2 ☐ Peri-urban
3 ☐ Urban

**6. What is your house roof made of?**
1 ☐ Thatch
2 ☐ Corrugate
3 ☐ Tiles

**7. What is your house floor made of?**
1 ☐ Mud
2 ☐ Cement
3 ☐ Tiles

**8. Do you have access to clean water?**
1 ☐ Yes
2 ☐ No
3 ☐ Don't know

**9. Where do you get water?**
1 ☐ Lake
2 ☐ Well
3 ☐ Standpipe
4 ☐ Domestic tap

**10. How long does it take you to get to the water source?**
1 ☐ Less than 10 mins
2 ☐ More than 10 mins
3 ☐ More than 30 mins
4 ☐ More than 1 hr
77 ☐ Other (specify)
☐

**11. Do you have electricity (mains or generator) in your house?**
1 ☐ Yes
2 ☐ No

**12. What type of toilet does the house you are living in have?**

1 ☐ None
2 ☐ Flush to sewer
3 ☐ Flush to septic tank
4 ☐ Bucket
5 ☐ Covered pit latrine
6 ☐ Uncovered pit latrine
7 ☐ Ventilation improved pit latrine
77 ☐ Other (specify)

**13. How many rooms are there in the house you are living in?**

**14.1 Which of the following items are found in your house? (Allow for multiple answers)**

1 ☐ Fridge
2 ☐ Radio
3 ☐ Mobile phone
4 ☐ Motorbike
5 ☐ TV
6 ☐ Video
7 ☐ Bicycle
8 ☐ Car

**14.2Do you own a mobile phone?**

1 ☐ Yes
2 ☐ No

**14.3 What type of radio does the house that you live in have?**

1 ☐ Full system
2 ☐ Medium
3 ☐ Individual

**15. How many adults live together in the same house as you (excluding visitors)? (If none (0) go to question 18)**

**16. Who are they? (Allow for multiple answers)**

1 ☐ Spouse/Partner
2 ☐ Brother/Sister/Cousins
3 ☐ Parents
4 ☐ Aunt/Uncle
5 ☐ Own children
6 ☐ Other people's children
7 ☐ Friend/s
8 ☐ Lodger
9 ☐ Landlord/landlady
77 ☐ Other (specify)

**17. Who of the people that live in the house you are living in contribute to the household income?**

1 ☐ Spouse/Partner
2 ☐ Brother/Sister/Cousins
3 ☐ Parents
4 ☐ Aunt/Uncle
5 ☐ Own children
6 ☐ Other people's children
7 ☐ Friend/s
8 ☐ Lodger
9 ☐ Landlord/landlady
77 ☐ Other (specify)

**18. Who of the people that do not live in the house you are living in contribute to the household income?**

1 ☐ Spouse/Partner
2 ☐ Brother/Sister/Cousins
3 ☐ Parents
4 ☐ Aunt/Uncle
5 ☐ Own children
6 ☐ Other people's children
7 ☐ Friend/s
8 ☐ Lodger
9 ☐ Landlord/landlady
77 ☐ Other (specify)

**19. How many children live in the house you are living in?**

**20. How many children are dependent on you? (even if they are not your Own)?**

**21. What do you spend most of the time doing? Obudde bwo obusinga obumala okola ki?**

1 ☐ Farming –home garden
2 ☐ Farming -other
3 ☐ Fishing
4 ☐ Labouring
5 ☐ Office job
6 ☐ Business
7 ☐ Housework
8 ☐ Looking after children
9 ☐ Looking after sick person
10 ☐ Bed ridden
77 ☐ Other (specify)

**22. What is your current employment status?**

1 ☐ Working full-time
2 ☐ Working part-time
3 ☐ Working occasionally
4 ☐ Full-time student
5 ☐ Not working due to ill health
6 ☐ Not working due to lack of employment
77 ☐ Other (specify)

**23. In general, how many hours do you work per day?**

**24. What was your personal income last month?**

**25. How many days in the past month have you been unable to work due to ill health?**

**26. Approximately how much money did your family spend last month?**

**27.How do you compare your overall economic situation now with six months ago?**

1 ☐ Improved
2 ☐ Stayed the same
3 ☐ Deteriorated

**28.Did you have a paid job six months ago?**

1 ☐ Yes (Go to question 32)
2 ☐ No

**29. Which is the main reason for not having a paid job six months ago?**

1 ☐ Ill health
2 ☐ Lack of employment (Go to 30)
77 ☐ Other (specify)

**30. Was your HIV status the reason for not being employed six months ago?**

1 ☐ Yes
2 ☐ No

**31. Has your ill health preventing you from looking for a job?**

1 ☐ Yes
2 ☐ No

**32. Which of the following was your main mode of transport to come here?**

1 ☐ Walking
2 ☐ By boda boda bicycle
3 ☐ By boda boda motorbike
4 ☐ By bus
5 ☐ By taxi
6 ☐ Special hire
7 ☐ Private bicycle
8 ☐ Private motorbike
9 ☐ Private car
77 ☐ Other (specify)

**33. If yes, how much did you spend on transport to come here today?**

☐ Declined to answer

**34. How long did the trip last?**

1 ☐ Less than 10 mins
2 ☐ More than 10 mins
3 ☐ More than 30 mins
4 ☐ More than 1 hr
5 ☐ More than 2 hrs
77 ☐ Other (specify)

**35. Did you miss studies or work in coming here today?**

1 ☐ Yes
2 ☐ No

**36. Did you lose any wages in coming here today?**

1 ☐ Yes
2 ☐ No (Go to question 38)

**37. If so, how much?**

☐ Don't know

**38. Did anyone accompany you to the clinic today?**

1 ☐ Yes
2 ☐ No (Go to question 42)

**39. Who accompanied you to the clinic today?**

1 ☐ Partner/Spouse
2 ☐ Child/Children
3 ☐ Other relative
77 ☐ Other (specify)

**40. What would your companion be doing as a main activity if he/she had not accompanied you to the clinic today?**

1 ☐ Housework
2 ☐ Childcare
3 ☐ Caring for a relative
4 ☐ Attending school
5 ☐ On sick leave
6 ☐ Seeking work
7 ☐ Paid work
77 ☐ Other (specify)

**41. Did your companion lose wages in coming here today?**

1 ☐ Yes
2 ☐ No

**42. Are you abstaining from having sex?**

1 ☐ Yes
2 ☐ No

**43.How do you feel about your QoL since the last six months?**

1 ☐ Improved
2 ☐ Stayed the same
3 ☐ Deteriorated

**44. Why do you feel that your QoL has improved/stayed the same/deteriorated?**

**45. What tribe are you?**

1 ☐ Muganda
2 ☐ Munyankole
3 ☐ Luo/Acholi
4 ☐ Mugisu/Musoga
77 ☐ Other (specify)

**46. To what religion do you belong?**

1 ☐ Protestant
2 ☐ Roman Catholic
3 ☐ Born again Christian
4 ☐ Muslim
77 ☐ Other (specify)

**APPENDIX IIa**
**Twelve months follow up socio-economic questionnaire – Luganda version**

**Date** ☐ **HRQoL ID** ☐ **12months FUP** ☐ **2Week FUP12months** ☐

**1. Emyaka** ☐

**2. Muntu ki?**
1 ☐ Musajja
2 ☐ Mukazi

**3. Oli mufumbo?**
1 ☐ Ndi wa bussa
2 ☐ Ndi mufumbo
3 ☐ Tubera fembi naye tetuli bafumbo
4 ☐ Twayawukana
5 ☐ Nanoba
6 ☐ Namwandu/ Semwandu

**4. Wakoma mu kibina kya kumekka?**
1 ☐ Sasoma n'akamu
2 ☐ Samalako Pulayimale
3 ☐ Namalako Pulayimale
4 ☐ Samalako Siniya
5 ☐ Namalako Siniya
6 ☐ Tekiniko/ essomero ly'eby'mikono
7 ☐ Samalako Yunivasite
8 ☐ Namalako Yunivasite
9 ☐ Neyongerayo nga maze Yunivasite

**5. Obeera wa?**
1 ☐ Kyalo
2 ☐ Simukyalo ate si mu kibuga
3 ☐ Mu kibuga

**6. Enyumba yo bagiseeresa ki?**
1 ☐ Subi
2 ☐ Mabaati
3 ☐ Mategula

**7. Omwaliriro gwe nyumba yo gufunana gutya?**
1 ☐ Budongo
2 ☐ Sementi
3 ☐ Mategula

**8. Osobola okufuna amazzi agatukula?**
1 ☐ Yee
2 ☐ Nedda
3 ☐ Simanyi

**9. Amazzi ogagya wa?**
1 ☐ Ku nyanja
2 ☐ Ku luzzi
3 ☐ Tapu eri ebweru w'enyumba
4 ☐ Tapu eri mu nyumba

**10. Kikutwalira edakika mekka okutuka wogya amazzi?**
1 ☐ Eddakika ezitawera 10
2 ☐ Eddakika ezisuka 10
3 ☐ Eddakika ezizuka 30
4 ☐ Okusoba mu sawa emu
77 ☐ Ekirala (kiwandike wo)
☐

**11. Orina amasanyalazze (aga UEB oba jenereta) mu nyumba yo?**
1 ☐ Yee
2 ☐ Nedda

**12. Enyumba mw'osula erina kabuyonjo efanana etya?**

1. ☐ Teyina kabuyonjo
2. ☐ Y'amazzi go sikka negagenda mu muffulejje
3. ☐ Y'amazzi go sikka negagenda mu muffulejje
4. ☐ Kadoli
5. ☐ Ey'ekinya erina ekibikako
6. ☐ Ey'ekinya etarina kibikako
7. ☐ Ey'ekinya enongosemu

77 ☐ Ekirala (kiwandike wo)

**13. Enyumba yo erina ebisenge bimekka?**

**14.1 Ku bintu bino, biriwa ebiri mu nju yo?**

1 ☐ Firigi
2 ☐ Radiyo
3 ☐ Akasimu k'omungalo
4 ☐ Pikipiki
5 ☐ T.V
6 ☐ Vidiyo
7 ☐ Eggali
8 ☐ Emotoka

**14.2 Oyina esiimu ey'omungalo?**

1 ☐ Yee
2 ☐ Nedda

**14.3 Radio eri munju mw'obeera efaanana etya?**

1 ☐ Nenne ya mizindalo
2 ☐ Ntono ntono, ya kumezza
3 ☐ Katono, kamungalo

15. **Bantu abakulu bamekka ababeera mu nyumba mwosula (nga tobaliddemu abagenyi?** *(Answer bweba TEWALI N'OMU (0), genda ku kibuuzo 18)*

**16. Be bani?** (Bonna bawandike)

1 ☐ Mwami/Mukyala wange
2 ☐ Baganda bange
3 ☐ Bazzade
4 ☐ Senga/Kojja/mama omuto/ tata omuto
5 ☐ Abaana bange
6 ☐ Abaana bantu abalala
7 ☐ Mikwano gyange
8 ☐ Omupangisa
9 ☐ Landilodi

77 ☐ Omulala (Muwandike wo)

**17. Ani ku bantu ababera mu nyumba mw'osula abawayo eri enyingiza ye nyumba eyo?**

1 ☐ Mwami/Mukyala wange
2 ☐ Baganda bange
3 ☐ Bazzade
4 ☐ Senga/Kojja/mama omuto/ tata omuto
5 ☐ Abaana bange
6 ☐ Abaana bantu abalala
7 ☐ Mikwano gyange
8 ☐ Omupangisa
9 ☐ Landilodi

77 ☐ Omulala (Muwandike wo)

**18. Ani ku bantu abatabera mu nyumba mwosula abawayo eri enyingiza ye nyumba eyo?**

1 ☐ Mwami/Mukyala wange
2 ☐ Baganda bange
3 ☐ Bazzade
4 ☐ Senga/Kojja/mama omuto/ tata omuto
5 ☐ Abaana bange
6 ☐ Abaana bantu abalala
7 ☐ Mikwano gyange
8 ☐ Omupangisa
9 ☐ Landilodi
77 ☐ Omulala (Muwandike wo))

**19. Abaana bamekka ababeera mu nyumba mwosula?**

**20. Abaana bamekka bolabirira wadde si gwe abazaala?**

**21. Obudde bwo obusinga obumala okola ki?**

1 ☐ Nima ewaka
2 ☐ Nimira abantu abalala
3 ☐ Nvuba
4 ☐ Mpakasa
5 ☐ Nkola mu ofisi
6 ☐ Nsubula
7 ☐ Nkola egy'awaka
8 ☐ Ndabira baana
9 ☐ Ndabirira mulwadde
10 ☐ Nsiibba mu buliri olw'obulwadde
77 ☐ Ekirala (kiwandike wo)

**22. Olina omulimo kati?**

1 ☐ Nkola buli lunaku
2 ☐ Nkola kitunda kya lunaku
3 ☐ Nkola lumu na lumu
4 ☐ Nsoma
5 ☐ Sikola olw'obulwadde
6 ☐ Sikola kubanga sirina mulimo
77 ☐ Ekirala (kiwandike wo)

**23. Okutwalira awamu, okola sawa mekka olunaku?**

**24. Wayingiza sente mekka omwezi oguwedde?**

**25. Mumwezi oguwedde olemeddwa okukola enaku mekka olwobulwadde?**

**26. Amakka go gasasanya sente nga mekka omwezi oguwedde?**

**27. Ebyensimbi byo leero obigerageranya otya ne bwebyali emyezi mukaga emabegga?**

1 ☐ Bilongose
2 ☐ Bisigadde kyekimu
3 ☐ Biyononese

**28. Walino omulimo emyezi mukagga emabegga?**

1 ☐ Yee (Genda ku kibuuzo 32)
2 ☐ Nedda

**29. Nsonga ki enkulu lwaki tewalina mulimo omwaka gumu emabega?**

1 ☐ Bulwadde
2 ☐ Nabulwa omulimo (Genda ku kibuuzo30)
77 ☐ Ekirala (kiwandike wo)

**30. Okubba nga olina akawuka kamukenenya yeyali ensonga lwaki tewalina muriimo emyezi mukaga emabegga?**

1 ☐ Yee
2 ☐ Nedda

**31. Obukosefu mu mubiiri bukulemesezza okunonya omuriimo?**

1 ☐ Yee
2 ☐ Nedda

**32. Kuzino, eri wa eyabadde entambula enkulu gyewakozeseza okugya wano?**

1 ☐ Kutambula
2 ☐ Boda y'akagali
3 ☐ Boda y'epiki
4 ☐ Baasi
5 ☐ Taxi
6 ☐ Specilo
7 ☐ Eggali yange
8 ☐ Epiki piki yange
9 ☐ Emotoka yange
77 ☐ Ekirala (kiwandike wo)

**33. Oba yee, wasasanyiza sente mekka kuntambula gye wakozeseza okugya wano leero?**

☐ Yaganye okuddamu

**34. Olugendo lwa badde lwa sawa mekka?**

1 ☐ Eddakika ezitawera 10
2 ☐ Eddakika ezisuka 10
3 ☐ Eddakika ezizuka 30
4 ☐ Okusoba mu sawa emu
5 ☐ Okusoba mu sawa biiri
77 ☐ Ekirala (kiwandike wo)

**35. Ofiriddwa emirimo gyo oba okusoma bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**36. Offiridwa omusala gwona bwoze wano leero?**

1 ☐ Yee
2 ☐ Nedda(Genda ku kibuuzo 38)

**37. Oba yee, omusala gwenkana wa?**

☐ Simanyi

**38. Waliwo akuwerekedde ku dwaliro leero?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 42)

**39. Ani akuwelekedde ku dwaliro leero?**

1 ☐ Mwami/mukyala wange
2 ☐ Omwana/abaana bange
3 ☐ Abenganda abalala
77 ☐ Ekirala (kiwandike wo)

**40. Oyo akuwelekedde yandibadde akola ki ekikulu singa takuwelekedde ku dwaliro leero?**

1 ☐ Akola emirimo egy'awakka
2 ☐ Alabirira abaana
3 ☐ Alabirira abenganda
4 ☐ Asoma
5 ☐ Afunye livu olw'obulwadde
6 ☐ Anonya mulimo
7 ☐ Akola mulimo nebamusasula
77 ☐ Ekirala (kiwandike wo)

**41. Oyo akuwerekedde affiridwa omusala gwona bwazze wano leero?**

1 ☐ Yee
2 ☐ Nedda

**42. Wewala ekikolwa eky'obufumbu?**

1 ☐ Yee
2 ☐ Nedda

**43. Embeera y'obulamu bwo ogigera geranya otya ne bweyali emyezi mukaga emabegga?**

1 ☐ Elongose
2 ☐ Esigadde kyekimu
3 ☐ Eyononese

**44. Lwaki olowoza embeera y'obulamu bwo elongose/ esigadde kyekimu/ eyononese?**

**45. Oli wa gwanga ki?**

1 ☐ Muganda
2 ☐ Munyankole
3 ☐ Luo/Acholi
4 ☐ Mugisu/Musoga
77 ☐ Ekirala (kiwandike wo)

**46. Oli wa ddini ki?**

1 ☐ Mupoto
2 ☐ Mukatulikki
3 ☐ Mulokole
4 ☐ Musilamu
**77** ☐ Ekirala (kiwandike wo)

**APPENDIX IIb**
**Medical Outcomes Study Health Survey for HIV – English Version**

**Date:** **[DATE]** ☐ **Household ID:** **[HH IDNO]** ☐ **HRQoL ID:** **[IDNO]** ☐

1. Age ☐ **[AGE]**

2. Sex **[SEX]**
1 ☐ Male
2 ☐ Female

3. In general, would you say your health is:
1 ☐ Excellent **[HEAGEN]**
2 ☐ Very Good
3 ☐ Good
4 ☐ Fair
5 ☐ Poor

4. How much **bodily** pain have you generally had during the **past 30 days**?
1 ☐ None **[BODPAIN]**
2 ☐ Very mild
3 ☐ Mild
4 ☐ Moderate
5 ☐ Severe
6 ☐ Very severe

5. During **the past 30 days,** how much did **pain** interfere with your normal work (including work outside the home and housework)?
1 ☐ Not at all **[PAIN30]**
2 ☐ A little bit
3 ☐ Moderately
4 ☐ Quite a bit
5 ☐ Extremely

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

a. The kinds or amounts of vigorous activities you can do like, digging, fetching water from a well, carrying a big bunch of matoke, and splitting firewood. **[VIGOR]**
1 ☐ Yes, limited a lot
2 ☐ Yes, limited a little
3 ☐ No, not limited

b. The kinds or amounts of **moderate** activities you can do, like washing clothes, moving a jerrican of water, or moving a bundle of firewood from one place to another **[MODERATE]**
1 ☐ Yes, limited a lot
2 ☐ Yes, limited a little
3 ☐ No, not limited

c. Walking uphill, climbing stairs.
1 ☐ Yes, limited a lot **[WALKHILL]**
2 ☐ Yes, limited a little
3 ☐ No, not limited

d. Bending, lifting light objects or kneeling
1 ☐ Yes, limited a lot **[BEND]**
2 ☐ Yes, limited a little
3 ☐ No, not limited

e. Walking a distance as long as a football pitch. **[WALK]**
1 ☐ Yes, limited a lot
2 ☐ Yes, limited a little
3 ☐ No, not limited

f. Eating, dressing, bathing or using the latrine/toilet
1 ☐ Yes, limited a lot **[EATING]**
2 ☐ Yes, limited a little
3 ☐ No, not limited

7. Does your health keep you from working at a job, doing work around the house or going to school? **[HEALKP]**
1 ☐ Yes
2 ☐ No

8. Have you been unable to do certain kinds or amounts of work, housework or schoolwork because of your health?
1 ☐ Yes **[DOWORK]**
2 ☐ No

For each of the following questions, please tell me the answer that comes closest to the way you have been feeling during the past 30 days

9. Have you been limited by your health from visiting and spending time with friends and/or family? **[HEALIM]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

10.How much of the time, during the past 30 days:

a. Have you been a **very nervous person**?

1 ☐ All of the time **[NERVOUS]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

b. Have you felt **calm and peaceful**?

1 ☐ All of the time **[CALM]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

c. Have you felt **depressed?**

1 ☐ All of the time **[DEPRESS]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

d. Have you been a **happy person**?

1 ☐ All of the time **[HAPPY]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

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

1 ☐ All of the time **[DEPCHEER]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

11.How often during the **past 30 days.**

a. Did you feel full of life and energy?

1 ☐ All of the time **[FULLIFE]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

b. Did you feel totally without energy?

1 ☐ All of the time **[NOENERG]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

c. Did you feel tired? **[TIRED]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

d. Did you have enough energy to do the things you wanted to do? **[ENGHEN]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

e. Did you feel weighed down by your health problems? **[WEIGH]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

f. Were you discouraged by your health problems? **[DISC]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

g. Did you feel despair over your health problems? **[DESPAIR]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

h. Were you afraid because of your health?

1 ☐ All of the time **[AFRAID]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

12. How much of the time, during the **past 30 days:**

a. Did you have difficulty reasoning and making decisions or learning new things?

1 ☐ All of the time **[REASON]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

b. Did you forget things that happened recently, for example, where you put things and the appointments you made?

1 ☐ All of the time **[FORGET]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

c. Did you have trouble keeping your attention on any activity for long? **[TROUBLE]**

1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

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

1 ☐ All of the time **[DIFFACT]**
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

13. Please tell me the answer that comes closest to describing whether the following statement is true or false for you:

a. You are somewhat ill **[ILL]**

1 ☐ Definitely true
2 ☐ Mostly true
3 ☐ Don't know
4 ☐ Mostly false
5 ☐ Definitely false

b. You are as healthy as anybody you know

1 ☐ Definitely true **[HEALTHY]**
2 ☐ Mostly true
3 ☐ Don't know
4 ☐ Mostly false
5 ☐ Definitely false

c. Your health is excellent. **[EXHLTH]**

1 ☐ Definitely true
2 ☐ Mostly true
3 ☐ Don't know
4 ☐ Mostly false
5 ☐ Definitely false

d. You have been feeling bad lately

1 ☐ Definitely true **[FEELBAD]**
2 ☐ Mostly true
3 ☐ Don't know
4 ☐ Mostly false
5 ☐ Definitely false

14. In the last 30 days, how has your life been in general? **[LIFE30]**

1 ☐ Very well; could hardly be better
2 ☐ Pretty good
3 ☐ Good and bad parts about equal
4 ☐ Pretty bad
5 ☐ Very bad; could hardly be worse

15. How would you rate your physical health and emotional condition now compared to **30** days ago?

1 ☐ Much better **[RATE]**
2 ☐ A little better
3 ☐ About the same
4 ☐ A little worse
5 ☐ Much worse

**APPENDIX IIb**
**Medical Outcomes Study Health Survey for HIV - Luganda Version**

| Date | | HRQoL ID | | Original ☐ | 2 Weeks Follow up ☐ |
|---|---|---|---|---|---|

1. Emyaka ☐

2. Muntu ki?
1 ☐ Musajja
2 ☐ Mukazi

3. Okutwarila awamu, wandigambye nti embeera y' obulamu bwo:
1 ☐ Nungi Nyo Nyo
2 ☐ Nungi Nyo
3 ☐ Nungi
4 ☐ Bwetyo bwetyo
5 ☐ Mbi

4. Okutwalira awamu ofunye **okulumizibwa mumubiri** kwenkanawa **mu naku amakumi asatu eziyise?**
1 ☐ Tewali
2 ☐ Kutono ddala
3 ☐ Kutono
4 ☐ Kwakigero
5 ☐ Kwamaanyi
6 ☐ Kwamaanyi ddala

5. Munaku **amakumi asatu eziyise okulumizibwa** kutaataganyizza (kwataataganya kyenkanawa emirimu gyo egyabulijjo, nga otwalidemu egyawaka n'egitali gyawaka)?
1 ☐ Tewali
2 ☐ Katono ddala
3 ☐ Kwakigero
4 ☐ Nyo
5 ☐ Nyo ddala

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

*a. Emirimu/ebintu by'okola nga **by'amaanyi mangi** gamba nga okulima, okukima amazzi kuluzzi, okwetikka enkota y'etooke ennene, okwasa enku*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

*b. Emirimu/ebintu by'okola nga **by'amaanyi** agekigero gamba nga okwoza engoye, okusitula ekidomolera kyamazzi oba ekinywa ky'enku okuva mukifo ekimu okukissa mu kilala.*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

*c. Okulinya akasozi / amadaala*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

*d. okukutama/okweweta, okusitula ebintu ebiwewuka. Oba okufukamira.*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

*e. Okutambula akabanga akenkana nga obuwanvu bw'ekisaawe ky'omupiira.*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

*f. Okulya, okwambala, okunaaba, oba okugenda mu kabuyonjo.*
1 ☐ Eziyiza nyo
2 ☐ Eziyiza Katono
3 ☐ Teziyiza n'akatono

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

1 ☐ Yee
2 ☐ Nedda

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

1 ☐ Yee
2 ☐ Nedda

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

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

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

10. Mu naku amakumi asatu eziyise **mirundi emekka**

a. By' obadde nga owulira toterera /okutyemukirira?

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

b. Gy' obadde nga owulira obutefu n'emirembe?

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

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

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

d. Gy' obadde nga oli musanyufu?

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

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

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

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

*a. Bwe wawulirira nga ojjude obulamu n'aamanyi?*

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

*b. Bwe wawulirira ng'ogwereddemu ddala amaanyi?*

1 ☐ Ebisera byona
2 ☐ Ebisera ebisinga obungi
3 ☐ Ebisera bingi
4 ☐ Ebisera bitono
5 ☐ Ebisera bitono nyo

*c. Bwe wawulirira ng'okooye?*

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

d. *Wewabeerera nga olina amaanyi agakola ebintu byewayagala okukola?*

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

*e. Bwe wawulirira nga ozitooweredwa olwembeera y'obulamu bwo?*

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

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

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

*g. Bwe wawulirira nga oweddemu essuubi olw'embeera y'obulamu bwo?*

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

*h. Wewabereera nga embeera y'obulamu bwo ekutiisizza?*

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

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

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

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

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

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

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

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

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

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

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

*a. Oli mulwaddelwadde*

1 ☐ Kituufu nyo
2 ☐ Kituufu
3 ☐ Tomanyi
4 ☐ Sikituufu
5 ☐ Sikituufu nakamu

*b. Oli mulamu nga abantu abalala b'omanyi.*

1 ☐ Kituufu nyo
2 ☐ Kituufu
3 ☐ Tomanyi
4 ☐ Sikituufu
5 ☐ Sikituufu nakamu

*c. Oli mulamu ddala*

1 ☐ Kituufu nyo
2 ☐ Kituufu
3 ☐ Tomanyi
4 ☐ Sikituufu
5 ☐ Sikituufu nakamu

*d. Obadde owulira bubi gyebuvuddeko.*

1 ☐ Kituufu nyo
2 ☐ Kituufu
3 ☐ Tomanyi
4 ☐ Sikituufu
5 ☐ Sikituufu nakamu

14. **Mu naku amakumi asatu eziyise** obulamu bwo bubadde butya okutwalira awamu?

1 ☐ Bulungi ddala; nga tebusobola kusingawo
2 ☐ Bulungi
3 ☐ Bulungilungi
4 ☐ Bubi
5 ☐ Bubi nyo; nga tebusobola kusingawo

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

1 ☐ Erongokedde ddala
2 ☐ Erongosemu katono
3 ☐ Kumpi tekyuseeko
4 ☐ Ebizzemu katono
5 ☐ Ebijjidde ddala

**APPENDIX IIIa**

**WHO staging system for HIV infection and disease in adults and adolescents**

***Clinical stage I***

1. Asymptomatic
2. Generalized lymphadenopathy

Performance scale 1: asymptomatic, normal activity

***Clinical stage II***

3. Weight loss, <10% of body weight
4. Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oralulcerations, angular cheilitis)
5. Herpes zoster within the last five years
6. Recurrent upper respiratory tract infections (i.e. bacterial sinusitis).

And/or performance scale 2: symptomatic, normal activity

***Clinical stage III***

7. Weight loss, >10% of body weight
8. Unexplained chronic diarrhoea, >1 month
9. Unexplained prolonged fever (intermittent or constant), >1 month
10. Oral candidiasis (thrush)
11. Oral hairy leukoplakia
12. Pulmonary tuberculosis
13. Severe bacterial infections (i.e. pneumonia, pyomyositis)

And/or performance scale 3: bedridden <50% of the day during the last month

***Clinical stage IV***

14. HIV wasting syndrome *
15. Pneumocystis carinii pneumonia
16. Toxoplasmosis of the brain
17. Cryptosporidiosis with diarrhoea >1 month
18. Cryptococcosis, extrapulmonary
19. Cytomegalovirus disease of an organ other than liver, spleen or lymph nodes (ex: retinitis)
20. Herpes simplex virus infection, mucocutaneous >1 month, or visceral
21. Progressive multifocal leukoencephalopathy
22. Any disseminated endemic mycosis
23. Candidiasis of oesophagus, trachea, bronchi or lungs
24. Atypical mycobacteriosis, disseminated
25. Non-typhoid Salmonella septicaemia
26. Extrapulmonary tuberculosis
27. Lymphoma
28. Kaposi's sarcoma
29. HIV encephalopathy**

And/or performance scale 4: bedridden >50% of the day during last month

---

**Note:** both definitive and presumptive diagnoses are acceptable.

* HIV wasting syndrome: weight loss of >10% of body weight, plus either unexplained chronic diarrhea (>1 month) or chronic weakness and unexplained prolonged fever (>1 month).

** HIV encephalopathy: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection which could explain the findings.

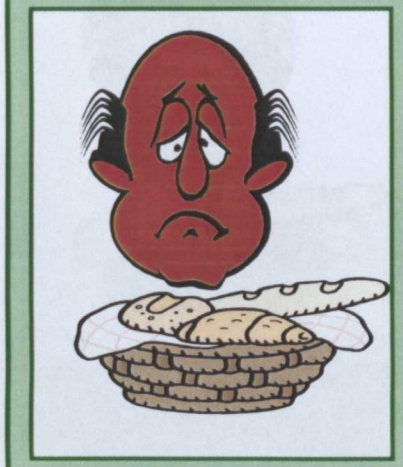
**APPENDIX IIIB** **Description of the health states used for data collection**

| Symptomatic HIV Infection | Minor AIDS Defining Illness | Major AIDS Defining Illness | Improved Health |
|---|---|---|---|
| Loss of appetite | Noticeable weight loss | Weight loss of 15 kilograms and no appetite | Normal weight |
| Ability to care for yourself and to cook, clean or household chores<br>Loss of appetite | You are less able to do many of the activities that you have always done | Not working due to tiredness | Ability to do work that is more physically demanding |
| Ability to do most activities but frequently tired | Frequently tired and as a result decreased work activities to a minimum | Sometimes bedridden due to lack of energy, but other days able to go around | Enough energy to do normal activities |
| Ability to work at jobs that are not too physically challenging | Increasingly forgetful and unstable emotionally | Unhappy and fearful about the future | Positive attitude towards life |
| Recurrent skin problems | Itchy rash on arms, legs and body that is not getting better | Hospitalisation at least once for a serious complication and constant fever | Appetite regained |
| Night sweats once or twice a month | Episodes of diarrhoea and fever 3-4 times a month | Recurrent episodes of dry cough, shortness of breath, vomiting and diarrhoea | No longer suffering from diarrhoea or night sweats |

**APPENDIX IIIc HEALTH STATES FOR DATA COLLECTION**

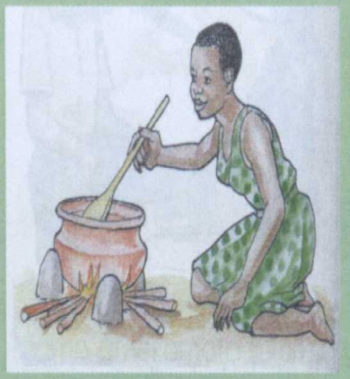
**SYMPTOMATIC HIV INFECTION –English version**

①



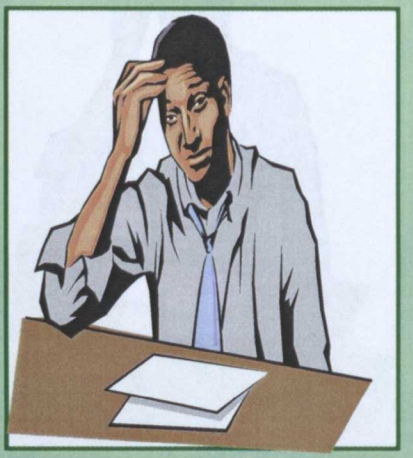
You have lost your appetite

②



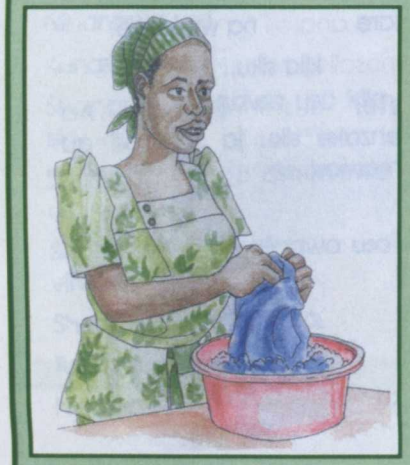
You are able to care for yourself and do not need any help with cooking, cleaning or household chores

③



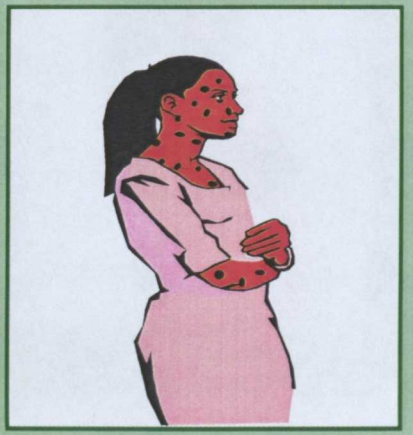
You are able to do most of the activities that you have always done but get tired more easily than in the past

④



You can work at a job that is not too physically challenging

⑤



You have recurrent skin problems

⑥

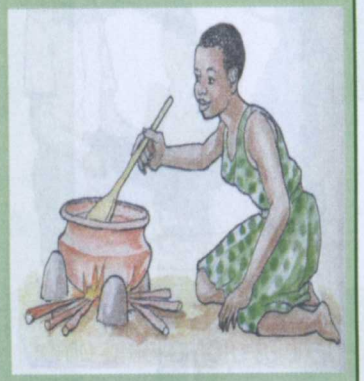
You have night sweats once or twice a month

**SYMPTOMATIC HIV INFECTION –Luganda version**

①

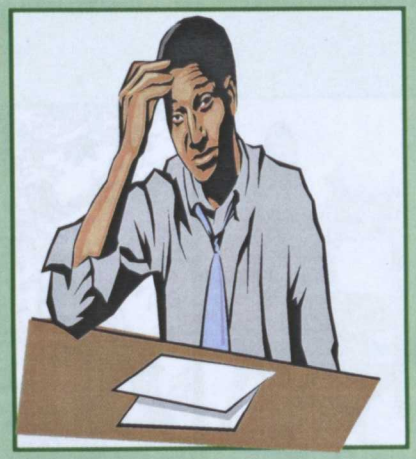
Toyagala kulya oba kunywa

②



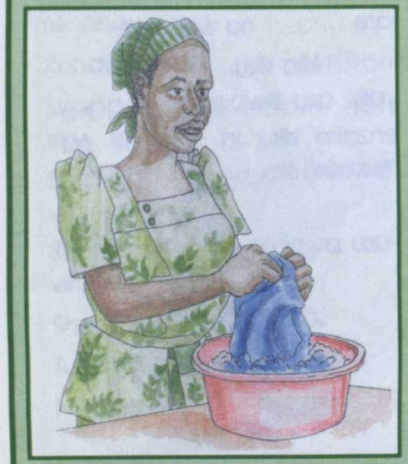
Osobola okwelabirira , okufumba, okulongosa n'okukola emiriimo gyo egy'awakka.

③



Osobola okukola emiriimo egyisinga naye okowa emirundi mingi

④



Osobola okukola emiriimo egitetagisa manyi mangi nyo

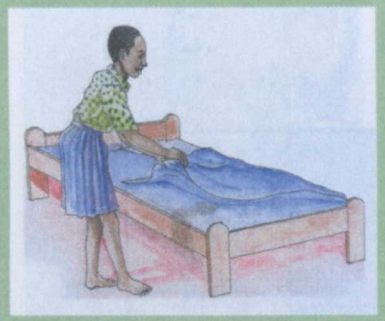
⑤

Ofuna endwadde z'olususu nga zigya n'eziwona ate neziddamu

⑥

Otuyana nyo ekisuse ekiro lumu oba ebiri mu mwezi

①



You are less able to do many of the activities that you have always done

②

You have lost weight that you have noticed

③


You are frequently tired and have had to decrease your work activities to a minimum

④

You have an itchy rash on your arms, legs and body that is not getting better

⑤

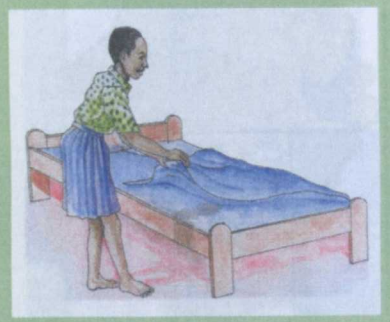
You find that you are becoming increasingly forgetful, and your emotions are unstable in comparison with the past

⑥

You have episodes of diarrhoea and fever 3-4 times a month

## MINOR AIDS DEFINING ILLNESS – Luganda version

①



Tokyayinza kukola emiriimo egyisinga gyewali okola

②

Omuntu alaba nti okozze

③


Oba mukowu ebisera bingi n'olwekyo okendeza ddala emiriimo gyewali okola

④

Olina endwadde y'olususu ku maggulu ne ku mikono ettawona

⑤

Werabira nyo ate onyiga nyiga mangu

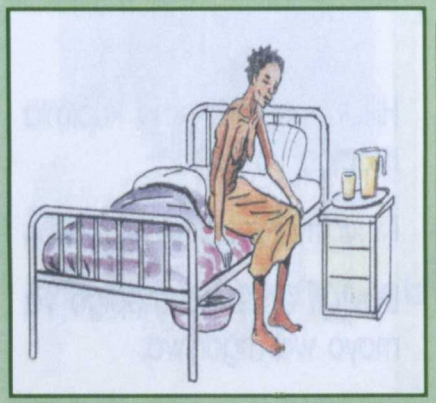
⑥

Ofuna omusujja n'okudukana emirundi essatu oba enna mu

## MAJOR AIDS DEFINING ILLNESS –English version

① 

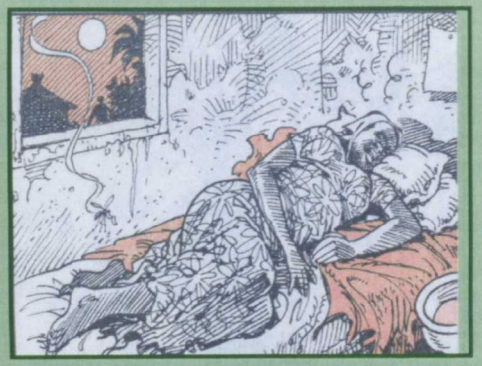
You are unhappy and fear for the future

② 

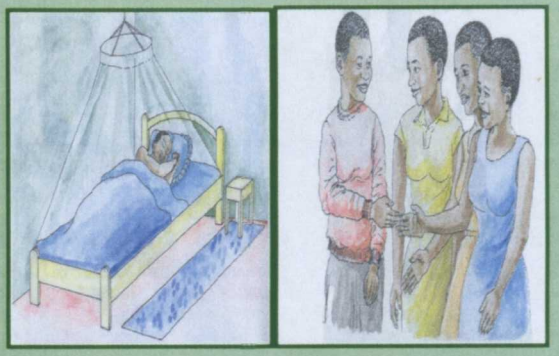
You have lost 15 kilograms and found that you have no appetite

③ 

You have been hospitalised once in the past for a serious complication and you have constantly had fever

④ 

You have stopped working because you are so tired

⑤ 

Sometimes you don't have energy and spend the day in bed, but other days you are able to go around

⑥ 

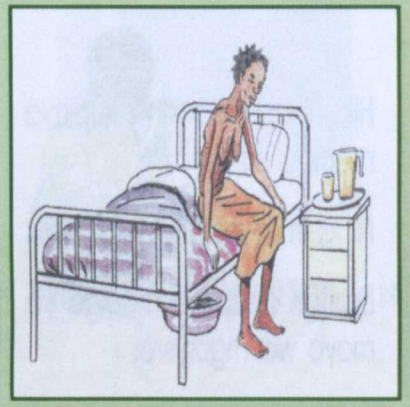
You have recurrent episodes of dry cough, shortness of breath vomiting and diarrhoea

## MAJOR AIDS DEFINING ILLNESS –Luganda version

①

Oli munakuwavu era otya ebinabawo mu biseera ebigya

②

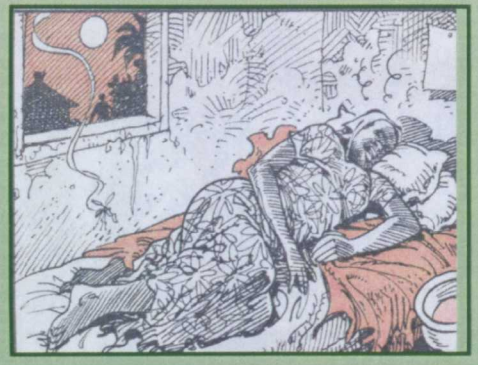


Okozze, kilo 15 nzikuvudde ko ate toyagala kulya na kunywa

③

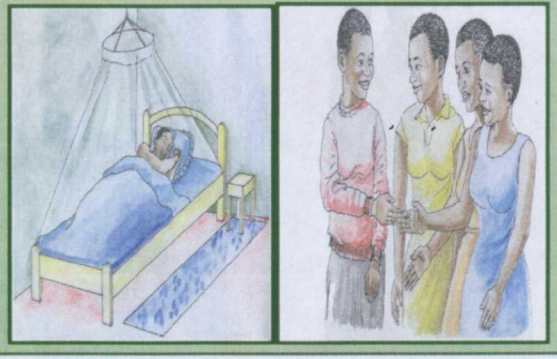
Bakuwaddeko ku kitanda olw'obulwadde obwamanyi ate buli kaseera olina omusujja

④



Tokyakola kubanga oli mukowu.

⑤



Ebiseera ebiimu osigala webasse olwebuula lyamanyi naye ennaku endala osobola okufuluma n'otambula

⑥

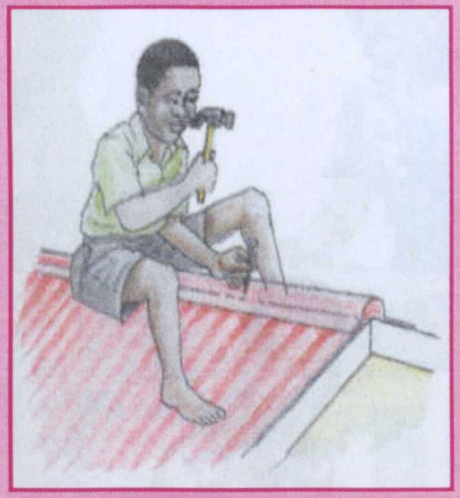
Okolola wadde toleta kikolondolwa, tossa bulungi, ate olina okuddukanna era osessema.

## IMPROVED HEALTH STATE – English version

①

You have recovered your normal weight

②



You have energy to do your normal activities

③

You have a positive attitude towards life

④

You can do work that is more physically demanding

⑤

You have regained your appetite

⑥

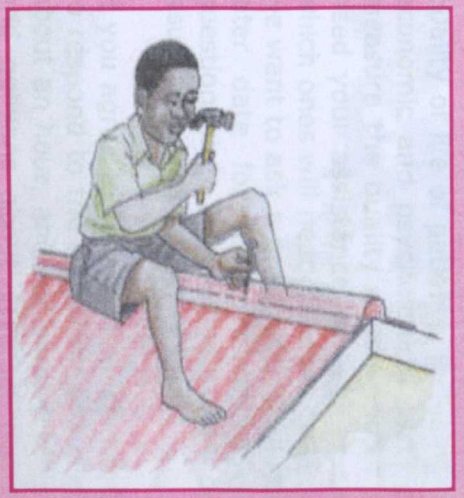
You no longer suffer from diarrhoea or night sweats

## IMPROVED HEALTH STATE – Luganda version

①

Olina omubiri gwo ogwa buligyo

②



Oyina amanyi okukola emiriimo gyo egya buligyo

③

Tewatya, olina essubi, oli musanyufu, weyagala.

④

Osobola okukola emiriimo egy'amanyi

⑤

Ozemu okwagala okulya n'okunywa

⑥

T'okyadukana era t'okyatuyana nyo ekiro.

**APPENDIX IV**
**Focus Group Discussion Information Sheet – English version**

## FOCUS GROUP DISCUSSION INFORMATION SHEET

## ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

We would like to invite you to participate in a study about health-related quality of life. Please read carefully this information or ask the interviewer to read it for you. A copy of this form will be given to you to keep. If you need more information please do not hesitate to ask us.

***Health-related quality of life research***
This type of study investigates the effect of the disease and its treatment on the physical, emotional and social well-being of patients.

***Why are we doing this study?***
We are conducting a study to find out how being HIV-positive affects the general quality of life of patients, including the effects on physical health, and the social, economic and psychological parts of life. We intend to use questionnaires to measure the quality of life impact on different areas of a person's life, but we need your assistance to help us understand which questions make sense and which ones will need changes to be more clearly understood. In order to do this, we want to ask a group of individuals to take our questionnaires and to meet at a later date for a group discussion with others who have also taken the questionnaire. The discussion will be focused on the questionnaire and general issues affecting quality of life.

If you agree to take part in the study, you will be asked by a trained interviewer to respond to the questionnaire reflecting your own quality of life. This will take about an hour, and will involve answering general questions about your attitudes and opinions about different areas of your current life. At the end of the interview, you will be asked to meet with other HIV-positive individuals who have completed the same questionnaires to discuss any common problems with understanding the questionnaire, and other general questions about quality of life for HIV-positive individuals in Uganda.

Please note that you are not required to share any personal information in the focus discussion group, which will emphasize common shared experiences. The focus discussion group will take about 2 hours. You will receive no payment for your participation but will be offered transport reimbursement and refreshment after the focus discussion group.

The information obtained from the interviews will be entered into computer files after all personal names have been replaced by code numbers, so that answers can never be traced back to you. Because one must be HIV-positive to take part in this study, others who attend the group discussions will know your status. To protect the anonymity of the discussions as much as possible, we will not ask group discussion participants to share their names with others, and will strictly

avoid asking any questions that require people to share private or sensitive information. Interviews will be tape recorded to make sure that the information will not be lost. After the interview, the tapes will be transcribed and translated into English and stored in a computer, again without any personal names. Only researchers will have access to these transcripts.

You are free to refuse to participate in this study and to withdraw at any time. You are equally free to refuse to answer any specific question. Refusal will not affect your participation in DART trial in any way. Please be sure to ask the interviewer if you have any questions. If you have additional questions or any complaints about the study please contact the study coordinator Dr. Brent Wolff or Dr. Paula Munderi (Tel: 041-320-042) at the MRC offices at Uganda Virus Research Institute, Entebbe, or the chairman of the UVRI Science and Ethics Committee Dr. Edward Mbidde Katongole at the offices of Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

**Consent for Focus Group Discussion – English Version**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| | |
|---|---|
| **NAME:**..... ..... | **DATE:** DD/MM/YY |
| **DATE OF BIRTH:** DD/MM/YYYY | **FGD ID :** ..... |

I have read or had read to me the information sheet for the questionnaire interview and the Focus Discussion Group that follows it. I understand that if I decide to be involved in the study I will be asked to answer a questionnaire lasting up to one hour and then take part in a focus group discussion with other HIV-positive individuals for up to two hours and free to withdraw at any time. I am also aware of the fact that if I decide not to participate in the study this will not affect my normal care and management in any way.

Any questions or concerns about the study will be answered at any time by the study co-ordinator

I agree to take part in this study

Name.....

Signature ..... Or thumbprint

Date.....

**Interviewer:**

Name.....

Signature .....

Date.....

**Focus Group Discussion Information Sheet – Luganda version**

**EBIKWATA KU LUKIIKO**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Omunonyereza Omukulu:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

Tukusaba wetabe mu kunonyereza ku mbeera y'obulamu. Tukusaba osome n'obwegendereza olupapula luno oba osabe omunonyereza alukusomere. Oggya kuwebwa olupapula luno oluteleke. Bwoba oyina kyoyagala okumanya, bambi totya kukitubuuza.

***Okunonyereza ku mbeera z'obulamu.***

Okunonyereza kuno kukwata ku ngeri obulwadde n'obujjanjabi bwabwo bwebwekuusa ku ngeri abalwadde gyebewulira mu mibiri, byebalowooza n'engeri gy'ebakolagana n'abantu abalala.

***Lwaki tukola okunonyereza kuno?***

Tukola okunonyereza kuno tusobole okutegeera engeri okuba n'akawuka ka siliimu gyekiyisa abakalina mu mibiri gyabwe, enkolagana yabwe n'abantu, eby'enfuna n'ebirowoozo byabwe. Tuggya kukozesa olupapula oluliko ebibuuzo okupima embeera y'obulamu mu ngeri ezitali zimu, naye twetaaga obuyambi bwo tusobole okutegeera oba ebibuuzo byetubuuza bitegeerekeka oba nga byetaaga okukyusa bisobole okuba nga bitegeerekekeka.

Bw'okkiriza okwetaba mu kunonyereza kuno, omunonyereza aggya kusaba oddemu ebibuuzo ebikwata ku mbeera y'obulamu bwo. Kino kiggya kutwala essaawa nga emu. Kiggya kwetagisa okuddamu ebibuuzo ebikwata ku bulamu bwo obwa bulijjo n'ebyo by'olowooza ku mbeera z'obulamu bwo ez'enjawulo. Ebibuuzo bwebinaggwa, ojja kusabibwa okwetaba mu lukiiko n'abantu abalala abalina akawuka ka siliimu era abazzeemu ebibuuzo byebimu. Mugya kuteesa ku bizibu byemufunye nga muddamu ebibuuzo era muteese ku bizibu ebirala abantu

abalina akawuka ka siliimu mu Uganda bye basanga mu mbeera zabwe eza bulijjo.

Mulukiiko luno toggya kusabibwa kwogera kuby'omunda ebikukwatako ng'omuntu. Essira liggya kuteekebwa ku bintu ebya bulijjo ebikwata ku buli omu. Olukiiko lujja kutwala essaawa nga bbiri. Toggya kusasulwa ssente naye oggya kuddizibwa ssente zewakozesezza okutambula n'ebyokunywa nga olukiiko luwedde.

Byemunatuwa biggya kuyingizibwa mu kyuma ki kalimagezi (kompyuta) nga amannya gonna gaggyiddwamu waleke kubawo ngeri yonna abantu abalala gyebanasobola okutegeera eyabyogera. Engeri gye kyetagisa omuntu okuba nga alina akawuka kasiliimu okusobola okwetaba mu kunonyereza kuno, abalala abanetaba mu lukiiko luno baggya kutegeera nti olina akawuka ako. Olwokukuuma ebyama by'olukiiko luno n'abalwetabyeemu, abogezi tebaggya kusabibwa kwogera oba kubulira balala mannya gabwe era tuggya kwewala okubuuza ebibuuzo ebikwata ku bulamubwo obw'omunda ne kubyamabyo. Olukiiko luggya kukwatibwa ku katambi okukakasa nti tewali kinafiirwa. Olukiiko nga luwedde, ebiri ku lutambi biggya ku wandiikibwa, bivvuunulibwe mu luzungu olwo bitelekebwe mu kyuma ki kalimagezi (computa) nga tebiriimu mannya ga muntu yenna. Abanonyereza bokka bebaggya okuba nga balina olukusa okusoma empapula mwebiri.

Oli wa ddembe okugaana okwetaba mu kunonyereza kuno oba okuvaamu essaawa yonna oba okugaana okuddamu ekibuuzo kyonna. Okugaana kwo, tekulina ngeri gye kunakosa enetaba yo mu kitongole kya DART.
Bwoba olina ekibuuzo kibuuze omunonyereza. Osobola n'okubuuza ba kayungirizi b'okunonyereza kuno: Dr. Brent Wolff oba Dr. Paula Munderi (Tel: 041-320-042) ku ofiisi za MRC mu Uganda Virus Research Institute, Entebbe, oba omukulu w'a kakiiko ka UVRI Science and Ethics Committee Dr. Edward Mbidde Katongole mu ofisi ya Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

**Focus Group Discussion consent form – Luganda version**

**OKUKKAKKASA OKWETABA MU KUNONYEREZA**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Omunonyoreza omukulu:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| **ERINNYA:** ..... ..... | **ENNAKU Z'OMWEZI:** ..... ..... |
|---|---|
| **OLUNAKU LWEWAZALIBWA:** ..... ..... | **HRQoL ID :** ..... ..... |

Nsomye oba bansomedde olupapula olukwata ku ku lukiiko olunabawo. Ntegedde nti bwenasalawo okwetaba mu kunonyereza kuno baggya kunsaba neetabe mu lukiiko n'abantu abalala abalina akawuka ka siliimu okumala essaawa bbiri. Ndi wa ddembe okuva mu kunonyereza kuno essaawa yonna. Ntegedde nti bwensalawo obuteetaba mu kunonyereza kuno, tekiggya kukosa endabirira n'enzijanjaba yange mu ngeri yonna.

Ebibuuzo byonna ebikwata ku kunonyereza kuno biggya kuddibwamu kayungirizi w'okunonyereza kuno obudde bwona.

Nzikirizza okwetaba mu kunonyereza kuno.

Erinnya.....

Omukono..... Oba Ekinkumu

Ennaku z'omwezi.....

**Anonyereza:**

Erinnya.....Omukono.....

Ennaku z'omwezi.....

## PILOT STUDY PARTICIPANT INFORMATION SHEET

## ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

We would like to invite you to participate in a health-related quality of life research study. Please read carefully this information or ask the interviewer to read it for you. A copy of this form will be given to you to keep. If you need more information please do not hesitate and ask us.

***Health-related quality of life research***

This type of study investigates the effect of the disease and its treatment on the physical, emotional and social well-being of patients.

***Why are we doing this study?***

We are conducting a study to find out how being HIV-positive affects the general quality of life of patients, including the effects on physical health, and the social, economic and psychological parts of life. We intend to use adjusted questionnaires to measure the quality of different areas of a person's life, but we need your assistance to help us understand which questions make sense and which ones will need changes to make them easier to understand. The questions that will be asked relate to your current health, pain and how do you feel.

If you agree to take part in the study, you will be asked by a trained interviewer to respond to questions in a face-to-face interview here at the clinic. The interview will last up to an hour.

The results from the questionnaire interviews will be entered into a computer after a code number has replaced your name, so that answers can never be traced back to you. Only researchers will have access to these transcripts.

You are free to refuse to participate in this study and withdraw at any time. You are equally free to refuse to answer any specific question. Refusal will not affect your participation in DART trial in any way. Please be sure to ask the interviewer if you have any questions. If you have additional questions or any complaints about the study please contact the study coordinator Dr. Brent Wolff or Dr. Paula Munderi (Tel: 041-320-042) at the MRC offices at Uganda Virus Research Institute, Entebbe, or the chairman of the UVRI Science and Ethics Committee Dr. Jonathan Mermin at the CDC offices of the Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

**CONSENT FORM PILOT STUDY**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| | |
|---|---|
| **NAME:**..... ..... | **DATE:** DD/MM/YY |
| **DATE OF BIRTH:** DD/MM/YYYY | **FGD ID :** ..... |

I have read or had read to me the information sheet for the questionnaire interview and the Focus Discussion Group that follows it. I understand that if I decide to be involved in the study I will be asked to answer a questionnaire lasting up to one hour. I am also aware of the fact that if I decide not to participate in the study this will not affect my normal care and management in any way.

Any questions or concerns about the study will be answered at any time by the study co-ordinator

I agree to take part in this study

**Participant's signature:** **Thumbprint:**

.....

**EBIKWATA KU KUNONYEREZA**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

Principal Investigator: Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

Tukusaba wetabe mu kunonyereza okukwata ku mbeera y'obulamu. Tukusaba osome n'obwegendereza oluppula luno oba osabe omunonyereza alukusomere. Oggya kuwebwa olupapula luno oluteleke. Bwoba oyina ky'oyagala okumanya, bambi totya kukitubuuza.

Okunonyereza kuno kuli ku ngeri obulwadde n'obujjanjabi bwe bwekusa ku byo mubiri, ebirowozo ne neyisa oba endabirira y'abalwadde.

Tukola okunonyereza kuno tusobole okulaba engeri obulwadde bwa silimu bwebukosa embeera y'obulamu bwaabo ababulina gamba nga emibiri gyabwe, ebyenfuna, enkolagana yabwe, n'ebirowozo. Empapula eziriko ebibuuzo ku mbeera y'obulamu zigya ku kozesebwa okumanya embeera z'obulamu ez'omuntu ezitali zimu. Twetagga obuyambi bwo tusobole okulaba oba ebibuuzo bitegerekeka era bilaga engeri gy'owulira muli. Ebibuuzo ebinabuzibwa bikwatta ku bulamu bwo, obulumi n'engeri gye wewulira kati.

Bw'okiriza okwetabba mu kunonyereza kunno, omunonyereza agya kusaba oddemu ebibuuzo nga muli babiri wano ku dwaliiro. Okubuzibwa kugya ku twala essawa emu.

By'onotuwa bigya kuyingizibwa mu kyuma ki kalimagezi (kompyuta) nga awali erinnya lyo waliwo e namba waleke kubawo ngeri yonna omuntu gya nasobola okutegera nti gwe wabyogera. Kino kigya kuuma byonna byonoyogera nga bya kyama. Byonna bigya kumibwa mu kabada nga kuliko kufulu era abanonyereza bokka bebanosobola okubitukako. Byonoddamu bigya gatibwa nebyo abalwadde abalala byebananaba batuwadde kibbe nga tewali ngeri gye kinasobola ku kosa obujjanjabi bwofuna.

Oli wa ddembe okugaana okwetaba mu kunonyereza kuno oba okuvaamu essaawa yonna oba okugaana okuddamu ekibuuzo kyonna. Okugaana kwo, tekulina ngeri gye kunakosa enetaba yo mu kitongole kya DART.

Bwoba olina ekibuuzo kibuuze omunonyereza. Osobola n'okubuuza ba kayungirizi b'okunonyereza kuno: Dr. Brent Wolff oba Dr. Paula Munderi (Tel: 041-320-042) ku

ofiisi za MRC mu Uganda Virus Research Institute, Entebbe, oba omukulu w'a kakiiko ka UVRI Science and Ethics Committee Dr. Jonathan Mermin mu ofisi ya CDC mu Uganda Virus Research Institute, Entebbe (Tel: 041-320-621).

**CONSENT FORM PILOT STUDY**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Omunonyoreza omukulu:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| | |
|---|---|
| **NAME:**..... ..... | **DATE:** DD/MM/YY |
| **DATE OF BIRTH:** DD/MM/YYYY | **FGD ID :** ..... |

Nsomye oba bansomedde olupapula olukwata ku bibuuzo ne ku lukiiko olunabawo oluvannyuma lw'ebibuuzo. Ntegedde nti bwenasalawo okwetaba mu kunonyereza kuno baggya kumbuuza ebibuuzo okumala essaawa ng'emu. Ndi wa ddembe okuva mu kunonyereza kuno essaawa yonna. Ntegedde nti bwensalawo obuteetaba mu kunonyereza kuno, tekiggya kukosa endabirira n'enzijanjaba yange mu ngeri yonna.

Ebibuuzo byonna ebikwata ku kunonyereza kuno biggya kuddibwamu kayungirizi w'okunonyereza kuno obudde bwona.

Nzikirizza okwetaba mu kunonyereza kuno.

**Omukono oba Erinnya:** **Ekinkumu. :**

.....

**APPENDIX V**

**HRQoL study information sheet - English**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

We would like to invite you to participate in a health-related quality of life research study. Please read carefully this information or ask the interviewer to read it for you. A copy of this form will be given to you to keep. If you need more information please do not hesitate and ask us.

***Health-related quality of life research***
This type of study investigates the effect of the disease and its treatment on the physical, emotional and social well-being of patients.

***Why are we doing this study?***
We are conducting a study to find out how being HIV-positive affects the general quality of life of patients, including the effects on physical health, and the social, economic and psychological parts of life. Health-related quality of life questionnaires will be used to measure the quality of different areas of a person's life, but we need your assistance to evaluate if the questionnaires are culturally adequate, reflect how you feel and if you perceive any changes in your quality of life over time. The questions that will be asked relate to your current health, pain and how do you feel.

If you agree to take part in the study, you will be asked by a trained interviewer to respond to questions in a face-to-face interview here at the clinic on three separate occasions over a period of one year. Each interview will last up to an hour. Your first interview could be today or next week, the second in six months and the third in twelve months.

The information given to us by you will be entered into computer files after a code number has replaced your name, so that answers can never be traced back to you and the information you provide is made confidential. The data will be kept key locked at all times and only researchers will have access to the data. Your answers will be combined with the answers of other patients involved in the study and reported in such a way that it will not identify the type of care that you may be receiving.

You are free to refuse to participate in this study and to withdraw at any time. You are equally free to refuse to answer any specific question or withdraw from the study at any time. Refusal will not affect your participation in DART trial or Entebbe Cohort study in any way. Please be sure to ask the interviewer if you have any questions. If you have additional questions or any complaints about the study please contact the study coordinator Dr. Brent Wolff or Dr. Paula Munderi (Tel: 041-320-042) at the MRC offices at Uganda Virus Research Institute, Entebbe, or the chairman of the UVRI Science and Ethics Committee Dr. Jonathan Mermin at the CDC offices of the Uganda Virus Research Institute, Entebbe (Tel: 041-320-621).

**HRQoL study consent form - English**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| | |
|---|---|
| **NAME:**..... ..... | **DATE:** DD/MM/YY |
| **DATE OF BIRTH:** DD/MM/YYYY | **HRQoL ID :** ..... |

I have read or had read to me the information sheet for the HRQoL sub-study. I understand that if I decide to be involved in the study I will be interviewed by the study co-ordinator three times over a period of one year each time lasting up to an hour. At any time I may withdraw from this study without giving any reason and I am aware of the fact that this will not affect my normal care and management in any way.

Any questions or concerns about the study will be answered at any time by the study co-ordinator.

I agree to take part in this study

**Participant's signature:** **Thumbprint:**

.....

**Interviewer:**

Name.....Signature.....

Date.....

**HRQoL study information sheet - Luganda**

**EBIKWATA KU KUNONYEREZA**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

Tukusaba wetabe mu kunonyereza okukwata ku mbeera y'obulamu. Tukusaba osome n'obwegendereza oluppula luno oba osabe omunonyereza alukusomere. Oggya kuwebwa olupapula luno oluteleke. Bwoba oyina kyoyagala okumanya, bambi totya kukitubuuza.

Okunonyereza kuno kuli ku ngeri obulwadde n'obujjanjabi bwe bwekusa ku byo mubiri, ebirowozo ne neyisa oba endabirira y'abalwadde.

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Bwokiriza okwetabba mu kunonyereza kunno, omunonyereza agya kusaba odemu ebibuuzo nga muli babiri wano ku dwaliiro emirundi essatu ejenjawulo mu mwaka. Buli mulundi lwonobuzibwa, kigya kutwala essawa emu. Okubuzibwa okusoka kuyinza okubawo leero oba wiiki egya. Okubuzibwa okw'okubiiri kugya kubawo oluvanyuma lwe myezi mukaga ate okw'okusatu kubewo oluvanyuma lwe myezi kumi nebiiri.

By'onotuwa bigya kuyingizibwa mu kyuma ki kalimagezi (kompyuta) nga awali erinya lyo waliwo e namba waleke kubawo ngeri yonna omuntu gya nasobola okutegera nti gwe wabyogera. Kino kigya kumu byonna byonoyogera nga bya kyama. Byonna bigya kumibwa mu kabada nga kuliko kufulu era abanonyereza boka bebanosobola okubitukako. By'onoddamu bigya gatibwa nebyo abalwadde

abalala byebananaba batuwadde kibbe nga tewali ngeri gye kinasobola ku kosa obujjanjabi bwofuna.

Oli wa ddembe okugaana okwetaba mu kunonyereza kuno oba okuvaamu essaawa yonna oba okugaana okuddamu ekibuuzo kyonna. Okugaana kwo, tekulina ngeri gye kunakosa enetaba yo mu kitongole kya DART.
Bwoba olina ekibuuzo kibuuze omunonyereza. Osobola n'okubuuza ba kayungirizi b'okunonyereza kuno: Dr. Brent Wolff oba Dr. Paula Munderi (Tel: 041-320-042) ku ofiisi za MRC mu Uganda Virus Research Institute, Entebbe, oba omukulu w'a kakiiko ka UVRI Science and Ethics Committee Dr. Jonathan Mermin mu ofisi ya CDC mu Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

**HRQoL study consent form - Luganda**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Tel. 00 44 151 705 3210; Fax: 00 44 151 707 9193; e-mail: amedina@liv.ac.uk.

| **NAME:**..... | **DATE:** DD/MM/YY |
|---|---|
| **DATE OF BIRTH:** | **HRQoL ID:** ..... |

Nsomye oba bansomedde olupapula olukwata ku kunonyereza okukwatta ku mbeera z'obulamu. Ntegedde nti bwenasalawo okwetaba mu kunonyereza kuno, omunonyereza aggya kumbuuza ebibuuzo emirundi essatu mu mwaka nga buli mulundi gutwala essawa emu. Ndi wa ddembe okuva mu kunonyereza kuno esaawa yonna ate nga siwa nsonga lwaki nvuddemu. Ntegedde nti bwenasalawo obuteetaba mu kunonyereza kuno, tekiggya kukosa endabirira n'enzijanjaba yange mu ngeri yona.

Ebibuuzo byonna ebikwata ku kunonyereza kuno biggya kuddibwamu kayungirizi w'okunonyereza kuno obudd
Nzikirizza okwetaba mu kunonyereza kuno.

**Erinya oba omukono:** **Ekinkumu:**

.....

**Anonyereza:**

Erinnya.....Omukono.....

Ennaku z'omwezi.....

**APPENDIX VI**
**The World Health Organization Quality of Life Survey for HIV Brief version (WHOQOL-HIV BREF)– English Version**

| Date | | HRQoL ID | | Original ☐ 2 Week Follow Up ☐ |
|---|---|---|---|---|

**1(G1) How would you rate your quality of life?**
1 ☐ Very poor
2 ☐ Poor
3 ☐ Neither poor nor good
4 ☐ Good
5 ☐ Very good

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

**3 (F1.4) To what extent do you feel that physical pain prevents you from doing what you need to do?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**4 (F50.1) How much are you bothered by any physical problems related to your HIV infection?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**5 (F11.3) How much do you need any medical treatment to function in your daily life?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**6 (F4.1) How much do you enjoy life?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**7 (F24.2) To what extent do you feel your life to be meaningful?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**8 (F52.2) To what extent are you bothered by people blaming you for your HIV status?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**9 (F53.4) How much do you fear the future?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**10 (F54.1) How much do you worry about death?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**APPENDIX VI**
**The World Health Organization Quality of Life Survey for HIV Brief version (WHOQOL-HIV BREF)– English Version**

**11 (F5.3) How well are you able to concentrate?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ Extremely

**12 (F16.1) How safe do you feel in your daily life?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ Extremely

**13 (F22.1) How healthy is your physical environment?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ Extremely

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

**14 (F2.1) Do you have enough energy for everyday life?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**15 (F7.1) Are you able to accept your bodily appearance?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**16 (F18.1) Have you enough money to meet your needs?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**17 (F51.1) To what extent do you feel accepted by the people you know?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**18 (F20.1) How available to you is the information that you need in your day-to-day life?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**19 (F21.1) To what extent do you have the opportunity for leisure activities?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

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

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

**APPENDIX VI**
**The World Health Organization Quality of Life Survey for HIV Brief version (WHOQOL-HIV BREF)– English Version**

**21 (F3.3) How satisfied are you with your sleep?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**22 (F10.3) How satisfied are you with your ability to perform your daily living activities?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**23 (F12.4) How satisfied are you with your capacity for work?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**24 (F6.3) How satisfied are you with yourself?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**25 (F13.3) How satisfied are you with your personal relationships?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**26 (F15.3) How satisfied are you with your sex life?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**27 (F14.4) How satisfied are you with the support you get from your friends?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**28 (F17.3) How satisfied are you with the conditions of your living place?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**29 (F17.3) How satisfied are you with your access to health services?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

**30 (F23.3) How satisfied are you with your transport?**
1 ☐ Very dissatisfied
2 ☐ Dissatisfied
3 ☐ Neither satisfied nor dissatisfied
4 ☐ Satisfied
5 ☐ Very Satisfied

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

**APPENDIX VI WHOQOL-HIV BREF questionnaire – Luganda version**

| Date | | HRQoL ID | | Original ☐ | 2 Week Follow Up ☐ |
|---|---|---|---|---|---|

**1(G1) Embeera y'obulamu bwo ogigera otya?**

1 ☐ Mbi nyo
2 ☐ Mbi
3 ☐ si mbi ate si nungi
4 ☐ Nungi
5 ☐ Nungi nyo

**2 (G4) Oli mu mativu kwenkana wa n'obulamu bwo obwo mu biiri?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**3 (F1.4) Obulumi bukuziyiza kwenkana ki okukola ebyo byewetaaga okukola?**

1 ☐ Tebunziyiza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**4 (F50.1) Ebizibu by'ofuna ebyekuusa ku bulwadde bwa silimu bwolina bukalubiriza kwenkana wa?**

1 ☐ Tebinkalubiriza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**5 (F11.3) Eddagala olyetagga kwenkanawa osobole okukola emirimo gyo egya buligyo?**

1 ☐ Silyetagga n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**6 (F4.1) Obulamu bwo obunyumirwa kwenkana wa?**

1 ☐ Sibunyumirwa n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**7 (F24.2) Obulamu bwo bulina amakulu kwenkana wa?**

1 ☐ Tebulina n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**8 (F52.2) Abantu okunenya olwokubba n'akawuka ka silimu ki kukoosa kwenkana wa?**

1 ☐ Tekinkoosa n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**9 (F53.4) Obulamu obugya mu masao obwelalikirira kwenkana wa?**

1 ☐ Sibwelalikirira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**10 (F54.1) Okuffa okwelalikirira kwenkana wa?**

1 ☐ Sikwelalikirira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**11 (F5.3) Ekintu okisako omutima kwenkana wa?**

1 ☐ Sikisako n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**12 (F16.1) Owulira obukumi bwenkana wa mu bulamu bwo obwa bulijjo?**

1 ☐ Siwulira bukumi n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**13 (F22.1) Eby'obuyonjo mu kitundu kyoberamu byenkana wa?**

1 ☐ Siwayonjo n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**Ebibuuzo ebiddako bikwata ku busobozi bwo okukola ebintu ebiimu mu wikki ebiri eziyise.**

**14 (F2.1) Olina amanyi agamala okubawo mu lunaku?**

1 ☐ Silina n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**15 (F7.1) Okiriiza engeri gyofanana?**

1 ☐ Sigyikiriiza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**16 (F18.1) Olina esente ezimala okusisinkana ebyetaggo byo?**

1 ☐ Silina n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**17 (F51.1) Abantu b'omanyi bakusembezza kwenkana wa?**

1 ☐ Tebansembezza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**18 (F20.1) Amawuliire ge wetagga bulijjo ogafuna kwenkana wa?**

1 ☐ Sigafuna n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**19 (F21.1) Olina mikisa gyenkana wa okufuna byokola okwewumuza mu?**

1 ☐ Silina n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**20 (F9.1) Osobobola kwenkana wa okuva mu kiffo kimu okudda mu kirala?**

1 ☐ Bubi nyo
2 ☐ Bubi
3 ☐ Si bubi ate si bulungi
4 ☐ Bulungi
5 ☐ Bulungi nyo

**Ebibuuzo ebiddako bikwata ku bumativu bwofunye mu bintu ebye njawulo mu bulamu bwo mu wikki ebiri eziyise**

**21 (F3.3) Oli mu mativu kwenkana wa n'otulo twolina?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**22 (F10.3) Oli mu mativu kwenkana wa n'engeri gyokolamu emiriimo gyo egya bulijjo?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**23 (F12.4) Ori mu mativu kwenkana wa n'obusobozi bwolina okola emiirimo?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**24 (F6.3) Oli mu mativu kwenkana wa nawe w'enyini?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**25 (F13.3) Oli mu mativu kwenkana wa n'enkolagano yo n'emikwano gyo egyo munda?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**26 (F15.3) Oli mu mativu kwenkana wa n'obulamu bwo obw'ekikolwa eky'ekyama?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**27 (F14.4) Oli mu mativu kwenkana wa n'obuyambi bwo'funa okuva eri mikwano gyo?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**28 (F17.3) Oli mu mativu kwenkana wa n'embeera y'ekiffo mwobeera?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**29 (F17.3) Oli mu mativu kwenkana wa n'obwangu bwolina okutukka ku bujjanjabi?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**30 (F23.3) Oli mu mativu kwenkana wa n'ebyentambula?**

1 ☐ Siri mu mativu na katono.
2 ☐ Siri mu mativu
3 ☐ obumativu bwakigero
4 ☐ Ndi mu mativu
5 ☐ Ndi mu mativu ddala

**31 (F8.1) Mirundi emekka lw'owulira obubi gamba nga wenyamidde, oba nga on'akuwadde oba nga oweddemu esuubi?**

1 ☐ Sikiwulira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**APPENDIX VII**
**Specific Quality of Life Questionnaire for HIV– English Version**

**Date** ☐ **HRQoL ID** ☐ **Original** ☐ **2 Week Follow up** ☐

**1. Age** ☐

**2. Sex**
1 ☐ Male
2 ☐ Female

*The following questions ask about certain things that you have experienced in the last 30 days.*

**3. How important to you is it to be free of any pain?**
1 ☐ Not important
2 ☐ A little important
3 ☐ Moderately important
4 ☐ Very important
5 ☐ Extremely important

**4. How hopeful do you feel about the future?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**5. Do you generally feel content?**
1 ☐ Never
2 ☐ Seldom
3 ☐ Quite often
4 ☐ Very often
5 ☐ Always

**6.To what extent can you count on your family and friends when you need them?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**7. To what extent do you feel accepted by the people you know?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**8. To what extent are you bothered by people blaming you for your HIV status?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**9. How much do you worry about death?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**10. Do you have any difficulty with sleeping?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**11. How much are you bothered by any unpleasant physical problems related to your HIV infection?**
1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**12. How much confidence do you have in yourself?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**13. How important to you is it to be free of dependence on medications or treatments?**

1 ☐ Not important
2 ☐ A little important
3 ☐ Moderately important
4 ☐ Very important
5 ☐ Extremely important

**14.How much do you feel discriminated against because of your health condition?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**15. Do you feel you are living in a safe and secure environment?**

1 ☐ Not at all
2 ☐ Slightly
3 ☐ Moderately
4 ☐ Very
5 ☐ Extremely

**16. How guilty do you feel about being HIV positive?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**17. How important to you is your sexual life?**

1 ☐ Not important
2 ☐ A little important
3 ☐ Moderately important
4 ☐ Very important
5 ☐ Extremely important

**18. To what extent are you concerned about your HIV status breaking your family line and your future generations?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**19. Do you have financial difficulties?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**20. Have you enough money to meet your needs?**

1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**21.To what extent do you feel comfortable with your physical environment (e.g. pollution, climate, noise, attractiveness)?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**22.To what extent do you feel comfortable with your ability to provide for or support others?**

1 ☐ Not at all
2 ☐ Slightly
3 ☐ Moderately
4 ☐ Very much
5 ☐ Extremely

**23. How alone do you feel in your life?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**24. To what extent do your personal beliefs give you the strength to face difficulties?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**25. How important is it for you to be forgiven and to forgive others?**

1 ☐ Not important
2 ☐ A little important
3 ☐ Moderately important
4 ☐ Very important
5 ☐ Extremely important

**26.To what extent do any feelings that you are suffering from fate or destiny bother you?**

1 ☐ Not at all
2 ☐ A little
3 ☐ A moderate amount
4 ☐ Very much
5 ☐ An extreme amount

**27. Are thoughts about death and dying important to you?**

1 ☐ Not important
2 ☐ A little important
3 ☐ Moderately important
4 ☐ Very important
5 ☐ Extremely important

**28. In what year did you first test positive for HIV??**

**29. In what year do you think you were infected?**

**30. How do you believe you were infected with HIV?**

1 ☐ Sex with a man
2 ☐ Sex with a woman
3 ☐ Injecting drugs
4 ☐ Blood products
5 ☐ Other specify

**APPENDIX VII**
**Specific Quality of Life Questionnaire for HIV- Luganda Version**

| Date | | HRQoL ID | | Original ☐ 2 Week Follow Up ☐ |
|---|---|---|---|---|

**1. Emyaka** ☐

**2. Muntu ki?**
1 ☐ Musajja
2 ☐ Mukazi

**Ebibuuzo ebiddako bikwata ku bintu byo yisemu mu nakku amakumi asatu eziyesi.**

**3. Okuba nga tolina bulumi kirina bukulu bwenkana gyoli?**
1 ☐ Sikikulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**4. Esuubi ly'olina kubulamu obwo mu maso lyenkanawa?**
1 ☐ Sirina subi n'akumu
2 ☐ Tono
3 ☐ Lya kigero
4 ☐ Lingi nyo
5 ☐ Lingi nyo ddala

**5. Okutwalira awamu, owulira oli mumativu?**
1 ☐ Siri mumativu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**6. Mikwano gyo n'abenganda zo oba subiriramu kwenkana wa bwo ba mu bwetavu?**
1 ☐ Sibasubiramu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**7. Abantu b'omanyi bakusembezza kwenkana wa?**
1 ☐ Not at all
2 ☐ A little
3 ☐ Moderately
4 ☐ Mostly
5 ☐ Completely

**8. Abantu okunenya olw'okubba n'akawuka ka silimu ki kukoosa kwenkana wa?**
1 ☐ Tekinkoosa n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**9. Okufa okwelalikirira kwenkana wa?**
1 ☐ Sikwelalikirira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**10. Otawanyizibwa mu tulo?**
1 ☐ Sitawanyizibwa n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**11. Ebizibu by'ofuna ebyekuusa ku bulwadde bwa silimu bwolina bikalubiriza kwenkana wa?**
1 ☐ Tebinkalubiriza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**12. Obuvumu bw'olina bwenkana wa?**

1 ☐ Silina buvumu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**13. Okuba nga tewesigamye ku dagala kirina bukulu bwenkana wa gyoli?**

1 ☐ Tekirina bukulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**14. Mirundi emekka gy'owulira nga abantu bakusosodde olw'embeera y'obulamu bwo?**

1 ☐ Sikiwulira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**15. Ekifo mw'owbera kirimu obukumi bwenkana wa?**

1 ☐ Tekirina bukumi n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**16. Owulira omusango gwenkana wa olwo kubba n'akawuka ka silimu?**

1 ☐ Sikiwulira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**17. Obulamu bwo obwokwegatta mu kikolwa ekyekyama bulina bukulu bwenkana wa gyoli?**

1 ☐ Tekilina bukulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**18. Engeri y'okuba n'akawuka ka sirimu gye ki kutula ku makka go oba olunyiriiri lwo olugya mu maso kikwelalikiriza kwenkana wa?**

1 ☐ Tekilina bukulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**19. Olina obuzibu mu by'efunal/ by'ensimbi?**

1 ☐ Silina buzibu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**20. Olina essente ezimala okusisikana ebyataggo byo ?**

1 ☐ Sirina sente n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**21. Oli mu mativu kwenkana wa n'embeera y'ekitundu mwoli (gamba embeera y'obudde, okuwowgana, obulungi bwe kiffo)?**

1 ☐ Siri mumativu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
**5** ☐ Nyo ddala

**22. Oli mu mativu kwenkana wa n'obusobozi bw'olina okuyamba abantu abalala?**

1 ☐ Siri mumativu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
**5 ☐ Nyo ddala**

**23. Owulira olekeddwawo obwomu kwenkana wa?**

1 ☐ Si kiwulira n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**24. By'okiririzamu bikuwa amanyi ag'okugumiira ebizibu kwenkana wa?**

1 ☐ Tebimpa manyi n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**25. Okusonyiwa n'okusonyibwa kirina bukulu bwenkanawa gyoli?**

1 ☐ Tebilina bukulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
**5 ☐ Nyo ddala**

**26. Okulowoza nti obonabona olw'omukisa omubi oguteebereka ki kwelalikiriza kwenkana wa?**

1 Tekinelalikiriza n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**27. Ebirowozo ku kuffa birina bukulu bwenkana wa gyoli?**

1 ☐ Tebirina makulu n'akamu
2 ☐ Katono
3 ☐ Kigero
4 ☐ Nyo
5 ☐ Nyo ddala

**28. Mwaka ki lwewekebeza n'ofuna obukakafu nti olina akawuka ka silimu?**

**29. Olowoza obulwadde wa bufuna mwaka ki?**

**30. Osubira obulwadde wa bufuna otya?**

1 ☐ Okwegata n'omusajja
2 ☐ Okwegata n'omukazi
3 ☐ Mu mpiiso
4 ☐ Mukufuna omusayi
5 ☐ Ekirala (kiwandike wo)

## APPENDIX VIIIa
## Trend analysis for perceived overall economic situation and perceived quality of life for both groups for the two follow up periods

### ART DART group six months

```
Table 1
ologit econ6 feelqol6 if group2==1
Iteration 0:   log likelihood = -262.44579
Iteration 1:   log likelihood = -257.63002
Iteration 2:   log likelihood = -257.60199
Iteration 3:   log likelihood = -257.60198

Ordered logistic regression                     Number of obs   =        245
                                                LR chi2(1)      =       9.69
                                                Prob > chi2     =     0.0019
Log likelihood = -257.60198                     Pseudo R2       =     0.0185

------------------------------------------------------------------------------
       econ6 |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    feelqol6 |   .6681448   .2281751     2.93   0.003     .2209299     1.11536
-------------+----------------------------------------------------------------
       /cut1 |  -.0641113   .2977082                     -.6476087    .5193862
       /cut2 |   1.084326   .3040145                      .4884686    1.680183
------------------------------------------------------------------------------
```

### ART DART group twelve months

```
Table 2
ologit econ12 feelqol12 if group2==1
Iteration 0:   log likelihood = -258.91609
Iteration 1:   log likelihood = -252.95714
Iteration 2:   log likelihood = -252.90997
Iteration 3:   log likelihood = -252.90994

Ordered logistic regression                     Number of obs   =        245
                                                LR chi2(1)      =      12.01
                                                Prob > chi2     =     0.0005
Log likelihood = -252.90994                     Pseudo R2       =     0.0232

------------------------------------------------------------------------------
      econ12 |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   feelqol12 |   .6662951   .2057146     3.24   0.001     .2631018    1.069488
-------------+----------------------------------------------------------------
       /cut1 |  -.0873771   .2805009                     -.6371487    .4623944
       /cut2 |   .9681708   .2845662                      .4104313     1.52591
------------------------------------------------------------------------------
```

## Non ART EC group six months

```
Table 3
ologit econ6 feelqol6 if group2==0
Iteration 0:   log likelihood = -113.50938
Iteration 1:   log likelihood = -110.84951
Iteration 2:   log likelihood = -110.84007
Iteration 3:   log likelihood = -110.84007

Ordered logistic regression                     Number of obs   =        117
                                                LR chi2(1)      =       5.34
                                                Prob > chi2     =     0.0209
Log likelihood = -110.84007                     Pseudo R2       =     0.0235
------------------------------------------------------------------------------
       econ6 |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    feelqol6 |   .4608302   .2020859     2.28   0.023     .0647492    .8569112
-------------+----------------------------------------------------------------
       /cut1 |  -.7160845   .4408873                     -1.580208    .1480387
       /cut2 |   .6150478   .4332163                     -.2340406    1.464136
------------------------------------------------------------------------------
```

## Non ART EC group twelve months

```
Table 3
ologit econ12 feelqol12 if group2==0
Iteration 0:   log likelihood = -118.45672
Iteration 1:   log likelihood = -118.05711
Iteration 2:   log likelihood = -118.05697

Ordered logistic regression                     Number of obs   =        117
                                                LR chi2(1)      =       0.80
                                                Prob > chi2     =     0.3712
Log likelihood = -118.05697                     Pseudo R2       =     0.0034
------------------------------------------------------------------------------
      econ12 |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
   feelqol12 |   .1780037   .1997724     0.89   0.373     -.213543    .5695504
-------------+----------------------------------------------------------------
       /cut1 |  -1.264564   .4264154                     -2.100323   -.4288054
       /cut2 |   .3051901   .4048486                     -.4882986    1.098679
------------------------------------------------------------------------------
```

**APPENDIX VIIIb**

**ASSET OF LIVING STANDARDS INDEX**

**BASELINE DATA ANALYSIS**

**ART DC Group DATA**

**Principal component analysis**

factor roof wall room elec lake well pipe tap fridge radio phone mbike tv video bicycle car, pc
(obs=276)

(principal components; 16 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 3.55626 | 1.69718 | 0.2223 | 0.2223 |
| 2 | 1.85907 | 0.54630 | 0.1162 | 0.3385 |
| 3 | 1.31277 | 0.06166 | 0.0820 | 0.4205 |
| 4 | 1.25111 | 0.10863 | 0.0782 | 0.4987 |
| 5 | 1.14248 | 0.12686 | 0.0714 | 0.5701 |
| 6 | 1.01562 | 0.08332 | 0.0635 | 0.6336 |
| 7 | 0.93230 | 0.09926 | 0.0583 | 0.6919 |
| 8 | 0.83304 | 0.08969 | 0.0521 | 0.7439 |
| 9 | 0.74335 | 0.03341 | 0.0465 | 0.7904 |
| 10 | 0.70994 | 0.05819 | 0.0444 | 0.8347 |
| 11 | 0.65175 | 0.04652 | 0.0407 | 0.8755 |
| 12 | 0.60523 | 0.06178 | 0.0378 | 0.9133 |
| 13 | 0.54345 | 0.10418 | 0.0340 | 0.9473 |
| 14 | 0.43927 | 0.07695 | 0.0275 | 0.9747 |
| 15 | 0.36232 | 0.32029 | 0.0226 | 0.9974 |
| 16 | 0.04203 | . | 0.0026 | 1.0000 |

Eigenvectors

| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | -0.13997 | -0.01142 | 0.07858 | 0.59905 | 0.09619 | 0.21004 |
| wall | -0.24031 | -0.00707 | -0.27455 | 0.33459 | 0.09647 | 0.20971 |
| room | -0.27868 | 0.24432 | -0.16536 | 0.04867 | -0.14239 | 0.10289 |
| elec | 0.34464 | 0.13671 | -0.01746 | 0.04512 | -0.39435 | 0.10767 |
| lake | -0.08001 | -0.06905 | 0.33743 | 0.05483 | 0.69429 | 0.12894 |
| well | -0.09669 | -0.60282 | -0.09022 | 0.20983 | -0.29883 | -0.08217 |
| pipe | -0.09406 | 0.67269 | 0.11297 | 0.10035 | -0.07912 | -0.08326 |
| tap | 0.30416 | -0.17796 | -0.16571 | -0.40687 | 0.20963 | 0.19424 |
| fridge | 0.39094 | 0.08257 | -0.18680 | 0.07706 | 0.07850 | 0.12115 |
| radio | 0.23005 | 0.06140 | 0.40210 | 0.11294 | 0.02114 | -0.04929 |
| phone | 0.31607 | 0.10914 | 0.05370 | 0.05530 | 0.16790 | -0.08687 |
| mbike | 0.06032 | -0.12017 | 0.43499 | -0.01817 | -0.18354 | 0.64077 |
| tv | 0.38147 | 0.05695 | 0.04515 | 0.21947 | -0.19662 | 0.20051 |
| video | 0.24548 | -0.03913 | -0.33073 | 0.39457 | 0.18450 | 0.05380 |
| bicycle | 0.08560 | -0.16547 | 0.44357 | 0.22279 | -0.11646 | -0.50655 |
| car | 0.29445 | -0.00117 | -0.17809 | 0.16297 | 0.17138 | -0.29455 |

Eigenvectors

| Variable | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|
| roof | -0.11807 | -0.43896 | 0.10879 | -0.53904 | 0.17804 | 0.03435 |
| wall | 0.34561 | 0.40692 | -0.36028 | 0.05573 | 0.03036 | -0.44295 |
| room | 0.42136 | -0.13190 | 0.37741 | 0.11309 | -0.09703 | 0.24619 |
| elec | 0.18729 | 0.01789 | 0.41463 | 0.09132 | -0.02874 | -0.02596 |
| lake | 0.11100 | 0.10764 | 0.45767 | 0.24722 | -0.12409 | -0.07995 |
| well | -0.10160 | -0.14413 | 0.06932 | 0.20035 | -0.20565 | -0.09165 |
| pipe | -0.19810 | 0.11391 | -0.11547 | 0.01487 | 0.05960 | 0.04269 |
| tap | 0.30480 | -0.08144 | -0.09050 | -0.33040 | 0.27278 | 0.14275 |
| fridge | 0.01261 | 0.12232 | 0.11394 | -0.22890 | 0.04397 | -0.24692 |
| radio | 0.42763 | -0.23359 | -0.43582 | -0.06876 | -0.55054 | 0.11522 |
| phone | -0.19004 | -0.44931 | -0.14320 | 0.43929 | 0.24333 | -0.32674 |
| mbike | -0.30214 | 0.30412 | -0.10958 | 0.05363 | 0.03080 | 0.19007 |
| tv | 0.13118 | 0.03404 | 0.13962 | 0.09687 | -0.02372 | -0.26081 |
| video | 0.01345 | 0.07599 | -0.17103 | 0.36788 | 0.15198 | 0.64025 |
| bicycle | 0.26418 | 0.31239 | 0.05983 | -0.08068 | 0.48414 | 0.07024 |
| car | -0.31873 | 0.32193 | 0.14300 | -0.26524 | -0.44526 | 0.06588 |

```
                Eigenvectors
    Variable |      13         14         15         16
-------------+--------------------------------------------
        roof |   -0.03407     0.05936    0.12295   -0.01313
        wall |    0.09947     0.06464    0.26576    0.04266
        room |    0.59402     0.01905   -0.16887   -0.01160
        elec |   -0.23413    -0.10868    0.63865    0.03766
        lake |   -0.14389    -0.03317    0.02402    0.18613
        well |    0.05338    -0.12098   -0.09422    0.57092
        pipe |   -0.08032    -0.00220   -0.06795    0.64838
         tap |    0.11765     0.23687    0.08814    0.46016
      fridge |    0.11197    -0.70828   -0.34776    0.01195
       radio |    0.00632    -0.12921    0.02010    0.01951
       phone |    0.43810     0.04295    0.18704   -0.01751
       mbike |    0.32878    -0.03472    0.05319   -0.01531
          tv |   -0.18491     0.55304   -0.51427   -0.04265
       video |   -0.16258    -0.06275   -0.03965   -0.02659
     bicycle |    0.17489    -0.02227   -0.02951    0.00078
         car |    0.36552     0.27674    0.17306    0.01138
```

The first eigenvector is then used to estimate the asset index of living standards to determine which other variables apart from electricity explains the welfare within the household.

```
score proxy_index
(based on unrotated principal components) (15 scorings not used)

 Scoring Coefficients
    Variable |      1
-------------+----------
        roof |  -0.13997
        wall |  -0.24031
        room |  -0.27868
        elec |   0.34464
        lake |  -0.08001
        well |  -0.09669
        pipe |  -0.09406
         tap |   0.30416
      fridge |   0.39094
       radio |   0.23005
       phone |   0.31607
       mbike |   0.06032
          tv |   0.38147
       video |   0.24548
     bicycle |   0.08560
         car |   0.29445
```

The correlation between the proxy asset index of living standard and family expenditure (consumption) reported by individuals was estimated.

```
corr proxy_index family expenditure -(obs=174)
                    | proxy_~x  family expenditure
--------------------+------------------
 proxy_index        |   1.0000
 family expenditure |  -0.2829   1.0000
```

```
ineqerr  index2dc
index2dc ----------------------------------- (unlabeled)(obs=276)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+-------------------------------------------------------------------
    Gini |    100   .1483962  -.0015142   .0083096     .1319081   .1648843
(N)
         |                                             .1302336   .1661373
(P)
         |                                             .1336814   .1700789
(BC)
---------+-------------------------------------------------------------------
                              N = normal, P = percentile, BC = bias-corrected
```

```
ineqerr  moneydc
moneydc ------------------------------------------------- (unlabeled)
1 values = 0. Not used in calculations.
(obs=173)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------
    Gini |    100   .5886581  -.0105132   .0407766    .5077485   .6695677
(N)      |                                             .4975624   .6496298
(P)      |                                             .5098221   .6606963
(BC)
---------+--------------------------------------------------------------
                                N = normal, P = percentile, BC = bias-corrected
```

**Non ART EC Group DATA**

The same mathematical process was followed with the Non ART EC data.

**Principal component analysis**

factor roof wall room elec lake well pipe tap fridge radio phone mbike tv video bicycle car, pc
(obs=159)

(principal components; 16 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 4.63078 | 2.58917 | 0.2894 | 0.2894 |
| 2 | 2.04160 | 0.83614 | 0.1276 | 0.4170 |
| 3 | 1.20547 | 0.07749 | 0.0753 | 0.4924 |
| 4 | 1.12798 | 0.07857 | 0.0705 | 0.5629 |
| 5 | 1.04941 | 0.12989 | 0.0656 | 0.6285 |
| 6 | 0.91951 | 0.03944 | 0.0575 | 0.6859 |
| 7 | 0.88008 | 0.10182 | 0.0550 | 0.7409 |
| 8 | 0.77826 | 0.10015 | 0.0486 | 0.7896 |
| 9 | 0.67811 | 0.08007 | 0.0424 | 0.8319 |
| 10 | 0.59804 | 0.02033 | 0.0374 | 0.8693 |
| 11 | 0.57771 | 0.12426 | 0.0361 | 0.9054 |
| 12 | 0.45346 | 0.02389 | 0.0283 | 0.9338 |
| 13 | 0.42956 | 0.09704 | 0.0268 | 0.9606 |
| 14 | 0.33252 | 0.04550 | 0.0208 | 0.9814 |
| 15 | 0.28702 | 0.27653 | 0.0179 | 0.9993 |
| 16 | 0.01050 | . | 0.0007 | 1.0000 |

Eigenvectors

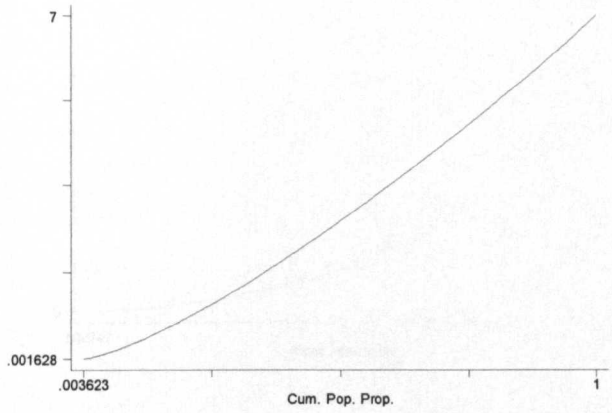
| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | -0.20880 | 0.03331 | 0.27182 | 0.02289 | 0.01115 | 0.57316 |
| wall | -0.29165 | -0.06692 | 0.02875 | 0.17493 | -0.30347 | 0.15802 |
| room | -0.26435 | 0.27568 | -0.04852 | -0.03866 | -0.21736 | -0.08811 |
| elec | 0.31217 | 0.18541 | -0.09318 | 0.04983 | -0.03679 | -0.13381 |
| lake | -0.04760 | -0.08158 | 0.77620 | 0.28110 | -0.27283 | -0.16023 |
| well | -0.18703 | -0.53123 | -0.29191 | 0.05706 | 0.17345 | -0.09128 |
| pipe | 0.03463 | 0.64730 | -0.04828 | -0.22410 | 0.08267 | 0.18722 |
| tap | 0.32928 | -0.22461 | -0.09427 | 0.07498 | -0.22415 | -0.05293 |
| fridge | 0.35372 | -0.06886 | -0.00895 | -0.04533 | -0.11817 | 0.10086 |
| radio | 0.15224 | 0.10660 | 0.13040 | 0.32533 | 0.43904 | -0.03911 |
| phone | 0.30060 | 0.12935 | 0.03311 | 0.32533 | 0.03614 | -0.25521 |
| mbike | -0.01525 | 0.06834 | -0.19580 | 0.67736 | 0.25295 | 0.38950 |
| tv | 0.34983 | 0.06286 | 0.14870 | -0.00881 | 0.02638 | -0.06668 |
| video | 0.31007 | -0.12048 | -0.01675 | -0.11555 | -0.17061 | 0.33962 |
| bicycle | 0.05549 | -0.20358 | 0.36935 | -0.36685 | 0.59539 | 0.08580 |
| car | 0.31088 | -0.16826 | -0.00155 | -0.07894 | -0.20319 | 0.43965 |

```
                Eigenvectors
    Variable |      7          8          9         10         11         12
-------------+------------------------------------------------------------
        roof |   0.51165   -0.35040   -0.18384    0.11030   -0.13406    0.08968
        wall |   0.00765    0.13170    0.59345   -0.13199    0.34147    0.45568
        room |  -0.16256    0.34788   -0.24284    0.59894    0.08028    0.16166
        elec |   0.18423   -0.27986   -0.00873    0.52258    0.04410    0.21823
        lake |  -0.14548    0.01429   -0.07311    0.08965   -0.03505   -0.16741
        well |   0.15363   -0.04403    0.15972    0.30080   -0.13059   -0.00844
        pipe |  -0.07528    0.01500    0.10206   -0.18293    0.01039    0.00272
         tap |   0.01706    0.05341   -0.45503   -0.30408    0.24022    0.12444
      fridge |   0.10927   -0.05030   -0.04033    0.15594    0.58240    0.05108
       radio |   0.47617    0.64479    0.00718   -0.01817    0.04121    0.02727
       phone |  -0.11262   -0.18465    0.14615   -0.05229   -0.44694    0.47842
       mbike |  -0.42787   -0.14537   -0.09367    0.08415    0.17420   -0.15426
          tv |   0.12300   -0.19947    0.44328    0.10195    0.16725   -0.30813
       video |  -0.18882    0.30748    0.26851    0.23570   -0.26855   -0.32764
     bicycle |  -0.37091   -0.02074   -0.00082    0.11650    0.17815    0.32954
         car |  -0.06542    0.21688   -0.07900   -0.01250   -0.27950    0.31630


                Eigenvectors
    Variable |     13         14         15         16
-------------+--------------------------------------
        roof |   0.20427   -0.09498    0.21203    0.00234
        wall |  -0.13724   -0.08919    0.15401    0.01455
        room |   0.31001    0.21313    0.23651    0.00812
        elec |  -0.61424   -0.15712    0.02638    0.00879
        lake |  -0.12638   -0.01828   -0.18851    0.30597
        well |   0.09660    0.07072   -0.10361    0.61009
        pipe |  -0.01567   -0.03044   -0.10213    0.65106
         tap |  -0.02417   -0.05192    0.53357    0.33127
      fridge |   0.41904   -0.19476   -0.49812   -0.00335
       radio |  -0.05027   -0.02092   -0.00067   -0.00603
       phone |   0.44600   -0.14236    0.02819    0.00591
       mbike |  -0.05197    0.07236    0.01104    0.00131
          tv |   0.16989    0.55671    0.35042    0.00440
       video |   0.05024   -0.49148    0.22331    0.00042
     bicycle |  -0.02660   -0.04811    0.16615    0.00971
         car |  -0.16755    0.53506   -0.28981   -0.00219

score proxy_index
(based on unrotated principal components)
(15 scorings not used)

              Scoring Coefficients
    Variable |      1
-------------+----------
        roof |  -0.20880
        wall |  -0.29165
        room |  -0.26435
        elec |   0.31217
        lake |  -0.04760
        well |  -0.18703
        pipe |   0.03463
         tap |   0.32928
      fridge |   0.35372
       radio |   0.15224
       phone |   0.30060
       mbike |  -0.01525
          tv |   0.34983
       video |   0.31007
     bicycle |   0.05549
         car |   0.31088

corr proxy_index family expenditure
(obs=115)

                     | proxy_~x  family expenditure
---------------------+------------------
 proxy_index         |   1.0000
 family expenditure  |  -0.5044   1.0000
```

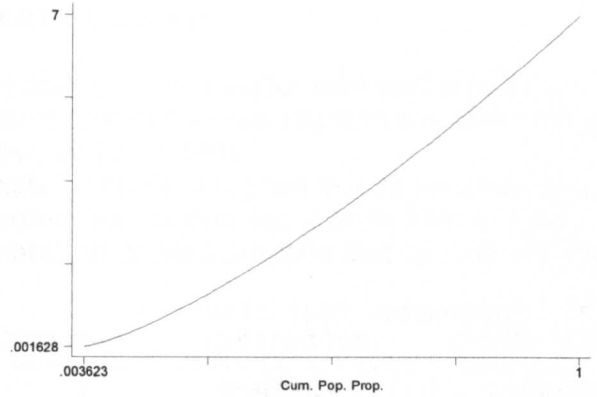
```
ineqerr index2ec

index2ec ------------------------------------------------ (unlabeled)
(obs=159)
Bootstrap statistics
Variable |   Reps   Observed       Bias    Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
-
    Gini |    100    .109175  -.0030061    .0133208    .0827437   .1356062
(N)
         |                                              .0808627   .1353289
(P)
         |                                              .0865429   .1366253
(BC)
---------+--------------------------------------------------------------------
                              N = normal, P = percentile, BC = bias-corrected

ineqerr  moneyec

moneyec ------------------------------------------------ (unlabeled)
(obs=115)
Bootstrap statistics
Variable |   Reps   Observed       Bias    Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
-
    Gini |    100    .5194304  -.0097765    .0273593    .4651437   .5737172
(N)
         |                                              .4576651    .559037
(P)
         |                                              .4701042   .5622128
(BC)
---------+--------------------------------------------------------------------
                              N = normal, P = percentile, BC = bias-corrected
```

Unfortunately the curves of Lorenz did not help to differentiate between the groups see graphs below.

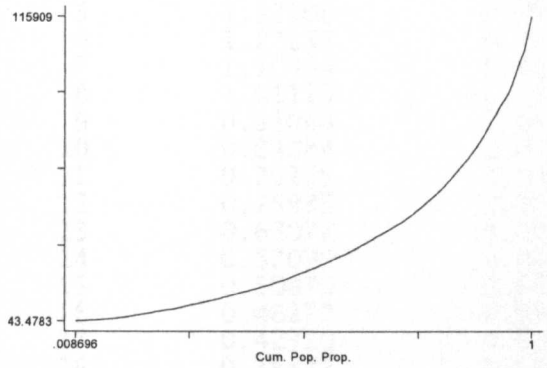
**Graph 5.1 Asset index of living standards -Lorenz curve ART DC group**



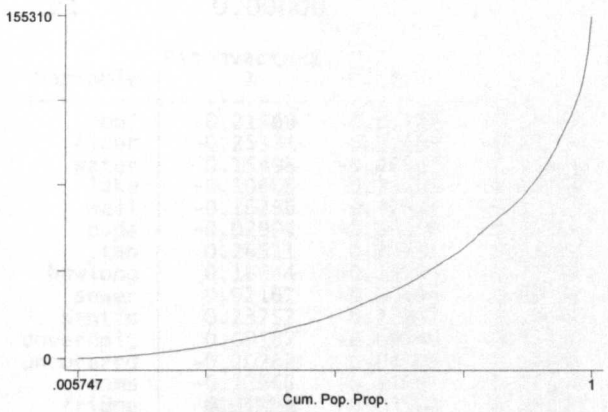
**Graph 5.2 Asset index of living standards -Lorenz curve Non ART EC group**




**Graph 5.3 Family expenditure -Lorenz curve ART DC group**




**Graph 5.4 Family expenditure -Lorenz curve Non ART EC group**



**SIX MONTHS ANALYSIS**

**ART DC Group**

factor roof floor water lake well pipe tap howlong notoilet sewer septic bucket coverdpit uncovered improved rooms fridge radio phone mbike tv video bicycle car, pc (obs=248)
note: notoilet dropped due to zero variance
note: bucket dropped due to zero variance
note: improved dropped due to zero variance

(principal components; 20 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 3.92488 | 1.65471 | 0.1869 | 0.1869 |
| 2 | 2.27017 | 0.26203 | 0.1081 | 0.2950 |
| 3 | 2.00814 | 0.56796 | 0.0956 | 0.3906 |
| 4 | 1.44018 | 0.11718 | 0.0686 | 0.4592 |
| 5 | 1.32300 | 0.09147 | 0.0630 | 0.5222 |
| 6 | 1.23153 | 0.12759 | 0.0586 | 0.5809 |
| 7 | 1.10394 | 0.09281 | 0.0526 | 0.6334 |
| 8 | 1.01113 | 0.10069 | 0.0481 | 0.6816 |
| 9 | 0.91044 | 0.06960 | 0.0434 | 0.7249 |
| 10 | 0.84084 | 0.04856 | 0.0400 | 0.7650 |
| 11 | 0.79228 | 0.03289 | 0.0377 | 0.8027 |
| 12 | 0.75939 | 0.12861 | 0.0362 | 0.8389 |
| 13 | 0.63078 | 0.05979 | 0.0300 | 0.8689 |
| 14 | 0.57099 | 0.06225 | 0.0272 | 0.8961 |
| 15 | 0.50874 | 0.02602 | 0.0242 | 0.9203 |
| 16 | 0.48272 | 0.05952 | 0.0230 | 0.9433 |
| 17 | 0.42320 | 0.03448 | 0.0202 | 0.9634 |
| 18 | 0.38872 | 0.01617 | 0.0185 | 0.9820 |
| 19 | 0.37255 | 0.36617 | 0.0177 | 0.9997 |
| 20 | 0.00639 | 0.00639 | 0.0003 | 1.0000 |
| 21 | 0.00000 | . | 0.0000 | 1.0000 |

Eigenvectors

| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | -0.21569 | 0.01748 | -0.10161 | 0.09116 | 0.34133 | -0.35310 |
| floor | -0.25531 | 0.22693 | -0.09354 | 0.23111 | 0.04405 | -0.09460 |
| water | 0.15498 | -0.40967 | 0.13420 | -0.25023 | -0.13556 | -0.02721 |
| lake | -0.10666 | 0.25329 | -0.02092 | 0.60526 | 0.06601 | 0.14674 |
| well | -0.16238 | 0.42028 | -0.12562 | -0.45826 | 0.07381 | -0.00982 |
| pipe | -0.02994 | -0.59786 | -0.05047 | 0.10786 | 0.17120 | 0.12639 |
| tap | 0.26511 | 0.23701 | 0.21303 | 0.06220 | -0.34168 | -0.22920 |
| howlong | 0.18944 | -0.13303 | 0.17166 | 0.45552 | -0.08340 | -0.14349 |
| sewer | 0.01167 | -0.00465 | 0.00283 | -0.12852 | 0.03195 | 0.47194 |
| septic | 0.23752 | 0.12887 | 0.24008 | 0.02608 | -0.36322 | 0.02212 |
| coverdpit | 0.09187 | -0.09840 | -0.63996 | 0.04119 | -0.17241 | -0.20111 |
| uncovered | -0.20262 | 0.04508 | 0.54494 | -0.02390 | 0.32187 | 0.08640 |
| rooms | -0.22668 | -0.14897 | 0.22280 | 0.06017 | -0.07090 | -0.12592 |
| fridge | 0.37104 | 0.07160 | 0.01799 | 0.04013 | 0.21987 | -0.08050 |
| radio | 0.17361 | -0.00771 | -0.14891 | 0.14932 | 0.11857 | 0.26312 |
| phone | 0.30047 | 0.01457 | 0.02118 | -0.05732 | 0.34675 | 0.13419 |
| mbike | 0.10022 | 0.08838 | -0.03645 | -0.03120 | 0.33779 | -0.06248 |
| tv | 0.34170 | -0.00204 | -0.04296 | -0.00949 | 0.30924 | -0.21408 |
| video | 0.32120 | 0.11567 | 0.04070 | 0.00776 | 0.17916 | -0.11294 |
| bicycle | 0.04124 | 0.09529 | -0.16404 | 0.14414 | -0.04130 | 0.53390 |
| car | 0.26884 | 0.14853 | 0.02887 | -0.06437 | -0.05367 | 0.16332 |

**score proxy_index**
(based on unrotated principal components)
(19 scorings not used)

```
            Scoring Coefficients
    Variable |      1
-------------+----------
        roof |  -0.21569
       floor |  -0.25531
       water |   0.15498
        lake |  -0.03562
        well |   0.00000
        pipe |   0.17419
         tap |   0.41619
     howlong |   0.18944
       sewer |   0.01167
      septic |   0.23752
   coverdpit |   0.09187
   uncovered |  -0.20262
       rooms |  -0.22668
      fridge |   0.37104
       radio |   0.17361
       phone |   0.30047
       mbike |   0.10022
          tv |   0.34170
       video |   0.32120
     bicycle |   0.04124
         car |   0.26884
```

```
corr proxy_index money
(obs=190)
             | proxy_~x    money
-------------+------------------
 proxy_index |   1.0000
       money |  -0.3687   1.0000
```

**ineqerr index2**

```
index2 ------------------------------------------------------------ (unlabeled)
(obs=248)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100    .125981  -.0009622   .0093554     .1074179   .1445441
(N)
         |                                             .1074881   .1426283
(P)
         |                                             .1092607   .1466706
(BC)
---------+--------------------------------------------------------------------
                              N = normal, P = percentile, BC = bias-corrected
```

**ineqerr money**

```
money -------------------------------------------------------------- (unlabeled)
2 values = 0. Not used in calculations.
(obs=190)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .4928297   -.007406   .0244554     .4443049   .5413545
(N)
         |                                             .4396214   .5269907
(P)
         |                                              .452889   .5424197
(BC)
---------+--------------------------------------------------------------------
                              N = normal, P = percentile, BC = bias-corrected
```

**NON ART EC GROUP**

factor roof floor water lake well pipe tap howlong notoilet sewer septic bucket coverdpit uncovered improved rooms fridge radio phone mbike tv video bicycle car, pc
(obs=141)
note: notoilet dropped due to zero variance
note: bucket dropped due to zero variance
note: improved dropped due to zero variance

(principal components; 20 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 3.90061 | 1.55379 | 0.1857 | 0.1857 |
| 2 | 2.34682 | 0.18457 | 0.1118 | 0.2975 |
| 3 | 2.16225 | 0.62127 | 0.1030 | 0.4005 |
| 4 | 1.54098 | 0.13957 | 0.0734 | 0.4738 |
| 5 | 1.40141 | 0.18382 | 0.0667 | 0.5406 |
| 6 | 1.21760 | 0.05749 | 0.0580 | 0.5986 |
| 7 | 1.16011 | 0.12455 | 0.0552 | 0.6538 |
| 8 | 1.03556 | 0.03188 | 0.0493 | 0.7031 |
| 9 | 1.00368 | 0.07053 | 0.0478 | 0.7509 |
| 10 | 0.93315 | 0.18426 | 0.0444 | 0.7953 |
| 11 | 0.74889 | 0.08208 | 0.0357 | 0.8310 |
| 12 | 0.66681 | 0.01993 | 0.0318 | 0.8628 |
| 13 | 0.64688 | 0.07688 | 0.0308 | 0.8936 |
| 14 | 0.57000 | 0.10984 | 0.0271 | 0.9207 |
| 15 | 0.46016 | 0.08209 | 0.0219 | 0.9426 |
| 16 | 0.37807 | 0.03874 | 0.0180 | 0.9606 |
| 17 | 0.33934 | 0.06689 | 0.0162 | 0.9768 |
| 18 | 0.27244 | 0.06775 | 0.0130 | 0.9898 |
| 19 | 0.20469 | 0.19417 | 0.0097 | 0.9995 |
| 20 | 0.01053 | 0.01053 | 0.0005 | 1.0000 |
| 21 | -0.00000 | . | -0.0000 | 1.0000 |

Eigenvectors

| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | -0.18882 | -0.03030 | 0.01775 | 0.35926 | 0.40580 | 0.09217 |
| floor | 0.02118 | 0.18939 | 0.09203 | 0.35826 | -0.31639 | -0.06758 |
| water | 0.10621 | 0.21228 | 0.38414 | 0.30324 | -0.04339 | 0.13085 |
| lake | -0.08678 | -0.21050 | -0.28104 | -0.46845 | 0.22374 | -0.00703 |
| well | -0.17126 | -0.12941 | -0.36846 | 0.37409 | -0.38277 | -0.05590 |
| pipe | -0.05916 | 0.03130 | 0.56028 | -0.06834 | 0.27710 | -0.33865 |
| tap | 0.30728 | 0.21573 | -0.15946 | -0.05721 | -0.06331 | 0.49384 |
| howlong | 0.27565 | 0.26937 | 0.20353 | -0.11293 | 0.04004 | 0.29121 |
| sewer | 0.08764 | 0.11491 | 0.05096 | -0.35440 | -0.46481 | -0.16631 |
| septic | 0.30608 | 0.13636 | -0.23529 | 0.06335 | 0.16231 | -0.31322 |
| coverdpit | 0.10751 | -0.52726 | 0.23497 | 0.13444 | -0.13627 | 0.00224 |
| uncovered | -0.22238 | 0.46452 | -0.14695 | -0.04386 | 0.18462 | 0.15298 |
| rooms | -0.28238 | 0.24808 | 0.04548 | -0.06524 | -0.15752 | -0.06752 |
| fridge | 0.31411 | 0.02503 | -0.01919 | -0.07154 | -0.09043 | -0.29529 |
| radio | 0.14080 | -0.23507 | 0.04289 | -0.00181 | 0.02723 | 0.21145 |
| phone | 0.31999 | -0.03292 | 0.12404 | -0.10898 | 0.00982 | 0.03621 |
| mbike | 0.02032 | -0.02447 | 0.10328 | -0.03500 | -0.00815 | 0.06735 |
| tv | 0.38721 | -0.04174 | -0.05018 | 0.04007 | -0.05773 | -0.01501 |
| video | 0.26698 | 0.09983 | -0.23478 | 0.17226 | 0.29842 | -0.35347 |
| bicycle | -0.03627 | -0.27430 | 0.03303 | -0.04729 | 0.09524 | 0.30256 |
| car | 0.23648 | -0.07331 | -0.15596 | 0.25482 | 0.15485 | 0.12280 |

```
score proxy_index
(based on unrotated principal components); (19 scorings not used)

             Scoring Coefficients
    Variable |       1
-------------+----------
        roof |  -0.18882
       floor |   0.02118
       water |   0.10621
        lake |  -0.06104
        well |  -0.12111
        pipe |   0.00000
         tap |   0.35389
     howlong |   0.27565
       sewer |   0.08764
      septic |   0.30608
   coverdpit |   0.10751
   uncovered |  -0.22238
       rooms |  -0.28238
      fridge |   0.31411
       radio |   0.14080
       phone |   0.31999
       mbike |   0.02032
          tv |   0.38721
       video |   0.26698
     bicycle |  -0.03627
         car |   0.23648


corr proxy_index money
(obs=104)
             | proxy_~x    money
-------------+------------------
 proxy_index |   1.0000
       money |  -0.3985   1.0000
```

**ineqerr money**

```
money ------------------------------------------------------------ (unlabeled)
(obs=104)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .4963499  -.0023662   .0261714    .4444202  .5482796  (N)
         |                                            .4357103  .5454704  (P)
         |                                            .4357103  .5454704 (BC)
---------+--------------------------------------------------------------------
                        N = normal, P = percentile, BC = bias-corrected
```

**ineqerr index2**

```
index2 ------------------------------------------------------------ (unlabeled)
(obs=141)
Bootstrap statistics
Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .0990143   .0011632   .0103536    .0784704  .1195581  (N)
         |                                            .0788363  .1181556  (P)
         |                                            .0748615  .1176747 (BC)
---------+--------------------------------------------------------------------
                        N = normal, P = percentile, BC = bias-corrected
```

## TWELVE MONTHS ANALYSIS

## ART DC Group

```
factor  roof floor water lake well pipe tap howlong elec notoilet sewer septic bucket
coverdpit uncovered improved rooms fridge radio phone mbike tv video bicycle car
mphone radiotype, pc
(obs=191)
note:  notoilet dropped due to zero variance
note:  sewer dropped due to zero variance
note:  bucket dropped due to zero variance
note:  improved dropped due to zero variance
```

(principal components; 21 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 4.79309 | 2.61844 | 0.2084 | 0.2084 |
| 2 | 2.17465 | 0.12950 | 0.0946 | 0.3029 |
| 3 | 2.04515 | 0.41140 | 0.0889 | 0.3919 |
| 4 | 1.63375 | 0.07965 | 0.0710 | 0.4629 |
| 5 | 1.55411 | 0.28179 | 0.0676 | 0.5305 |
| 6 | 1.27232 | 0.09084 | 0.0553 | 0.5858 |
| 7 | 1.18148 | 0.21436 | 0.0514 | 0.6372 |
| 8 | 0.96712 | 0.06207 | 0.0420 | 0.6792 |
| 9 | 0.90505 | 0.05812 | 0.0393 | 0.7186 |
| 10 | 0.84693 | 0.02397 | 0.0368 | 0.7554 |
| 11 | 0.82296 | 0.09642 | 0.0358 | 0.7912 |
| 12 | 0.72654 | 0.08959 | 0.0316 | 0.8227 |
| 13 | 0.63695 | 0.02230 | 0.0277 | 0.8504 |
| 14 | 0.61465 | 0.04389 | 0.0267 | 0.8772 |
| 15 | 0.57076 | 0.08326 | 0.0248 | 0.9020 |
| 16 | 0.48750 | 0.01773 | 0.0212 | 0.9232 |
| 17 | 0.46977 | 0.07266 | 0.0204 | 0.9436 |
| 18 | 0.39711 | 0.02657 | 0.0173 | 0.9609 |
| 19 | 0.37054 | 0.05086 | 0.0161 | 0.9770 |
| 20 | 0.31968 | 0.10977 | 0.0139 | 0.9909 |
| 21 | 0.20990 | 0.20990 | 0.0091 | 1.0000 |
| 22 | 0.00000 | 0.00000 | 0.0000 | 1.0000 |
| 23 | -0.00000 | . | -0.0000 | 1.0000 |

Eigenvectors

| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | 0.19676 | 0.11190 | -0.01885 | 0.45138 | 0.22974 | 0.01101 |
| floor | 0.23404 | -0.15505 | -0.10131 | 0.11382 | 0.27115 | 0.10715 |
| water | -0.11726 | 0.34533 | 0.03385 | -0.21587 | -0.10698 | -0.09195 |
| lake | -0.05398 | 0.16945 | -0.00230 | -0.14536 | -0.38332 | 0.40957 |
| well | -0.09569 | 0.37148 | 0.36179 | -0.12352 | 0.37928 | -0.06006 |
| pipe | -0.16447 | -0.47871 | -0.17218 | 0.08391 | 0.07536 | 0.06309 |
| tap | 0.30221 | 0.13904 | -0.13793 | 0.07713 | -0.28715 | -0.18284 |
| howlong | -0.21065 | 0.14223 | 0.23440 | -0.04179 | 0.38963 | 0.17655 |
| elec | -0.27615 | 0.11409 | 0.02132 | 0.14275 | -0.08620 | 0.15877 |
| septic | 0.21540 | 0.21055 | -0.17863 | 0.31729 | 0.01483 | -0.11946 |
| coverdpit | 0.06540 | -0.34652 | 0.54670 | -0.02960 | -0.06295 | -0.11168 |
| uncovered | -0.18234 | 0.24756 | -0.47219 | -0.13795 | 0.05742 | 0.17935 |
| rooms | 0.23181 | 0.13933 | 0.25733 | 0.19900 | 0.05050 | 0.26223 |
| fridge | 0.33630 | 0.05669 | -0.03621 | -0.07618 | -0.15842 | 0.07300 |
| radio | 0.05801 | -0.23775 | -0.03115 | 0.17750 | 0.02912 | 0.44946 |
| phone | 0.24784 | -0.04741 | -0.11990 | -0.29848 | 0.28110 | 0.25453 |
| mbike | 0.07582 | -0.08322 | 0.19516 | -0.11899 | -0.30862 | 0.27332 |
| tv | 0.33217 | -0.02613 | 0.04397 | -0.18849 | 0.02322 | -0.07832 |
| video | 0.25625 | 0.02803 | 0.06491 | -0.12429 | -0.06218 | 0.12364 |
| bicycle | 0.01705 | 0.21836 | 0.21723 | 0.18279 | -0.14988 | 0.33248 |
| car | 0.23236 | 0.15735 | -0.03934 | 0.20915 | 0.11908 | 0.03902 |
| mphone | -0.19134 | 0.05798 | 0.12920 | 0.42478 | -0.26568 | -0.19072 |
| radiotype | -0.23126 | -0.06668 | -0.08352 | 0.23640 | 0.04709 | 0.26540 |

```
score proxy_index
(based on unrotated principal components)
(20 scorings not used)

                Scoring Coefficients
    Variable |      1
-------------+----------
        roof |   0.19676
       floor |   0.23404
       water |  -0.11726
        lake |   0.00344
        well |   0.03700
        pipe |   0.00000
         tap |   0.44398
     howlong |  -0.21065
        elec |  -0.27615
      septic |   0.31232
   coverdpit |   0.25456
   uncovered |   0.00000
       rooms |   0.23181
      fridge |   0.33630
       radio |   0.05801
       phone |   0.24784
       mbike |   0.07582
          tv |   0.33217
       video |   0.25625
     bicycle |   0.01705
         car |   0.23236
      mphone |  -0.19134
   radiotype |  -0.23126

corre proxy_index money
(obs=170)

             | proxy_~x    money
-------------+------------------
 proxy_index |   1.0000
       money |   0.2679   1.0000


ineqerr idex2

idex2 ------------------------------------------------------------ (unlabeled)
(obs=191)

Bootstrap statistics

Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .3045035  -.0017162   .0136123    .2774937  .3315133  (N)
         |                                            .2784108  .3292418  (P)
         |                                            .2809707  .3340315 (BC)
---------+--------------------------------------------------------------------
                            N = normal, P = percentile, BC = bias-corrected

ineqerr money

money ------------------------------------------------------------- (unlabeled)
2 values = 0. Not used in calculations.
(obs=216)

Bootstrap statistics

Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .5305255  -.0012201   .0254142    .4800983  .5809527  (N)
         |                                            .4847029  .5760243  (P)
         |                                            .4847029  .5760243 (BC)
---------+--------------------------------------------------------------------
                            N = normal, P = percentile, BC = bias-corrected
```

**Non ART EC Group**

```
factor  roof floor water lake well pipe tap howlong elec notoilet
sewer septic bucket coverdpit uncovered improved rooms fridge radio
phone  mbike tv video bicycle car mphone radiotype, pc
(obs=78)
note:  sewer dropped due to zero variance
note:  bucket dropped due to zero variance
note:  improved dropped due to zero variance
note:  radio dropped due to zero variance
```

(principal components; 21 components retained)

| Component | Eigenvalue | Difference | Proportion | Cumulative |
|---|---|---|---|---|
| 1 | 4.27540 | 1.70708 | 0.1859 | 0.1859 |
| 2 | 2.56832 | 0.12443 | 0.1117 | 0.2976 |
| 3 | 2.44389 | 0.79104 | 0.1063 | 0.4038 |
| 4 | 1.65285 | 0.13057 | 0.0719 | 0.4757 |
| 5 | 1.52228 | 0.19270 | 0.0662 | 0.5419 |
| 6 | 1.32958 | 0.07800 | 0.0578 | 0.5997 |
| 7 | 1.25159 | 0.09598 | 0.0544 | 0.6541 |
| 8 | 1.15561 | 0.07527 | 0.0502 | 0.7043 |
| 9 | 1.08034 | 0.18914 | 0.0470 | 0.7513 |
| 10 | 0.89120 | 0.07085 | 0.0387 | 0.7900 |
| 11 | 0.82035 | 0.16606 | 0.0357 | 0.8257 |
| 12 | 0.65429 | 0.01102 | 0.0284 | 0.8542 |
| 13 | 0.64327 | 0.06819 | 0.0280 | 0.8821 |
| 14 | 0.57508 | 0.08597 | 0.0250 | 0.9071 |
| 15 | 0.48911 | 0.12767 | 0.0213 | 0.9284 |
| 16 | 0.36145 | 0.03935 | 0.0157 | 0.9441 |
| 17 | 0.32210 | 0.02312 | 0.0140 | 0.9581 |
| 18 | 0.29898 | 0.02379 | 0.0130 | 0.9711 |
| 19 | 0.27519 | 0.07023 | 0.0120 | 0.9831 |
| 20 | 0.20496 | 0.02082 | 0.0089 | 0.9920 |
| 21 | 0.18414 | 0.18414 | 0.0080 | 1.0000 |
| 22 | 0.00000 | 0.00000 | 0.0000 | 1.0000 |
| 23 | 0.00000 | . | 0.0000 | 1.0000 |

Eigenvectors

| Variable | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| roof | 0.17059 | -0.30949 | 0.18139 | 0.02355 | 0.11027 | 0.04600 |
| floor | 0.26517 | -0.06638 | 0.07402 | -0.17900 | -0.27463 | 0.22783 |
| water | -0.16748 | 0.03755 | 0.27402 | 0.48301 | -0.23256 | -0.10845 |
| lake | -0.08852 | 0.06134 | 0.21517 | 0.51513 | -0.39255 | -0.13269 |
| well | -0.20126 | 0.10705 | 0.32157 | -0.07887 | 0.43520 | 0.07676 |
| pipe | -0.03535 | 0.16091 | -0.50376 | -0.16520 | -0.16731 | 0.02290 |
| tap | 0.27736 | -0.32918 | 0.20203 | -0.00647 | 0.01747 | -0.02638 |
| howlong | -0.27621 | 0.24971 | -0.05805 | 0.18057 | 0.08153 | 0.08287 |
| elec | -0.34931 | 0.05018 | 0.02374 | -0.09145 | 0.07411 | -0.09493 |
| notoilet | -0.00530 | 0.04286 | -0.12040 | 0.07355 | 0.23927 | -0.61014 |
| septic | 0.20041 | -0.36752 | 0.16934 | 0.03077 | 0.11739 | -0.06710 |
| coverdpit | 0.12797 | 0.37477 | 0.25855 | -0.32881 | -0.22515 | -0.19918 |
| uncovered | -0.21373 | -0.21789 | -0.30318 | 0.29487 | 0.11689 | 0.36381 |
| rooms | 0.14328 | 0.32513 | 0.20267 | 0.01029 | 0.10824 | 0.03014 |
| fridge | 0.24211 | 0.15999 | -0.05906 | 0.19540 | 0.22053 | 0.25171 |
| phone | 0.31748 | 0.05790 | -0.18880 | 0.10590 | -0.00001 | -0.17796 |
| mbike | 0.04641 | 0.05258 | -0.17110 | 0.02532 | -0.14544 | 0.15631 |
| tv | 0.30082 | 0.10039 | -0.10391 | 0.27930 | 0.22614 | -0.11415 |
| video | 0.15285 | 0.17684 | 0.01388 | 0.09236 | 0.07190 | 0.02692 |
| bicycle | -0.01166 | 0.24753 | 0.20007 | -0.08242 | -0.12121 | 0.22886 |
| car | 0.07599 | 0.25242 | 0.14526 | 0.07978 | 0.38085 | 0.24912 |
| mphone | -0.26955 | -0.20115 | 0.23393 | -0.14769 | -0.06349 | 0.16262 |
| radiotype | -0.26635 | -0.12247 | -0.00627 | -0.14542 | 0.19350 | -0.26422 |

```
score proxy_index
            (based on unrotated principal components)
            (20 scorings not used)

               Scoring Coefficients
    Variable |       1
-------------+----------
        roof |    0.17059
       floor |    0.26517
       water |   -0.16748
        lake |   -0.24002
        well |   -0.45724
        pipe |   -0.37470
         tap |    0.00000
     howlong |   -0.27621
        elec |   -0.34931
    notoilet |    0.04280
      septic |    0.29473
   coverdpit |    0.33922
   uncovered |    0.00000
       rooms |    0.14328
      fridge |    0.24211
       phone |    0.31748
       mbike |    0.04641
          tv |    0.30082
       video |    0.15285
     bicycle |   -0.01166
         car |    0.07599
      mphone |   -0.26955
   radiotype |   -0.26635


corr proxy_index money
(obs=75)

             | proxy_~x    money
-------------+------------------
 proxy_index |   1.0000
       money |   0.3441   1.0000


ineqerr index2

index2 ------------------------------------------------------------ (unlabeled)
(obs=78)

Bootstrap statistics

Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .2691212   -.001967    .019902     .2296312   .3086111  (N)
         |                                             .2330974   .3055274  (P)
         |                                             .2348812   .3169301 (BC)
---------+--------------------------------------------------------------------
                          N = normal, P = percentile, BC = bias-corrected
ineqerr money

money -------------------------------------------------------------- (unlabeled)
(obs=114)

Bootstrap statistics

Variable |   Reps   Observed       Bias   Std. Err.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
    Gini |    100   .5729653   -.0043793   .0300679     .5133041   .6326265  (N)
         |                                             .5081228   .6254568  (P)
         |                                             .5123894   .6292981 (BC)
---------+--------------------------------------------------------------------
                          N = normal, P = percentile, BC = bias-corrected
```

**APPENDIX IX PREFERENCE ELICITATION METHODS RESPONSE SHEET - ENGLISH**

**Date:** **Household ID:** **HRQoL ID:**

**Age:** **Sex:**

## Visual Analogue Scale (VAS)

1. How are you feeling today?

2. Which of these conditions of life is the worst for you?

1 ☐ **Symptomatic HIV**
2 ☐ **Minor AIDS defining illness**
3 ☐ **Major AIDS defining illness**

3. Which of these conditions of life is the best for you?

1 ☐ **Symptomatic HIV**
2 ☐ **Minor AIDS defining illness**
3 ☐ **Major AIDS defining illness**

4. Which of these conditions of life is in an intermediate place?

1 ☐ **Symptomatic HIV**
2 ☐ **Minor AIDS defining illness**
3 ☐ **Major AIDS defining illness**

**VAS valuation of health states**

**5. Symptomatic HIV**
**6. Minor AIDS defining illness**
**7. Major AIDS defining illness**

8. Having ranked these conditions of life would you like to change your ranking for how you feel today?

1 ☐ **Yes**
2 ☐ **No (Go to question 10)**

**9.** Which is your new value for how you feel today?

**10. What value would you give to death?**

## Standard Gamble

**11. Symptomatic HIV**

**12. Minor AIDS defining illness**

**13. Major AIDS defining illness**

## Time Trade-Off (TTO)

**14. Symptomatic HIV**

**15. Minor AIDS defining illness**

**16. Major AIDS defining illness**

**PREFERENCE ELICITATION METHODS RESPONSE SHEET HRQoL -Luganda**

**Date** ☐ **HRQoL ID** ☐ **Original** ☐ **2 weeks follow up** ☐

**Sex** 1 ☐ Male 2 ☐ Female **Age** ☐

## Visual Analogue Scale

**1. Wewulira otya leero?**

☐

**2. Mukulaba kwo, mbeera ki kuzino esaatu esingayo obubi?**

1 ☐ Health State 1
2 ☐ Health State 2
3 ☐ Health State 3

**3. Mukulaba kwo, mbeera ki kuzino esaatu esingayo obulungi?**

1 ☐ Health State 1
2 ☐ Health State 2
3 ☐ Health State 3

**4. Mukulaba kwo, mbeera ki kuzino esaatu ensamu samu?**

1 ☐ Health State 1
2 ☐ Health State 2
3 ☐ Health State 3

5. Health State 1 ☐

6. Health State 2 ☐

7. Health State 3 ☐

**8. Nga bwo maze okusengekka embeera ezo esaatu, wandiyagadde odemu okuwa ekigeero kyengeri gye wewulira leero?**

1 ☐ Yee
2 ☐ Nedda (Genda ku kibuuzo 10)

**9. Wewa kigeero ki ekipya?**

☐

**10. Okuffa wandi kuwadde kigeero ki?**

☐

## Standard Gamble

11. Health State 1

☐

12. Health State 2

☐

13. Health State 3

☐

## Time Trade-Off

14. Health State 1

☐

15. Health State 2

☐

16. Health State 3

☐

**APPENDIX X**

**PREFERENCE ELICITATION TOOL GUIDELINES**

**VISUAL ANALOGUE SCALE INTERVIEWER GUIDELINES**

The objective of this exercise is to assess how you are feeling today. For this I am going to ask you some questions and use some visual aids in order to make it easier for you.

This meter ruler has two extremes (Point to both extremes). 100 (Point to 100 and put the pointer), is one of the extremes and represents the best life condition that you could think of (you are healthy, in a solvent financial situation, emotional stable, mentally bright, happy, etc.). In contrast 0 (Point to 0 and put the pointer) is the other extreme and represents the worst life condition that you could think of (sick, depressed, weak, with financial problems, sad, worried, etc.).

**Exercise 1**

Having explained how this metre ruler works and keeping in mind that 100, is best life condition that you could think of and 0 is the worst life condition. Using this ruler please show me how you are feeling today?

Write the answer in the preference elicitation methods response sheet (Visual Analogue Scale, Question 1)

Now I will explain to you about three different conditions of life related to HIV/AIDS.

**Symptomatic HIV Infection (SHI) - Health State 1**

In this condition of life you have, (show patients the pictures as you read out the explanation besides each picture)

**Minor AIDS Defining Illness (MIADI) - Health State 2**

In this condition of life you have, (show patients the pictures as you read out the explanation besides each picture)

**Major AIDS Defining Illness (MAADI) - Health State 3**

In this condition of life you have, (show patients the pictures as you read out the explanation besides each picture)

**Exercise 2**

Which of these conditions of life is the worst for you? -Write the answer in the preference elicitation methods response sheet (Visual Analogue Scale, Question 2)

Which of these conditions of life is the best for you? -Write the answer in the preference elicitation methods response sheet (Visual Analogue Scale, Question 3)

Which of these conditions of life is in an intermediate place? -Write the answer in the preference elicitation methods response sheet (Visual Analogue Scale, Question 4)

Using the same conditions of life that I have explained to you, (point the health states to the individual) where would you place them against the ruler (point the ruler). Remember that 100 (point to 100) represents the best condition of life and 0 (point to 0) represents the worst condition of life. Allow individual to think about it.

**Exercise 3**

Ask the individual to place EACH health state near the ruler and use the pointers to specify the exact number that s/he means. Write the answer in the preference elicitation methods response sheet for the best health state (Visual Analogue Scale, Question 5)

Write the answer in the preference elicitation methods response sheet for the intermediate health state (Visual Analogue Scale, Question 6)

Write the answer in the preference elicitation methods response sheet for the worst health state (Visual Analogue Scale, Question 7)

**Exercise 4**

Having ranked these conditions of life would you like to change your ranking for how you feel today?

Write the answer in the preference elicitation methods response sheet (Visual Analogue Scale, Question 8 and 9 if the individual changes her/his mind)

**Exercise 5**

Using the same metre ruler what value would you give to death?

**TIME TRADE OFF INTERVIEWER GUIDELINES**

In this exercise, we will use the three predetermined HIV/AIDS health states and the better condition of life that you have already seen (show the individual the four conditions of life).

**Step One**

We will also use a board that is called Time Trade-Off (show the individual the Time Trade Off Board). This board is divided in two sections labelled Life A and Life B (Point at the two sections). Life B represents an intermediate condition of life in which you would live for ten years and then you would die (Point to Life B –HIV/AIDS predetermined health states) and life A (Point to Life A –Improved Health State) in which the number of years that you will spend in a better condition of life can be varied using the diamond pointer (Point to the pointer, and move it up and down). The objective of this exercise is to assess how you many years would you be willing to give up in order to attain a better condition of life.

**Step Two**

Place the Better condition of life (pink card) on the top section of the board and the HIV/AIDS predetermined health state - intermediate condition of life (green card) on the bottom of the board.

In Life B, you will live in this condition, (show individual the Symptomatic HIV/AIDS health state card as you read out the explanation besides each picture) for ten years without deterioration and then you will die.

In Life A, you will live in this condition, (show individual the pictures of the Improved Health State as you read out the explanation besides each picture) for ten years without deterioration and then you will die.

Of these two choices: Life A and Life B, which would you, choose?

**This is not an assessment but a warming up exercise**

Step Three

Adjust the pointer at Life A to point at 9 years. This time, in Life A, you will live in this condition, (show individual the pictures of Improved Health State as you read out the explanation besides each picture) for NINE years without deterioration and then you will die.

In Life B, you will live in this condition, (show individual the pictures of Symptomatic HIV Infection - health state card as you read out the explanation besides each picture) for TEN years without deterioration and then you will die.

Of these two choices: Life A and Life B, which would you choose?

While adjusting the pointer to point at 1 year; then go back to 8 years and repeat step 3 until the individual would prefer to stay in Life B to Life A.

Note that you can adjust the pointer to represent three quarterly values in a year, that is, three months, half a year (six months) or nine years. Adjust the pointer at these values as well. Examples of answers from this can be 4 years and 9 months, 7 years and 3 months and Two years and a half/ six months.

When you arrive at the year (or year and months) where the individual would prefer to stay in Life B (predetermined HIV/AIDS health state) than to give up **x** years of his/ her life for the Improved Health State as shown by Life A, fill the number of year (or year and months) in the square of question 14 in the preference elicitation methods response sheet.

Replace Symptomatic HIV Infection by Minor AIDS Defining Illness (MIADI) and repeat Step 1, Step 2 and Step 3. Fill in the answer in the square of question 15 in the preference elicitation methods response sheet.

Replace Minor AIDS Defining Illness (MIADI) by Major AIDS Defining Illness (MAAIDI) and repeat Step 1, Step 2 and Step 3. Fill in the answer in the square of question 16 in the preference elicitation methods response sheet.

**STANDARD GAMBLE INTERVIEWER GUIDELINES**

The aim of this exercise is to find out the probability value at which you are indifferent between the predetermined HIV/AIDS health states and the risk of taking a hypothetical drug once for achieving a better condition of life but that can also has attached an immediate but painless death. The amount of risk will be changed until we find out how much risk you will take to avoid the intermediate condition of life. In order to make the task easier to understand, we will use a visual aid similar to a game board.

Take the individual through each of the health states to be valued, one at a time in not a pre-determined order if desired with the interviewer moving the scale as appropriate.

The game board is divided in two (Point to the chance board).

Lower part –Choice B

Choice B (Point to choice B) is simple because it describes a condition of life, which is certain to occur.

This is a description of an intermediate condition of life that you will live in for 10 years and then you will die.

Upper part –Choice A, is subdivided in two:

Left hand side (point to the left hand side)

The **improved health state** is described in the pink card. The chances of treatment **success** are also represented in **pink**. In this state the individual will also live for 10 years and then he/she will die

Right hand side (point to the right hand side)

Describes the situation where the treatment has attached a risk of failing which will cause an immediate but painless death

You will be asked to pick either Choice A (Point to choice A) or Choice B (Point to choice B). There are no right or wrong answers; we just want to know what you think.

## Exercise 1

### Health State 1

In this condition of life, you have ... (show the individual the pictures as you read out the explanations besides each picture). Place the green health state card 1 in the bottom part of the chance board. Now show the individual the pictures as you read out the explanation besides each picture of the pink card, place the ink card in the left hand side of the chance board. Place the percentage of the pink card at 90% and ask the individual if s/he prefers A or B. keep altering the percentage of the pink card and the percentage of the immediate death until the individual gets to an indifferent point. Fill the square to question 11.

### Health State 2

In this condition of life, you have ... (show the individual the pictures as you read out the explanations besides each picture). Replace the green health state card 1 with the green health state card 2 in the bottom part of the chance board. Place the percentage of the pink card at 90% and ask the individual if s/he prefers A or B. keep altering the percentage of the pink card and the percentage of the immediate death until the individual gets to an indifferent point. Fill the square to question 12.

### Health State 3

In this condition of life, you have ... (show the individual the pictures as you read out the explanations besides each picture). Replace the green health state card 2 with the green health state card 3 in the bottom part of the chance board. Place the percentage of the pink card at 90% and ask the individual if s/he prefers A or B. keep altering the percentage of the pink card and the percentage of the immediate death until the individual gets to an indifferent point. Fill the square to question 13.

**APPENDIX XI**

## HRQoL TEST-RESTEST SUB-SAMPLE INFORMATION SHEET

## ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

We would like to invite you to participate in an evaluation of the health-related quality of life research study. Please read carefully this information or ask the interviewer to read it for you. A copy of this form will be given to you to keep. If you need more information please do not hesitate and ask us.

We want to confirm that the information obtained from our questionnaires is free from errors. For this we need your assistance to evaluate if the information obtained in a repeated interview is the same information that you have already given us. If you agree to participate in this sub-sample, you will be asked by a trained interviewer to respond to the same questionnaires in a face-to-face interview held here at the clinic after two weeks have passed since your first interview.

The new information will be entered into a computer after a code number has replaced your name, so that answers can never be traced back to you and making the information that you provide completely confidential. The data will be kept key locked at all times and only researchers will have access to the data. Your answers will be combined with the answers of other patients involved in the study and reported in such a way that it will not be possible to identify the type of care that you may be receiving.

You are free to refuse to participate in this evaluation and withdraw at any time. You are equally free to refuse to answer any specific question or to withdraw from the study at any time. Refusal will not affect your participation in DART trial or Entebbe Cohort study in any way. Please be sure to ask the interviewer if you have any questions. If you have additional questions or any complaints about the study please contact the study coordinator Dr. Brent Wolff or Dr. Paula Munderi (Tel: 041-320-042) at the MRC offices at Uganda Virus Research Institute, Entebbe, or the chairman of the UVRI Science and Ethics Committee Dr. Jonathan Mermin at the CDC offices of the Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

## CONSENT FOR HRQoL SUB-SAMPLE TEST-RETEST

| NAME: | DATE: |
|---|---|
| DATE OF BIRTH: | HRQoL TEST-RETEST ID : |

I have read or had read to me the information sheet for the HRQoL test-retest sub-sample. I understand that if I decide to be involved in the study I will be re-interviewed after two weeks subsequent to each one of the three HRQoL assessments. I am also aware that at any time I may withdraw from this study and sub-sample without giving any reason and that this will not affect my normal care and management in any way.

Any questions or concerns about the study will be answered at any time by the study co-ordinator:

I agree to take part in this study

**Participant's signature:** **Thumbprint:**

.....

**EBIKWATA KU KUNONYEREZA**

**ADAPTATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQoL) INSTRUMENTS FOR PEOPLE LIVING WITH HIV/AIDS IN UGANDA**

**Principal Investigator:** Antonieta Medina Lara, HIV/AIDS & STI Knowledge Programme, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK.

Tukusaba wetabe mu kunonyereza okukwata ku mbeera y'obulamu. Tukusaba osome nobwegenderreza olupapula luno oba osabe omunonyereza alukusomere. Ogya kuwebwa olupapula luno oluteleke. Bwoba oyina kyoyagala okumanya, bambi totya kukitubuuza.

Twagala okukakasa oba byetufuna okuva mu bibuuzo byaffe bituufu. Twetaga okulaba oba ebyo byetunafuna nga tuzemu okubuza byebimu n'ebyo bye watuwakko emabegga. Bw'okiriza okwetaba mu kunonyereza kuno omunonyereza agya kusaba oddemu ebibuuzo byebimu wano ku dwaliiro oluvanyuma lwa wikki biiri.

By'onotuwa bigya kuyingizibwa mu kyuma ki kalimagezi (kompyuta) nga awali erinya lyo waliwo e namba waleke kubawo ngeri yonna omuntu gya nasobola okutegera nti gwe wabyogera. Kino kigya kumu byonna byonoyogera nga bya kyama. Byonna bigya kumibwa mu kabada nga kuliko kufulu era abanonyereza boka bebanosobola okubitukako. Byonoddamu bigya gatibwa nebyo abalwadde abalala byebananaba batuwadde kibbe nga tewali ngeri gye kinasobola ku kosa obujjanjabi bwofuna.

Oli wa ddembe okugaana okwetaba mu kunonyereza kuno oba okuvaamu essaawa yonna oba okugaana okuddamu ekibuuzo kyonna. Okugaana kwo, tekulina ngeri gye kunakosa enetaba yo mu kitongole kino.

Bwoba olina ekibuuzo kibuuze omunonyereza. Osobola n'okubuuza ba kayungirizi b'okunonyereza kuno: Dr. Brent Wolff oba Dr. Paula Munderi (Tel: 041-320-042) ku ofiisi za MRC mu Uganda Virus Research Institute, Entebbe, oba omukulu w'a kakiiko ka UVRI Science and Ethics Committee Dr. Jonathan Mermin mu ofisi ya CDC mu Uganda Virus Research Institute, Entebbe (Tel: 041-320-621)

## CONSENT FOR HRQoL SUB-SAMPLE TEST-RETEST

| NAME: | DATE: |
|---|---|
| DATE OF BIRTH: | HRQoL TEST-RETEST ID : |

Nsomye oba bansomedde olupapula olukwata ku kunonyereza okunabawo. Ntegedde nti bwenasalawo okwetaba mu kunonyereza kuno baggya kumbuza ebibuuzo emirundi essatu mu mwaka ate n'oluvanyuma lwa buli wiiki biri buli lwebambuuza ebibuuzo. Ntegedde nti ndi wa ddembe okuva mu kunonyereza kuno esaawa yonna ate nga siwa nsonga lwaki nvuddemu. Ntegedde nti bwenasalawo obuteetaba mu kunonyereza kuno, tekiggya kukosa endabirira n'enzijanjaba yange mu ngeri yona.

Ebibuuzo byonna ebikwata ku kunonyereza kuno biggya kuddibwamu kayungirizi w'okunonyereza kuno obudde bwona.

Nzikirizza okwetaba mu kunonyereza kuno.

**Siginikya oba erinya:** **Ekinkumu:**

.....

## APPENDIX XIIa
## Empirical validity for PEM analysis

### ART DART Group – Baseline

### Generic model including CD4, sex, gender for VAS

Table 1

```
regress vas cd4 age sex dum1 dum3  dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.7106147 | 11 | 2.15551043 | Number of obs | = 798 |
| Residual | 13.1934187 | 786 | .01678552 | F( 11, 786) | = 128.41 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.6425 |
| | | | | Adj R-squared | = 0.6375 |
| Total | 36.9040334 | 797 | .046303681 | Root MSE | = .12956 |

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4 | -.0001401 | .0001285 | -1.09 | 0.276 | -.0003923 | .000112 |
| age | .0015426 | .0011124 | 1.39 | 0.166 | -.000641 | .0037262 |
| sex | .0280862 | .0169633 | 1.66 | 0.098 | -.0052125 | .0613849 |
| dum1 | .2203491 | .0765605 | 2.88 | 0.004 | .0700619 | .3706364 |
| dum3 | -.2290808 | .0765605 | -2.99 | 0.003 | -.379368 | -.0787936 |
| dum1a | -.0011211 | .0015731 | -0.71 | 0.476 | -.0042092 | .001967 |
| dum1cd4 | .0000611 | .0001817 | 0.34 | 0.737 | -.0002955 | .0004178 |
| dum1sex | .0088521 | .0239897 | 0.37 | 0.712 | -.0382394 | .0559435 |
| dum3a | .0001379 | .0015731 | 0.09 | 0.930 | -.0029502 | .0032259 |
| dum3cd4 | .000028 | .0001817 | 0.15 | 0.877 | -.0003286 | .0003846 |
| dum3sex | .0006899 | .0239897 | 0.03 | 0.977 | -.0464016 | .0477814 |
| _cons | .3036953 | .0541364 | 5.61 | 0.000 | .1974262 | .4099644 |

Table 2

```
regress vas age sex dum1 dum3  dum1a dum1sex dum3a dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.6715167 | 8 | 2.95893959 | Number of obs | = 798 |
| Residual | 13.2325167 | 789 | .016771251 | F( 8, 789) | = 176.43 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.6414 |
| | | | | Adj R-squared | = 0.6378 |
| Total | 36.9040334 | 797 | .046303681 | Root MSE | = .1295 |

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | .0013622 | .0010995 | 1.24 | 0.216 | -.0007962 | .0035205 |
| sex | .0270099 | .0169274 | 1.60 | 0.111 | -.0062181 | .0602379 |
| dum1 | .2221961 | .0763311 | 2.91 | 0.004 | .0723599 | .3720322 |
| dum3 | -.2282337 | .0763311 | -2.99 | 0.003 | -.3780698 | -.0783976 |
| dum1a | -.0010424 | .001555 | -0.67 | 0.503 | -.0040948 | .00201 |
| dum1sex | .0093218 | .0239389 | 0.39 | 0.697 | -.0376697 | .0563132 |
| dum3a | .000174 | .001555 | 0.11 | 0.911 | -.0028784 | .0032264 |
| dum3sex | .0009053 | .0239389 | 0.04 | 0.970 | -.0460862 | .0478968 |
| _cons | .2994629 | .0539743 | 5.55 | 0.000 | .1935127 | .405413 |

Table 3

```
regress vas sex dum1 dum3 dum1sex dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.5370406 | 5 | 4.70740812 | Number of obs | = 801 |
| Residual | 13.6951676 | 795 | .017226626 | F( 5, 795) | = 273.26 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.6322 |
| | | | | Adj R-squared | = 0.6299 |
| Total | 37.2322082 | 800 | .04654026 | Root MSE | = .13125 |

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| sex | .0204569 | .0167387 | 1.22 | 0.222 | -.0124004 | .0533142 |
| dum1 | .179492 | .0404603 | 4.44 | 0.000 | .1000704 | .2589135 |
| dum3 | -.2220687 | .0404603 | -5.49 | 0.000 | -.3014903 | -.1426471 |
| dum1sex | .0118622 | .0236721 | 0.50 | 0.616 | -.034605 | .0583294 |
| dum3sex | .0014437 | .0236721 | 0.06 | 0.951 | -.0450235 | .0479109 |
| _cons | .3585015 | .0286097 | 12.53 | 0.000 | .3023419 | .414661 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for VAS

Table 4

```
regress vas  feel1 age sex dum1 dum3  dum1a  dum1feel dum1sex dum3a  dum3feel dum3sex

      Source |       SS       df       MS              Number of obs =     798
-------------+------------------------------           F( 11,   786) =  129.62
       Model |  23.7899584    11  2.16272349           Prob > F      =  0.0000
    Residual |  13.1140751   786  .016684574           R-squared     =  0.6446
-------------+------------------------------           Adj R-squared =  0.6397
       Total |  36.9040334   797  .046303681           Root MSE      =  .12917

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |    .084063   .0417888     2.01   0.045     .0020322    .1660938
         age |   .0013102    .001097     1.19   0.233    -.0008432    .0034636
         sex |   .0256181   .0168977     1.52   0.130     -.007552    .0587881
        dum1 |   .2326093   .0807334     2.88   0.004     .0741307    .3910879
        dum3 |  -.2081518   .0807334    -2.58   0.010    -.3666303   -.0496732
       dum1a |  -.0010282   .0015514    -0.66   0.508    -.0040736    .0020172
    dum1feel |  -.0229101   .0590982    -0.39   0.698    -.1389191     .093099
     dum1sex |   .0097011    .023897     0.41   0.685    -.0372084    .0566106
       dum3a |   .0002013   .0015514     0.13   0.897    -.0028441    .0032467
    dum3feel |  -.0441822   .0590982    -0.75   0.455    -.1601912    .0718269
     dum3sex |   .0016368    .023897     0.07   0.945    -.0452727    .0485463
       _cons |   .2612541   .0570871     4.58   0.000     .1491928    .3733153
------------------------------------------------------------------------------
```

Table 5

```
regress vas  feel1 sex dum1 dum3   dum1feel dum1sex dum3feel dum3sex

      Source |       SS       df       MS              Number of obs =     801
-------------+------------------------------           F(  8,   792) =  173.15
       Model |  23.6881131     8  2.96101414           Prob > F      =  0.0000
    Residual |  13.5440951   792   .01710113           R-squared     =  0.6362
-------------+------------------------------           Adj R-squared =  0.6326
       Total |  37.2322082   800   .04654026           Root MSE      =  .13077

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |   .0924706   .0421994     2.19   0.029     .0096348    .1753064
         sex |   .0192278   .0166871     1.15   0.250    -.0135283    .0519839
        dum1 |   .1893084   .0495095     3.82   0.000     .0921231    .2864938
        dum3 |  -.1989867   .0495095    -4.02   0.000     -.296172   -.1018014
    dum1feel |  -.0203829   .0596789    -0.34   0.733    -.1375304    .0967647
     dum1sex |   .0121331   .0235991     0.51   0.607     -.034191    .0584572
    dum3feel |  -.0479273   .0596789    -0.80   0.422    -.1650748    .0692202
     dum3sex |   .0020807   .0235991     0.09   0.930    -.0442434    .0484048
       _cons |   .3139672   .0350085     8.97   0.000     .2452468    .3826876
------------------------------------------------------------------------------
```

Table 6

```
regress vas  feel1 dum1 dum3   dum1feel dum3feel

      Source |       SS       df       MS              Number of obs =     801
-------------+------------------------------           F(  5,   795) =  274.53
       Model |  23.5771219     5  4.71542438           Prob > F      =  0.0000
    Residual |  13.6550863   795  .017176209           R-squared     =  0.6332
-------------+------------------------------           Adj R-squared =  0.6309
       Total |  37.2322082   800   .04654026           Root MSE      =  .13106

------------------------------------------------------------------------------
         vas |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |    .094105   .042268     2.23   0.026     .0111349    .1770751
        dum1 |    .208693   .0321585     6.49   0.000     .1455673    .2718187
        dum3 |  -.1956624   .0321585    -6.08   0.000    -.2587881   -.1325367
    dum1feel |  -.0193515    .059776    -0.32   0.746    -.1366889    .0979858
    dum3feel |  -.0477504    .059776    -0.80   0.425    -.1650878     .069587
       _cons |   .3446867   .0227395    15.16   0.000     .3000501    .3893233
------------------------------------------------------------------------------
```

## Gamma regression to check the robustness of the results

Table 7

```
glm vas feel1 dum1 dum3, f(gamma) l(log)
Iteration 0:   log likelihood =  59.078974
Iteration 1:   log likelihood =  59.463218
Iteration 2:   log likelihood =  59.463337
Iteration 3:   log likelihood =  59.463337

Generalized linear models                         No. of obs      =        801
Optimization     : ML                             Residual df     =        797
                                                  Scale parameter =   .199768
Deviance         =  134.3904695                   (1/df) Deviance =  .1686204
Pearson          =  159.2151247                   (1/df) Pearson  =   .199768

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]

                                                  AIC             = -.1384852
Log likelihood   =  59.46333718                   BIC             = -5194.241
------------------------------------------------------------------------------
             |                 OIM
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |    .198423   .0802491     2.47   0.013     .0411377    .3557083
        dum1 |   .4112236   .0386845    10.63   0.000     .3354033    .4870439
        dum3 |   -.822048   .0386833   -21.25   0.000    -.8978659   -.7462301
       _cons |  -1.037183   .0488509   -21.23   0.000    -1.132929   -.9414366
------------------------------------------------------------------------------
```

## Generic model including CD4, sex, gender for TTO

Table 8

```
regress tto cd4 age sex dum1 dum3  dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex

      Source |       SS       df       MS              Number of obs =     795
-------------+------------------------------           F( 11,   783) =   91.08
       Model |  39.2621475    11  3.56928613           Prob > F      =  0.0000
    Residual |  30.6849041   783  .039188894           R-squared     =  0.5613
-------------+------------------------------           Adj R-squared =  0.5551
       Total |  69.9470516   794  .088094523           Root MSE      =  .19796

------------------------------------------------------------------------------
         tto |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         cd4 |   2.66e-07   .0001963     0.00   0.999    -.0003852    .0003857
         age |   .0009643   .0017019     0.57   0.571    -.0023764    .0043051
         sex |   .0209115   .0259824     0.80   0.421    -.0300919    .0719149
        dum1 |   .2431317    .116982     2.08   0.038     .0134961    .4727672
        dum3 |  -.2973448    .116982    -2.54   0.011    -.5269803   -.0677092
       dum1a |   .0017966   .0024068     0.75   0.456    -.0029279    .0065212
    dum1cd4 |  -.0002358   .0002777    -0.85   0.396    -.0007809    .0003092
    dum1sex |  -.0148437   .0367447    -0.40   0.686    -.0869734    .0572861
       dum3a |   .0006151   .0024068     0.26   0.798    -.0041095    .0053396
    dum3cd4 |   .0000567   .0002777     0.20   0.838    -.0004884    .0006018
    dum3sex |  -.0059892   .0367447    -0.16   0.871     -.078119    .0661405
       _cons |   .4219742   .0827188     5.10   0.000     .2595974    .5843511
------------------------------------------------------------------------------
```

Table 9

```
regress tto age sex dum1 dum3  dum1a dum1sex dum3a dum3sex

      Source |       SS       df       MS              Number of obs =     795
-------------+------------------------------           F(  8,   786) =  125.28
       Model |  39.2024361     8  4.90030451           Prob > F      =  0.0000
    Residual |  30.7446156   786  .039115287           R-squared     =  0.5605
-------------+------------------------------           Adj R-squared =  0.5560
       Total |  69.9470516   794  .088094523           Root MSE      =  .19778

------------------------------------------------------------------------------
         tto |      Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0009647   .0016818     0.57   0.566    -.0023366     .004266
         sex |   .0209136   .0259115     0.81   0.420    -.0299503    .0717776
        dum1 |   .2360167   .1165721     2.02   0.043     .0071872    .4648461
        dum3 |  -.2956343   .1165721    -2.54   0.011    -.5244638   -.0668049
       dum1a |   .0014959   .0023784     0.63   0.530    -.0031729    .0061646
    dum1sex |  -.0167107   .0366444    -0.46   0.648    -.0886432    .0552218
       dum3a |   .0006874   .0023784     0.29   0.773    -.0039814    .0053561
    dum3sex |  -.0055404   .0366444    -0.15   0.880    -.0774729    .0663921
       _cons |   .4219823   .0824289     5.12   0.000     .2601754    .5837891
------------------------------------------------------------------------------
```

Table 10
regress tto sex dum1 dum3 dum1sex dum3sex

| Source | SS | df | MS | Number of obs | = | 798 |
|---|---|---|---|---|---|---|
| Model | 38.9173242 | 5 | 7.78346483 | F( 5, 792) | = | 194.25 |
| Residual | 31.7352132 | 792 | .040069714 | Prob > F | = | 0.0000 |
| | | | | R-squared | = | 0.5508 |
| | | | | Adj R-squared | = | 0.5480 |
| Total | 70.6525373 | 797 | .088648102 | Root MSE | = | .20017 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| sex | .014883 | .0256147 | 0.58 | 0.561 | -.0353977 | .0651637 |
| dum1 | .299883 | .0619915 | 4.84 | 0.000 | .178196 | .4215701 |
| dum3 | -.2686257 | .0619915 | -4.33 | 0.000 | -.3903128 | -.1469387 |
| dum1sex | -.0230409 | .0362246 | -0.64 | 0.525 | -.0941486 | .0480667 |
| dum3sex | -.0061111 | .0362246 | -0.17 | 0.866 | -.0772188 | .0649965 |
| _cons | .465117 | .0438346 | 10.61 | 0.000 | .3790712 | .5511627 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for TTO

Table 11
regress tto feel1 age sex dum1 dum3 dum1a dum1feel dum1sex dum3a dum3feel dum3sex

| Source | SS | df | MS | Number of obs | = | 795 |
|---|---|---|---|---|---|---|
| Model | 39.5153286 | 11 | 3.5923026 | F( 11, 783) | = | 92.43 |
| Residual | 30.431723 | 783 | .038865547 | Prob > F | = | 0.0000 |
| | | | | R-squared | = | 0.5649 |
| | | | | Adj R-squared | = | 0.5588 |
| Total | 69.9470516 | 794 | .088094523 | Root MSE | = | .19714 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .0905012 | .0646391 | 1.40 | 0.162 | -.0363852 | .2173876 |
| age | .0008874 | .0016773 | 0.53 | 0.597 | -.0024052 | .0041799 |
| sex | .0198215 | .0258404 | 0.77 | 0.443 | -.0309033 | .0705462 |
| dum1 | .2080575 | .1234252 | 1.69 | 0.092 | -.0342259 | .4503409 |
| dum3 | -.2765803 | .1234252 | -2.24 | 0.025 | -.5188637 | -.034297 |
| dum1a | .0014434 | .0023721 | 0.61 | 0.543 | -.0032129 | .0060998 |
| dum1feel | .0614222 | .0914135 | 0.67 | 0.502 | -.1180222 | .2408667 |
| dum1sex | -.0174519 | .0365439 | -0.48 | 0.633 | -.0891875 | .0542837 |
| dum3a | .0007231 | .0023721 | 0.30 | 0.761 | -.0039333 | .0053795 |
| dum3feel | -.0418588 | .0914135 | -0.46 | 0.647 | -.2213033 | .1375856 |
| dum3sex | -.0050353 | .0365439 | -0.14 | 0.890 | -.0767709 | .0667003 |
| _cons | .3807864 | .0872748 | 4.36 | 0.000 | .2094662 | .5521067 |

Table 12
regress tto feel1 sex dum1 dum3 dum1feel dum1sex dum3feel dum3sex

| Source | SS | df | MS | Number of obs | = | 798 |
|---|---|---|---|---|---|---|
| Model | 39.3170345 | 8 | 4.91462932 | F( 8, 789) | = | 123.75 |
| Residual | 31.3355028 | 789 | .039715466 | Prob > F | = | 0.0000 |
| | | | | R-squared | = | 0.5565 |
| | | | | Adj R-squared | = | 0.5520 |
| Total | 70.6525373 | 797 | .088648102 | Root MSE | = | .19929 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .1022767 | .0651543 | 1.57 | 0.117 | -.0256196 | .230173 |
| sex | .0140565 | .0255066 | 0.55 | 0.582 | -.0360125 | .0641254 |
| dum1 | .2661111 | .0765789 | 3.47 | 0.001 | .1157886 | .4164336 |
| dum3 | -.2454822 | .0765789 | -3.21 | 0.001 | -.3958047 | -.0951597 |
| dum1feel | .0686388 | .0921421 | 0.74 | 0.457 | -.1122339 | .2495115 |
| dum1sex | -.0235957 | .0360718 | -0.65 | 0.513 | -.0944038 | .0472125 |
| dum3feel | -.0470375 | .0921421 | -0.51 | 0.610 | -.2279102 | .1338352 |
| dum3sex | -.005731 | .0360718 | -0.16 | 0.874 | -.0765391 | .0650772 |
| _cons | .4147944 | .0541495 | 7.66 | 0.000 | .3085004 | .5210885 |

Table 13
regress tto feel1 dum1 dum3 dum1feel dum3feel

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 39.2951867 | 5 | 7.85903735 | Number of obs | = 798 |
| Residual | 31.3573506 | 792 | .039592614 | F( 5, 792) | = 198.50 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.5562 |
| | | | | Adj R-squared | = 0.5534 |
| Total | 70.6525373 | 797 | .088648102 | Root MSE | = .19898 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .103018 | .0650396 | 1.58 | 0.114 | -.0246524 | .2306883 |
| dum1 | .2279756 | .0495767 | 4.60 | 0.000 | .1306583 | .3252928 |
| dum3 | -.2547446 | .0495767 | -5.14 | 0.000 | -.3520619 | -.1574274 |
| dum1feel | .0673945 | .0919799 | 0.73 | 0.464 | -.1131587 | .2479477 |
| dum3feel | -.0473397 | .0919799 | -0.51 | 0.607 | -.2278929 | .1332135 |
| _cons | .4375126 | .035056 | 12.48 | 0.000 | .3686989 | .5063263 |

## Gamma regression to check the robustness of the results

Table 14
glm tto feel1 dum1 dum3, f(gamma) l(log)

```
Iteration 0:   log likelihood = -118.44806
Iteration 1:   log likelihood = -117.32455
Iteration 2:   log likelihood = -117.32304
Iteration 3:   log likelihood = -117.32304
```

| | | | |
|---|---|---|---|
| Generalized linear models | | No. of obs | = 798 |
| Optimization | : ML | Residual df | = 794 |
| | | Scale parameter | = .3564956 |
| Deviance | = 151.0187559 | (1/df) Deviance | = .1901999 |
| Pearson | = 283.0575331 | (1/df) Pearson | = .3564956 |
| Variance function: V(u) = u^2 | | [Gamma] | |
| Link function | : g(u) = ln(u) | [Log] | |
| | | AIC | = .3040678 |
| Log likelihood | = -117.3230419 | BIC | = -5154.575 |

| tto | OIM Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .2256605 | .1104102 | 2.04 | 0.041 | .0092605 | .4420605 |
| dum1 | .4285169 | .0517729 | 8.28 | 0.000 | .3270439 | .5299899 |
| dum3 | -.8425394 | .0517732 | -16.27 | 0.000 | -.944013 | -.7410659 |
| _cons | -.8289976 | .0666485 | -12.44 | 0.000 | -.9596263 | -.6983689 |

## Generic model including CD4, sex, gender for SG

Table 15
regress sg cd4 age sex dum1 dum3 dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 13.3174491 | 11 | 1.2106772 | Number of obs | = 792 |
| Residual | 41.1152781 | 780 | .052711895 | F( 11, 780) | = 22.97 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.2447 |
| | | | | Adj R-squared | = 0.2340 |
| Total | 54.4327273 | 791 | .068815079 | Root MSE | = .22959 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4 | -.0000915 | .0002277 | -0.40 | 0.688 | -.0005385 | .0003556 |
| age | .0001409 | .0019741 | 0.07 | 0.943 | -.0037343 | .004016 |
| sex | .0311888 | .0301701 | 1.03 | 0.302 | -.0280353 | .090413 |
| dum1 | .1641442 | .1357174 | 1.21 | 0.227 | -.1022704 | .4305588 |
| dum3 | -.137491 | .1357174 | -1.01 | 0.311 | -.4039056 | .1289236 |
| dum1a | .0005007 | .0027918 | 0.18 | 0.858 | -.0049796 | .005981 |
| dum1cd4 | -.0003657 | .0003221 | -1.14 | 0.257 | -.000998 | .0002665 |
| dum1sex | .0074099 | .0426669 | 0.17 | 0.862 | -.0763456 | .0911655 |
| dum3a | .0002461 | .0027918 | 0.09 | 0.930 | -.0052342 | .0057264 |
| dum3cd4 | .000095 | .0003221 | 0.30 | 0.768 | -.0005372 | .0007273 |
| dum3sex | -.0192031 | .0426669 | -0.45 | 0.653 | -.1029586 | .0645525 |
| _cons | .2682063 | .0959667 | 2.79 | 0.005 | .0798227 | .4565899 |

Table 16
regress sg age sex dum1 dum3 dum1a dum1sex dum3a dum3se

| Source | SS | df | MS | Number of obs = | 792 |
|---|---|---|---|---|---|
| Model | 13.0965208 | 8 | 1.6370651 | F( 8, 783) = | 31.01 |
| Residual | 41.3362065 | 783 | .05279209 | Prob > F = | 0.0000 |
| | | | | R-squared = | 0.2406 |
| | | | | Adj R-squared = | 0.2328 |
| Total | 54.4327273 | 791 | .068815079 | Root MSE = | .22977 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | .000024 | .001954 | 0.01 | 0.990 | -.0038117 | .0038597 |
| sex | .0304547 | .0301375 | 1.01 | 0.313 | -.0287053 | .0896146 |
| dum1 | .1531823 | .1354765 | 1.13 | 0.259 | -.1127578 | .4191225 |
| dum3 | -.134642 | .1354765 | -0.99 | 0.321 | -.4005822 | .1312982 |
| dum1a | .0000335 | .0027634 | 0.01 | 0.990 | -.005391 | .0054581 |
| dum1sex | .004475 | .0426209 | 0.10 | 0.916 | -.0791898 | .0881399 |
| dum3a | .0003675 | .0027634 | 0.13 | 0.894 | -.005057 | .005792 |
| dum3sex | -.0184403 | .0426209 | -0.43 | 0.665 | -.1021051 | .0652245 |
| _cons | .2654643 | .0957964 | 2.77 | 0.006 | .0774162 | .4535124 |

Table 17
regress sg sex dum1 dum3 dum1sex dum3sex

| Source | SS | df | MS | Number of obs = | 795 |
|---|---|---|---|---|---|
| Model | 13.0309749 | 5 | 2.60619498 | F( 5, 789) = | 49.49 |
| Residual | 41.5460062 | 789 | .052656535 | Prob > F = | 0.0000 |
| | | | | R-squared = | 0.2388 |
| | | | | Adj R-squared = | 0.2339 |
| Total | 54.5769811 | 794 | .068736752 | Root MSE = | .22947 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| sex | .0290402 | .0293943 | 0.99 | 0.323 | -.02866 | .0867405 |
| dum1 | .1555418 | .0710895 | 2.19 | 0.029 | .0159948 | .2950888 |
| dum3 | -.1202477 | .0710895 | -1.69 | 0.091 | -.2597947 | .0192993 |
| dum1sex | .0034056 | .0415698 | 0.08 | 0.935 | -.0781949 | .085006 |
| dum3sex | -.0186997 | .0415698 | -0.45 | 0.653 | -.1003002 | .0629008 |
| _cons | .2678019 | .0502679 | 5.33 | 0.000 | .1691272 | .3664765 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for SG

Table 18
regress sg feel1 age sex dum1 dum3 dum1a dum1feel dum1sex dum3a dum3feel dum3sex

| Source | SS | df | MS | Number of obs = | 792 |
|---|---|---|---|---|---|
| Model | 13.5621 | 11 | 1.23291818 | F( 11, 780) = | 23.53 |
| Residual | 40.8706272 | 780 | .05239824 | Prob > F = | 0.0000 |
| | | | | R-squared = | 0.2492 |
| | | | | Adj R-squared = | 0.2386 |
| Total | 54.4327273 | 791 | .068815079 | Root MSE = | .22891 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | -.1459494 | .0753314 | -1.94 | 0.053 | -.2938258 | .0019269 |
| age | .0001535 | .0019479 | 0.08 | 0.937 | -.0036701 | .0039772 |
| sex | .0324572 | .0300427 | 1.08 | 0.280 | -.0265169 | .0914313 |
| dum1 | .1548541 | .1433119 | 1.08 | 0.280 | -.1264687 | .4361768 |
| dum3 | -.1635523 | .1433119 | -1.14 | 0.254 | -.4448751 | .1177704 |
| dum1a | .0000368 | .0027547 | 0.01 | 0.989 | -.0053707 | .0054443 |
| dum1feel | -.0036965 | .1065347 | -0.03 | 0.972 | -.2128252 | .2054323 |
| dum1sex | .0045258 | .0424868 | 0.11 | 0.915 | -.0788762 | .0879278 |
| dum3a | .0003108 | .0027547 | 0.11 | 0.910 | -.0050967 | .0057182 |
| dum3feel | .0639255 | .1065347 | 0.60 | 0.549 | -.1452033 | .2730542 |
| dum3sex | -.0193174 | .0424868 | -0.45 | 0.649 | -.1027194 | .0640846 |
| _cons | .33147 | .1013368 | 3.27 | 0.001 | .1325448 | .5303952 |

Table 19
regress sg feel1 sex dum1 dum3 dum1feel dum1sex dum3feel dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 13.4531947 | 8 | 1.68164934 | Number of obs | = 795 |
| Residual | 41.1237864 | 786 | .052320339 | F( 8, 786) | = 32.14 |
| | | | | Prob > F | = 0.0000 |
| Total | 54.5769811 | 794 | .068736752 | R-squared | = 0.2465 |
| | | | | Adj R-squared | = 0.2388 |
| | | | | Root MSE | = .22874 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | -.1399217 | .0750517 | -1.86 | 0.063 | -.2872472 | .0074038 |
| sex | .0303836 | .0293092 | 1.04 | 0.300 | -.0271499 | .0879171 |
| dum1 | .1555139 | .0879311 | 1.77 | 0.077 | -.0170937 | .3281215 |
| dum3 | -.1498993 | .0879311 | -1.70 | 0.089 | -.3225069 | .0227083 |
| dum1feel | .0000569 | .1061391 | 0.00 | 1.000 | -.2082928 | .2084066 |
| dum1sex | .003405 | .0414494 | 0.08 | 0.935 | -.0779596 | .0847696 |
| dum3feel | .0604513 | .1061391 | 0.57 | 0.569 | -.1478984 | .268801 |
| dum3sex | -.0192801 | .0414494 | -0.47 | 0.642 | -.1006447 | .0620846 |
| _cons | .3364341 | .0621767 | 5.41 | 0.000 | .2143821 | .4584861 |

Table 20
regress sg feel1 dum1 dum3 dum1feel dum3feel

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 13.3199238 | 5 | 2.66398477 | Number of obs | = 795 |
| Residual | 41.2570573 | 789 | .052290313 | F( 5, 789) | = 50.95 |
| | | | | Prob > F | = 0.0000 |
| Total | 54.5769811 | 794 | .068736752 | R-squared | = 0.2441 |
| | | | | Adj R-squared | = 0.2393 |
| | | | | Root MSE | = .22867 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | -.138009 | .0750075 | -1.84 | 0.066 | -.2852468 | .0092289 |
| dum1 | .1609948 | .0572593 | 2.81 | 0.005 | .0485961 | .2733934 |
| dum3 | -.1809333 | .0572593 | -3.16 | 0.002 | -.2933319 | -.0685346 |
| dum1feel | .0002712 | .1060766 | 0.00 | 0.998 | -.2079545 | .208497 |
| dum3feel | .0592376 | .1060766 | 0.56 | 0.577 | -.1489881 | .2674633 |
| _cons | .3853407 | .0404885 | 9.52 | 0.000 | .3058628 | .4648186 |

## Gamma regression to check the robustness of the results

Table 21
glm sg feel1 dum1 dum3, f(gamma) l(log)

```
Iteration 0:   log likelihood =   174.7639
Iteration 1:   log likelihood =   187.4531
Iteration 2:   log likelihood =  187.45906
Iteration 3:   log likelihood =  187.45906

Generalized linear models                         No. of obs      =        795
Optimization     : ML                             Residual df     =        791
                                                  Scale parameter =  .5095236
Deviance         =  397.2138937                   (1/df) Deviance =  .5021667
Pearson          =  403.0331413                   (1/df) Pearson  =  .5095236

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]

                                                  AIC             = -.4615322
Log likelihood   =  187.4590581                   BIC             = -4885.355
```

| sghs | OIM Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | -.3777598 | .131591 | -2.87 | 0.004 | -.6356734 | -.1198462 |
| dum1 | .4144834 | .0620153 | 6.68 | 0.000 | .2929357 | .5360312 |
| dum3 | -.6512567 | .0620122 | -10.50 | 0.000 | -.7727984 | -.5297149 |
| _cons | -.9656269 | .079584 | -12.13 | 0.000 | -1.121609 | -.8096452 |

**Non ART EC group**
**Baseline data**

## Generic model including CD4, sex, gender for VAS

Table 22
regress vas cd4 age sex dum1 dum3 dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 17.226445 | 11 | 1.56604045 | Number of obs | = 450 |
| Residual | 9.32281732 | 438 | .021284971 | F( 11, 438) | = 73.57 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.6488 |
| | | | | Adj R-squared | = 0.6400 |
| Total | 26.5492623 | 449 | .05912976 | Root MSE | = .14589 |

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4b | -.0000415 | .000047 | -0.88 | 0.378 | -.0001339 | .0000509 |
| age | .0005238 | .0013214 | 0.40 | 0.692 | -.0020734 | .0031209 |
| sex | .0421146 | .0284858 | 1.48 | 0.140 | -.0138711 | .0981004 |
| dum1 | .2826791 | .107611 | 2.63 | 0.009 | .071181 | .4941771 |
| dum3 | -.1891863 | .107611 | -1.76 | 0.079 | -.4006843 | .0223117 |
| dum1a | -.0014634 | .0018688 | -0.78 | 0.434 | -.0051363 | .0022096 |
| dum1cd4 | .0000355 | .0000665 | 0.53 | 0.593 | -.0000951 | .0001662 |
| dum1sex | -.0063825 | .0402849 | -0.16 | 0.874 | -.0855583 | .0727933 |
| dum3a | -3.01e-06 | .0018688 | -0.00 | 0.999 | -.0036759 | .0036699 |
| dum3cd4 | .0000175 | .0000665 | 0.26 | 0.793 | -.0001132 | .0001482 |
| dum3sex | -.0355416 | .0402849 | -0.88 | 0.378 | -.1147174 | .0436342 |
| _cons | .3169444 | .0760924 | 4.17 | 0.000 | .1673927 | .4664961 |

Table 23
regress vas cd4 sex dum1 dum3 dum1cd4 dum1sex dum3cd4 dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 17.2090343 | 8 | 2.15112929 | Number of obs | = 450 |
| Residual | 9.340228 | 441 | .021179655 | F( 8, 441) | = 101.57 |
| | | | | Prob > F | = 0.0000 |
| | | | | R-squared | = 0.6482 |
| | | | | Adj R-squared | = 0.6418 |
| Total | 26.5492623 | 449 | .05912976 | Root MSE | = .14553 |

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4b | -.0000414 | .0000469 | -0.88 | 0.378 | -.0001336 | .0000507 |
| sex | .0406541 | .0281765 | 1.44 | 0.150 | -.0147227 | .096031 |
| dum1 | .2224722 | .0751024 | 2.96 | 0.003 | .0748691 | .3700754 |
| dum3 | -.1893101 | .0751024 | -2.52 | 0.012 | -.3369133 | -.041707 |
| dum1cd4 | .0000354 | .0000663 | 0.53 | 0.594 | -.000095 | .0001657 |
| dum1sex | -.0023021 | .0398476 | -0.06 | 0.954 | -.0806168 | .0760126 |
| dum3cd4 | .0000175 | .0000663 | 0.26 | 0.792 | -.0001129 | .0001478 |
| dum3sex | -.0355332 | .0398476 | -0.89 | 0.373 | -.1138479 | .0427815 |
| _cons | .3384936 | .0531054 | 6.37 | 0.000 | .2341225 | .4428648 |

## Gamma regression to check the robustness of the results

Table 24
glm vas cd4 sex dum1 dum3, f(gamma) link(log)

```
Iteration 0:   log likelihood =  45.423578
Iteration 1:   log likelihood =  45.937187
Iteration 2:   log likelihood =  45.937607
Iteration 3:   log likelihood =  45.937607

Generalized linear models                         No. of obs      =        450
Optimization     : ML                             Residual df     =        445
                                                  Scale parameter =  .2799023
Deviance         =  86.67320395                   (1/df) Deviance =  .1947712
Pearson          =  124.5565058                   (1/df) Pearson  =  .2799023

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]
                                                  AIC             = -.1819449
Log likelihood   =  45.93760726                   BIC             = -2631.942
```

| vas | Coef. | OIM Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4b | -.0000875 | .0000962 | -0.91 | 0.363 | -.000276 | .000101 |
| sex | .0664337 | .0590956 | 1.12 | 0.261 | -.0493916 | .182259 |
| dum1 | .4644938 | .0610946 | 7.60 | 0.000 | .3447506 | .584237 |
| dum3 | -.9732492 | .0610966 | -15.93 | 0.000 | -1.092996 | -.853502 |
| _cons | -1.015386 | .1173349 | -8.65 | 0.000 | -1.245358 | -.7854137 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for VAS

Table 25
regress vas feel1 age sex dum1 dum3 dum1a dum1feel1 dum1sex dum3a dum3feel dum3sex

```
      Source |       SS       df       MS              Number of obs =     450
-------------+------------------------------           F( 11,   438) =   81.98
       Model |  17.8695802    11  1.62450729           Prob > F      =  0.0000
    Residual |  8.67968207   438  .019816626           R-squared     =  0.6731
-------------+------------------------------           Adj R-squared =  0.6649
       Total |  26.5492623   449   .05912976           Root MSE      =  .14077
```

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .1980255 | .0583913 | 3.39 | 0.001 | .0832636 | .3127875 |
| age | .000237 | .0012778 | 0.19 | 0.853 | -.0022743 | .0027483 |
| sex | .0206971 | .0280032 | 0.74 | 0.460 | -.0343402 | .0757345 |
| dum1 | .2832257 | .1052848 | 2.69 | 0.007 | .0762995 | .4901519 |
| dum3 | -.1680064 | .1052848 | -1.60 | 0.111 | -.3749326 | .0389198 |
| dum1a | -.0015064 | .001807 | -0.83 | 0.405 | -.0050579 | .0020451 |
| dum1feel1 | .0326491 | .0825777 | 0.40 | 0.693 | -.1296488 | .194947 |
| dum1sex | -.0079614 | .0396025 | -0.20 | 0.841 | -.0857959 | .0698732 |
| dum3a | .0000692 | .001807 | 0.04 | 0.969 | -.0034823 | .0036207 |
| dum3feel | -.0493818 | .0825777 | -0.60 | 0.550 | -.2116797 | .1129161 |
| dum3sex | -.0298721 | .0396025 | -0.75 | 0.451 | -.1077066 | .0479625 |
| _cons | .2408491 | .0744476 | 3.24 | 0.001 | .0945302 | .387168 |

Table 26
regress vas feel1 dum1 dum3 dum1feel1 dum3feel

```
      Source |       SS       df       MS              Number of obs =     450
-------------+------------------------------           F(  5,   444) =  181.53
       Model |  17.8281624     5  3.56563248           Prob > F      =  0.0000
    Residual |  8.7210999   444  .019642117           R-squared     =  0.6715
-------------+------------------------------           Adj R-squared =  0.6678
       Total |  26.5492623   449   .05912976           Root MSE      =  .14015
```

| vas | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .2070685 | .0568537 | 3.64 | 0.000 | .0953326 | .3188044 |
| dum1 | .2177384 | .0467378 | 4.66 | 0.000 | .1258837 | .3095932 |
| dum3 | -.2115345 | .0467378 | -4.53 | 0.000 | -.3033893 | -.1196797 |
| dum1feel1 | .0267633 | .0804033 | 0.33 | 0.739 | -.1312551 | .1847817 |
| dum3feel | -.0617338 | .0804033 | -0.77 | 0.443 | -.2197522 | .0962846 |
| _cons | .2810787 | .0330486 | 8.51 | 0.000 | .2161275 | .3460298 |

## Gamma regression to check the robustness of the results

Table 27

```
glm vas feel1 sex dum1 dum3 dum1feel1 dum1sex dum3feel dum3sex, f(gamma) link(log)
Iteration 0:   log likelihood =  48.584834
Iteration 1:   log likelihood =   49.70423
Iteration 2:   log likelihood =  49.711918
Iteration 3:   log likelihood =  49.711918

Generalized linear models                         No. of obs      =        450
Optimization     : ML                             Residual df     =        441
                                                  Scale parameter =  .2573214
Deviance         =  79.31341791                   (1/df) Deviance =   .179849
Pearson          =  113.4787192                   (1/df) Pearson  =  .2573214

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]

                                                  AIC             = -.1809419
Log likelihood   =  49.71191839                   BIC             = -2614.865
------------------------------------------------------------------------------
             |                 OIM
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |   .5058166   .2071037     2.44   0.015     .0999008    .9117325
         sex |   .0562491   .0997054     0.56   0.573    -.1391698    .2516681
        dum1 |   .5992608   .2749942     2.18   0.029     .0602821     1.13824
        dum3 |  -.9567828   .2712921    -3.53   0.000    -1.488506   -.4250601
    dum1feel1|  -.1510208   .2923939    -0.52   0.606    -.7241023    .4220606
      dum1sex|  -.0284643   .1411858    -0.20   0.840    -.3051834    .2482547
     dum3feel|   .4125054    .285996     1.44   0.149    -.1480365    .9730473
      dum3sex|  -.1438765   .1420457    -1.01   0.311     -.422281     .134528
        _cons|  -1.312552   .1949964    -6.73   0.000    -1.694738   -.9303656
------------------------------------------------------------------------------
```

Table 28

```
glm vas feel1 dum1 dum3, f(gamma) link(log)

Iteration 0:   log likelihood =  48.444913
Iteration 1:   log likelihood =  49.109052
Iteration 2:   log likelihood =  49.109834
Iteration 3:   log likelihood =  49.109834

Generalized linear models                         No. of obs      =        450
Optimization     : ML                             Residual df     =        446
                                                  Scale parameter =  .2607292
Deviance         =  80.68068847                   (1/df) Deviance =  .1808984
Pearson          =  116.2852047                   (1/df) Pearson  =  .2607292

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]

                                                  AIC             = -.2004882
Log likelihood   =  49.10983398                   BIC             = -2644.044
------------------------------------------------------------------------------
             |                 OIM
         vas |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |    .598973   .1154345     5.19   0.000     .3727255    .8252206
        dum1 |   .4674498   .0589665     7.93   0.000     .3518777    .5830219
        dum3 |  -.9839603   .0589893   -16.68   0.000    -1.099577   -.8683434
        _cons|  -1.263603   .0752187   -16.80   0.000    -1.411029   -1.116177
------------------------------------------------------------------------------
```

## Generic model including CD4, sex, gender for TTO

Table 29

```
regress  tto cd4 age sex dum1 dum3 dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 21.8059921 | 11 | 1.98236292 | Number of obs | 450 |
| Residual | 54.4186794 | 438 | .12424356 | F( 11, 438) | 15.96 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.2861 |
| | | | | Adj R-squared | 0.2681 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .35248 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4b | -8.29e-06 | .0001136 | -0.07 | 0.942 | -.0002315 | .000215 |
| age | -.0037732 | .0031926 | -1.18 | 0.238 | -.0100479 | .0025016 |
| sex | -.1684801 | .0688221 | -2.45 | 0.015 | -.3037428 | -.0332174 |
| dum1 | -.0925783 | .2599902 | -0.36 | 0.722 | -.6035616 | .4184051 |
| dum3 | -.4108246 | .2599902 | -1.58 | 0.115 | -.9218079 | .1001588 |
| dum1a | .006216 | .004515 | 1.38 | 0.169 | -.0026579 | .0150898 |
| dum1cd4 | -.0000274 | .0001606 | -0.17 | 0.865 | -.0003431 | .0002883 |
| dum1sex | .0822833 | .0973292 | 0.85 | 0.398 | -.109007 | .2735736 |
| dum3a | .0033417 | .004515 | 0.74 | 0.460 | -.0055321 | .0122155 |
| dum3cd4 | .0001163 | .0001606 | 0.72 | 0.470 | -.0001994 | .000432 |
| dum3sex | -.00136 | .0973292 | -0.01 | 0.989 | -.1926503 | .1899303 |
| _cons | .9534869 | .1838408 | 5.19 | 0.000 | .5921671 | 1.314807 |

Table 30

```
regress  tto sex dum1 dum3 dum1a dum1sex dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 21.5050019 | 6 | 3.58416699 | Number of obs | 450 |
| Residual | 54.7196697 | 443 | .123520699 | F( 6, 443) | 29.02 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.2821 |
| | | | | Adj R-squared | 0.2724 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .35146 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| sex | -.1583602 | .0678473 | -2.33 | 0.020 | -.2917028 | -.0250177 |
| dum1 | .0543858 | .2181001 | 0.25 | 0.803 | -.3742537 | .4830252 |
| dum3 | -.2368075 | .1743029 | -1.36 | 0.175 | -.5793707 | .1057558 |
| dum1a | .0024392 | .0031833 | 0.77 | 0.444 | -.003817 | .0086954 |
| dum1sex | .0705203 | .0963586 | 0.73 | 0.465 | -.1188564 | .259897 |
| dum3sex | -.0053354 | .0959506 | -0.06 | 0.956 | -.1939103 | .1832395 |
| _cons | .7955031 | .1232507 | 6.45 | 0.000 | .5532743 | 1.037732 |

Table 31

```
regress  tto sex dum1 dum3 dum1sex dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 21.4324775 | 5 | 4.2864955 | Number of obs | 450 |
| Residual | 54.7921941 | 444 | .123405842 | F( 5, 444) | 34.73 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.2812 |
| | | | | Adj R-squared | 0.2731 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .35129 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| sex | -.1583602 | .0678157 | -2.34 | 0.020 | -.29164 | -.0250805 |
| dum1 | .1548385 | .1742218 | 0.89 | 0.375 | -.1875633 | .4972403 |
| dum3 | -.2368075 | .1742218 | -1.36 | 0.175 | -.5792093 | .1055944 |
| dum1sex | .0637329 | .0959059 | 0.66 | 0.507 | -.1247531 | .2522189 |
| dum3sex | -.0053354 | .0959059 | -0.06 | 0.956 | -.1938214 | .1831506 |
| _cons | .7955031 | .1231934 | 6.46 | 0.000 | .5533885 | 1.037618 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for TTO

Table 32

```
regress  tto feel1 age sex dum1 dum3 dum1a dum1feel1 dum1sex dum3a dum3feel dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.5860601 | 11 | 2.14418728 | Number of obs | 450 |
| Residual | 52.6386115 | 438 | .120179478 | F( 11, 438) | 17.84 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.3094 |
| | | | | Adj R-squared | 0.2921 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .34667 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .4449969 | .1437965 | 3.09 | 0.002 | .16238 | .7276139 |
| age | -.004409 | .0031466 | -1.40 | 0.162 | -.0105934 | .0017753 |
| sex | -.2126963 | .0689617 | -3.08 | 0.002 | -.3482333 | -.0771593 |
| dum1 | -.0667137 | .2592782 | -0.26 | 0.797 | -.5762977 | .4428703 |
| dum3 | -.2729096 | .2592782 | -1.05 | 0.293 | -.7824936 | .2366744 |
| dum1a | .0063665 | .00445 | 1.43 | 0.153 | -.0023795 | .0151125 |
| dum1feel1 | -.107413 | .203359 | -0.53 | 0.598 | -.5070937 | .2922677 |
| dum1sex | .0916026 | .0975266 | 0.94 | 0.348 | -.1000756 | .2832808 |
| dum3a | .0038089 | .00445 | 0.86 | 0.393 | -.0049372 | .0125549 |
| dum3feel | -.3191891 | .203359 | -1.57 | 0.117 | -.7188698 | .0804916 |
| dum3sex | .0354374 | .0975266 | 0.36 | 0.717 | -.1562408 | .2271156 |
| _cons | .8087266 | .1833374 | 4.41 | 0.000 | .4483963 | 1.169057 |

Table 33

```
regress  tto feel1 sex dum1 dum3 dum1feel1 dum1sex dum3feel dum3sex
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.2992269 | 8 | 2.91240336 | Number of obs | 450 |
| Residual | 52.9254447 | 441 | .120012346 | F( 8, 441) | 24.27 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.3057 |
| | | | | Adj R-squared | 0.2931 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .34643 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .4318571 | .1433906 | 3.01 | 0.003 | .1500433 | .7136709 |
| sex | -.1991855 | .0682368 | -2.92 | 0.004 | -.3332952 | -.0650758 |
| dum1 | .1882972 | .1881602 | 1.00 | 0.318 | -.1815048 | .5580993 |
| dum3 | -.1203453 | .1881602 | -0.64 | 0.523 | -.4901473 | .2494568 |
| dum1feel1 | -.0884396 | .2027849 | -0.44 | 0.663 | -.4869845 | .3101054 |
| dum1sex | .0720935 | .0965014 | 0.75 | 0.455 | -.1175662 | .2617532 |
| dum3feel | -.307838 | .2027849 | -1.52 | 0.130 | -.7063829 | .090707 |
| dum3sex | .0237658 | .0965014 | 0.25 | 0.806 | -.1658939 | .2134255 |
| _cons | .6321216 | .1330493 | 4.75 | 0.000 | .3706321 | .8936112 |

Table 34

```
regress  tto feel1 sex dum1 dum3 dum1feel1 dum1sex dum3feel
```

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 23.291948 | 7 | 3.32742114 | Number of obs | 450 |
| Residual | 52.9327236 | 442 | .119757293 | F( 7, 442) | 27.78 |
| | | | | Prob > F | 0.0000 |
| | | | | R-squared | 0.3056 |
| | | | | Adj R-squared | 0.2946 |
| Total | 76.2246716 | 449 | .169765416 | Root MSE | .34606 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .4268967 | .141818 | 3.01 | 0.003 | .1481754 | .705618 |
| sex | -.1873026 | .0481994 | -3.89 | 0.000 | -.282031 | -.0925742 |
| dum1 | .2065853 | .172703 | 1.20 | 0.232 | -.1328358 | .5460064 |
| dum3 | -.0837692 | .1154051 | -0.73 | 0.468 | -.3105801 | .1430417 |
| dum1feel1 | -.0834792 | .2015676 | -0.41 | 0.679 | -.4796292 | .3126709 |
| dum1sex | .0602106 | .0834838 | 0.72 | 0.471 | -.1038639 | .224285 |
| dum3feel | -.2979172 | .1985322 | -1.50 | 0.134 | -.6881015 | .0922672 |
| _cons | .6138336 | .1102807 | 5.57 | 0.000 | .3970939 | .8305733 |

Table 35
regress tto feel1 sex dum1 dum3

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 22.9267219 | 4 | 5.73168047 | Number of obs | = 450 |
| Residual | 53.2979497 | 445 | .119770673 | F( 4, 445) | = 47.86 |
| | | | | Prob > F | = 0.0000 |
| Total | 76.2246716 | 449 | .169765416 | R-squared | = 0.3008 |
| | | | | Adj R-squared | = 0.2945 |
| | | | | Root MSE | = .34608 |

| tto | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .2997646 | .0827032 | 3.62 | 0.000 | .1372272 | .462302 |
| sex | -.1672324 | .0393568 | -4.25 | 0.000 | -.2445807 | -.0898841 |
| dum1 | .2674333 | .0399618 | 6.69 | 0.000 | .1888961 | .3459705 |
| dum3 | -.2462333 | .0399618 | -6.16 | 0.000 | -.3247705 | -.1676961 |
| _cons | .6477056 | .080132 | 8.08 | 0.000 | .4902214 | .8051898 |

## Gamma regression to check the robustness of the results

Table 36
glm tto feel1 sex dum1 dum3, fam(gamma) l(log)

```
Iteration 0:   log likelihood = -119.97689
Iteration 1:   log likelihood = -109.49356
Iteration 2:   log likelihood = -109.48812
Iteration 3:   log likelihood = -109.48812
```

| | | | |
|---|---|---|---|
| Generalized linear models | | No. of obs | = 450 |
| Optimization | : ML | Residual df | = 445 |
| | | Scale parameter | = .8791741 |
| Deviance | = 126.6417942 | (1/df) Deviance | = .2845883 |
| Pearson | = 391.2324807 | (1/df) Pearson | = .8791741 |
| Variance function: V(u) = u^2 | | [Gamma] | |
| Link function | : g(u) = ln(u) | [Log] | |
| | | AIC | = .5088361 |
| Log likelihood | = -109.4881158 | BIC | = -2591.973 |

| tto | Coef. | OIM Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .6563651 | .2312581 | 2.84 | 0.005 | .2031075 | 1.109623 |
| sex | -.3974096 | .1085136 | -3.66 | 0.000 | -.6100924 | -.1847268 |
| dum1 | .440014 | .1084229 | 4.06 | 0.000 | .2275091 | .6525189 |
| dum3 | -.6554966 | .1084377 | -6.04 | 0.000 | -.8680306 | -.4429627 |
| _cons | -.3407129 | .2158991 | -1.58 | 0.115 | -.7638675 | .0824416 |

## Generic model including CD4, sex, gender for SG

Table 37
regress sg cd4 age sex dum1 dum3 dum1a dum1cd4 dum1sex dum3a dum3cd4 dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 1.22027319 | 11 | .110933926 | Number of obs | = 450 |
| Residual | 23.3486377 | 438 | .053307392 | F( 11, 438) | = 2.08 |
| | | | | Prob > F | = 0.0205 |
| Total | 24.5689109 | 449 | .054719178 | R-squared | = 0.0497 |
| | | | | Adj R-squared | = 0.0258 |
| | | | | Root MSE | = .23088 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| cd4b | -8.39e-06 | .0000744 | -0.11 | 0.910 | -.0001546 | .0001378 |
| age | .0009438 | .0020912 | 0.45 | 0.652 | -.0031663 | .0050539 |
| sex | -.0325178 | .0450801 | -0.72 | 0.471 | -.121118 | .0560824 |
| dum1 | .0951428 | .1702996 | 0.56 | 0.577 | -.2395632 | .4298488 |
| dum3 | -.0957017 | .1702996 | -0.56 | 0.574 | -.4304077 | .2390043 |
| dum1a | .0021235 | .0029574 | 0.72 | 0.473 | -.003689 | .0079361 |
| dum1cd4 | -.0000718 | .0001052 | -0.68 | 0.495 | -.0002786 | .000135 |
| dum1sex | -.0652143 | .0637529 | -1.02 | 0.307 | -.190514 | .0600853 |
| dum3a | .0002162 | .0029574 | 0.07 | 0.942 | -.0055963 | .0060288 |
| dum3cd4 | -.000035 | .0001052 | -0.33 | 0.739 | -.0002418 | .0001718 |
| dum3sex | .0228269 | .0637529 | 0.36 | 0.720 | -.1024727 | .1481265 |
| _cons | .2278582 | .12042 | 1.89 | 0.059 | -.0088146 | .4645311 |

## Generic model age, sex and including own health perception instead of CD4 cell counts for SG

Table 38
regress sg feel1 age sex dum1 dum3 dum1a dum1feel1 dum1sex dum3a dum3feel dum3sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 1.38510082 | 11 | .125918257 | Number of obs | 450 |
| Residual | 23.1838101 | 438 | .052931073 | F( 11, 438) | 2.38 |
| | | | | Prob > F | 0.0073 |
| | | | | R-squared | 0.0564 |
| | | | | Adj R-squared | 0.0327 |
| Total | 24.5689109 | 449 | .054719178 | Root MSE | .23007 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .1599512 | .0954308 | 1.68 | 0.094 | -.027608 | .3475104 |
| age | .0007147 | .0020883 | 0.34 | 0.732 | -.0033896 | .0048189 |
| sex | -.0486602 | .0457665 | -1.06 | 0.288 | -.1386095 | .0412892 |
| dum1 | .1564276 | .1720704 | 0.91 | 0.364 | -.1817587 | .4946139 |
| dum3 | -.0810168 | .1720704 | -0.47 | 0.638 | -.419203 | .2571695 |
| dum1a | .0024891 | .0029533 | 0.84 | 0.400 | -.0033153 | .0082934 |
| dum1feel1 | -.261178 | .1349595 | -1.94 | 0.054 | -.5264267 | .0040708 |
| dum1sex | -.0427936 | .0647237 | -0.66 | 0.509 | -.1700012 | .084414 |
| dum3a | .0003266 | .0029533 | 0.11 | 0.912 | -.0054777 | .006131 |
| dum3feel | -.0798235 | .1349595 | -0.59 | 0.555 | -.3450722 | .1854253 |
| dum3sex | .0290761 | .0647237 | 0.45 | 0.653 | -.0981315 | .1562836 |
| _cons | .1741542 | .1216721 | 1.43 | 0.153 | -.0649796 | .413288 |

Table 39
regress sg feel1 sex dum1 dum3 dum1feel1 dum1sex dum3feel

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 1.23100149 | 7 | .175857356 | Number of obs | 450 |
| Residual | 23.3379094 | 442 | .0528007 | F( 7, 442) | 3.33 |
| | | | | Prob > F | 0.0018 |
| | | | | R-squared | 0.0501 |
| | | | | Adj R-squared | 0.0351 |
| Total | 24.5689109 | 449 | .054719178 | Root MSE | .22978 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .1562212 | .0941673 | 1.66 | 0.098 | -.0288501 | .3412925 |
| sex | -.0368126 | .0320044 | -1.15 | 0.251 | -.0997124 | .0260872 |
| dum1 | .2777316 | .114675 | 2.42 | 0.016 | .0523556 | .5031077 |
| dum3 | -.0247249 | .0766291 | -0.32 | 0.747 | -.1753276 | .1258778 |
| dum1feel1 | -.2479002 | .1338411 | -1.85 | 0.065 | -.5109443 | .0151439 |
| dum1sex | -.0644585 | .0554333 | -1.16 | 0.246 | -.1734042 | .0444871 |
| dum3feel | -.0671304 | .1318256 | -0.51 | 0.611 | -.3262132 | .1919525 |
| _cons | .1811763 | .0732265 | 2.47 | 0.014 | .0372608 | .3250917 |

Table 40
regress sg feel1 dum1 dum3 dum1feel1 dum1sex

| Source | SS | df | MS | | |
|---|---|---|---|---|---|
| Model | 1.14745189 | 5 | .229490378 | Number of obs | 450 |
| Residual | 23.4214591 | 444 | .052751034 | F( 5, 444) | 4.35 |
| | | | | Prob > F | 0.0007 |
| | | | | R-squared | 0.0467 |
| | | | | Adj R-squared | 0.0360 |
| Total | 24.5689109 | 449 | .054719178 | Root MSE | .22968 |

| sghs | Coef. | Std. Err. | t | P>\|t\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| feel1 | .107289 | .0658818 | 1.63 | 0.104 | -.0221899 | .2367679 |
| dum1 | .3160828 | .0970741 | 3.26 | 0.001 | .1253011 | .5068645 |
| dum3 | -.0613333 | .0265207 | -2.31 | 0.021 | -.113455 | -.0092117 |
| dum1feel1 | -.198968 | .1156627 | -1.72 | 0.086 | -.4262825 | .0283464 |
| dum1sex | -.1012711 | .0452398 | -2.24 | 0.026 | -.1901819 | -.0123603 |
| _cons | .1428251 | .0405273 | 3.52 | 0.000 | .0631759 | .2224742 |

## Gamma regression to check the robustness of the results

Table 41

```
glm  sg feel1 sex dum1 dum3 dum1feel1, f(gamma) l(log)

Iteration 0:   log likelihood =   269.1482
Iteration 1:   log likelihood =  311.80851
Iteration 2:   log likelihood =  312.20266
Iteration 3:   log likelihood =  312.20286
Iteration 4:   log likelihood =  312.20286

Generalized linear models                         No. of obs      =        450
Optimization     : ML                             Residual df     =        444
                                                  Scale parameter =   1.303864
Deviance         =  247.7296861                   (1/df) Deviance =   .5579497
Pearson          =  578.9155859                   (1/df) Pearson  =   1.303864

Variance function: V(u) = u^2                     [Gamma]
Link function    : g(u) = ln(u)                   [Log]

                                                  AIC             = -1.360902
Log likelihood   =  312.2028612                   BIC             = -2464.776

------------------------------------------------------------------------------
             |                 OIM
       sghs |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       feel1 |   .7626076   .3400363     2.24   0.025     .0961486    1.429067
         sex |  -.2615914   .1304203    -2.01   0.045    -.5172104   -.0059724
        dum1 |   .8426685     .36304     2.32   0.020     .1311233    1.554214
        dum3 |  -.3544246   .1318946    -2.69   0.007    -.6129334   -.0959159
   dum1feel1 |  -1.308763   .6186505    -2.12   0.034    -2.521296     -.09623
       _cons |  -1.572359   .2883691    -5.45   0.000    -2.137552   -1.007166
------------------------------------------------------------------------------
```

## APPENDIX XIIb
## Longitudinal analysis for PEM analysis

```
Table 1
gllamm vasa age sex feel if group==1 & vasa~=., i(idno)

Iteration 0:   log likelihood = -531.94291  (not concave)
Iteration 6:   log likelihood =  409.27644

number of level 1 units = 745
number of level 2 units = 266

Condition Number = 461.67705

gllamm model

log likelihood = 409.27644

------------------------------------------------------------------------------
        vasa |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.0001301   .0007085    -0.18   0.854    -.0015187    .0012585
         sex |   .0202033   .0109594     1.84   0.065    -.0012768    .0416834
        feel |   .1553321   .0271649     5.72   0.000     .1020898    .2085743
       _cons |    .486245   .0379645    12.81   0.000     .4118359    .5606541
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .01947603 (.00125275)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00003836 (.00074518)
------------------------------------------------------------------------------


Table 2
gllamm vasa age sex feel if group==0 & vasa~=., i(idno)

Iteration 0:   log likelihood = -300.76093  (not concave)
Iteration 6:   log likelihood =  248.40309

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 270.75183

gllamm model

log likelihood = 248.40309

------------------------------------------------------------------------------
        vasa |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.0012097   .0007759    -1.56   0.119    -.0027304    .0003109
         sex |   .0251642   .0168968     1.49   0.136    -.0079529    .0582812
        feel |   .2043448   .0360309     5.67   0.000     .1337256    .2749641
       _cons |    .482027   .0467503    10.31   0.000     .3903982    .5736558
------------------------------------------------------------------------------
Variance at level 1
------------------------------------------------------------------------------

  .01509833 (.00136433)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00162888 (.00100612)
------------------------------------------------------------------------------
```

```
Table 3
gllamm vasb age sex feel if group==1 & vasb~=., i(idno)

Iteration 0:   log likelihood = -719.41127  (not concave)
Iteration 7:   log likelihood =  487.69736

number of level 1 units = 745
number of level 2 units = 266

Condition Number = 296.08355

gllamm model

log likelihood = 487.69736
```

| vasb | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | .0009005 | .0006365 | 1.41 | 0.157 | -.0003469 | .002148 |
| sex | .0149689 | .0098445 | 1.52 | 0.128 | -.004326 | .0342637 |
| feel | .1303827 | .0244263 | 5.34 | 0.000 | .0825081 | .1782574 |
| _cons | .275513 | .0341066 | 8.08 | 0.000 | .2086654 | .3423607 |

```
Variance at level 1
------------------------------------------------------------------------------

  .01580974 (.00081915)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 2.768e-15 (2.558e-09)
------------------------------------------------------------------------------


Table 4
gllamm vasb age sex feel if group==0 & vasb~=., i(idno)

Iteration 0:   log likelihood = -345.30168  (not concave)
Iteration 6:   log likelihood =  259.67011

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 273.55976

gllamm model

log likelihood = 259.67011
```

| vasb | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | -.0004531 | .0007324 | -0.62 | 0.536 | -.0018885 | .0009823 |
| sex | .0097268 | .0159571 | 0.61 | 0.542 | -.0215484 | .0410021 |
| feel | .1965974 | .0350188 | 5.61 | 0.000 | .1279618 | .2652329 |
| _cons | .2833509 | .0442442 | 6.40 | 0.000 | .1966339 | .3700679 |

```
Variance at level 1
------------------------------------------------------------------------------

  .01473723 (.00132011)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00098638 (.00089808)
------------------------------------------------------------------------------
```

```
Table 5
gllamm vasc age sex feel if group==1 & vasc~=., i(idno)

Iteration 0:   log likelihood = -1020.6256  (not concave)
Iteration 7:   log likelihood =   578.2359

number of level 1 units = 745
number of level 2 units = 266

Condition Number = 357.53723

gllamm model

log likelihood = 578.2359
```

| vasc | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | .0015825 | .0005636 | 2.81 | 0.005 | .0004778 | .0026872 |
| sex | .0062799 | .0087179 | 0.72 | 0.471 | -.0108069 | .0233667 |
| feel | .0528306 | .0216311 | 2.44 | 0.015 | .0104345 | .0952268 |
| _cons | .0862754 | .0302036 | 2.86 | 0.004 | .0270775 | .1454733 |

```
Variance at level 1
------------------------------------------------------------------------------

  .0123984 (.0006424)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 3.010e-15 (4.305e-09)
------------------------------------------------------------------------------


Table 6
gllamm vasc age sex feel if group==0 & vasc~=., i(idno)

Iteration 0:   log likelihood = -593.97146  (not concave)
Iteration 7:   log likelihood =  329.23402

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 311.88416

gllamm model

log likelihood = 329.23402
```

| vasc | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | -.0001702 | .0006141 | -0.28 | 0.782 | -.0013738 | .0010334 |
| sex | -.0076137 | .0133582 | -0.57 | 0.569 | -.0337952 | .0185679 |
| feel | .1524284 | .0291676 | 5.23 | 0.000 | .095261 | .2095958 |
| _cons | .1030015 | .0370877 | 2.78 | 0.005 | .0303109 | .175692 |

```
Variance at level 1
------------------------------------------------------------------------------

  .01035385 (.00093772)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .0006918 (.00064954)
------------------------------------------------------------------------------
```

```
Table 7
gllamm ttoa age sex feel if group==1 & ttoa~=., i(idno)

Iteration 0:   log likelihood = -286.48552  (not concave)
Iteration 6:   log likelihood = -41.945925

number of level 1 units = 745
number of level 2 units = 266

Condition Number = 288.8616

gllamm model

log likelihood = -41.945925

------------------------------------------------------------------------------
        ttoa |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.0000773    .001397    -0.06   0.956    -.0028153    .0026607
         sex |   .0006547   .0216002     0.03   0.976    -.0416808    .0429903
        feel |  -.0607853   .0497147    -1.22   0.221    -.1582242    .0366536
       _cons |   .8236209   .0740063    11.13   0.000     .6785713    .9686706
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .06057034 (.00387913)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00535468 (.00267811)
------------------------------------------------------------------------------


Table 8
gllamm ttoa age sex feel if group==0 & ttoa~=., i(idno)

Iteration 0:   log likelihood = -171.56575  (not concave)
Iteration 7:   log likelihood =  -50.99754

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 276.90933

gllamm model

log likelihood = -50.99754

------------------------------------------------------------------------------
        ttoa |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0011478   .0015247     0.75   0.452    -.0018405    .0041361
         sex |   -.065547   .0331689    -1.98   0.048    -.1305569   -.0005371
        feel |  -.0134393   .0756583    -0.18   0.859    -.1617268    .1348483
       _cons |   .9155062   .0926316     9.88   0.000     .7339516    1.097061
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .07584934 (.00540404)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 1.902e-18 (2.168e-10)
------------------------------------------------------------------------------
```

```
Table 9
gllamm ttob age sex feel if group==1 & ttob~=., i(idno)

Iteration 0:   log likelihood = -328.27471  (not concave)
Iteration 7:   log likelihood = -155.92507
Iteration 8:   log likelihood = -155.92507

number of level 1 units = 745
number of level 2 units = 266

Condition Number = 289.76135

gllamm model

log likelihood = -155.92507

------------------------------------------------------------------------------
        ttob |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0001338   .0016134     0.08   0.934    -.0030284    .0032961
         sex |  -.0010183   .0249484    -0.04   0.967    -.0499164    .0478798
        feel |  -.0206914   .0580204    -0.36   0.721    -.1344093    .0930266
       _cons |   .5411287   .0855985     6.32   0.000     .3733588    .7088986
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .08302817 (.00531142)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00637347 (.00358594)
------------------------------------------------------------------------------


Table 10
gllamm ttob age sex feel if group==0 & ttob~=., i(idno)

Iteration 0:   log likelihood = -213.91632  (not concave)
Iteration 7:   log likelihood = -137.81911

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 277.34383

gllamm model

log likelihood = -137.81911

------------------------------------------------------------------------------
        ttob |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.0014927    .001915    -0.78   0.436    -.0052461    .0022606
         sex |  -.0934377   .0416429    -2.24   0.025    -.1750562   -.0118192
        feel |   .1429176   .0948324     1.51   0.132    -.0429504    .3287857
       _cons |   .6958506   .1162358     5.99   0.000     .4680325    .9236686
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .11692751 (.01044567)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00093559 (.00639226)
------------------------------------------------------------------------------
```

```
Table 11
gllamm ttoc age sex feel if group==1 & ttoc~=., i(idno)

Iteration 0:   log likelihood = -316.95972  (not concave)
Iteration 8:   log likelihood = -131.22253

number of level 1 units = 744
number of level 2 units = 266

Condition Number = 291.14504

gllamm model

log likelihood = -131.22253

------------------------------------------------------------------------------
        ttoc |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0025253   .0015501     1.63   0.103    -.0005128    .0055635
         sex |   .0084412   .0239619     0.35   0.725    -.0385233    .0554056
        feel |   .0660358   .0563717     1.17   0.241    -.0444508    .1765224
       _cons |    .122716   .0824373     1.49   0.137    -.0388582    .2842901
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .07840408 (.00503442)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .0052094 (.00335634)
------------------------------------------------------------------------------


Table 12
gllamm ttoc age sex feel if group==0 & ttoc~=., i(idno)

Iteration 0:   log likelihood = -211.15531
Iteration 7:   log likelihood = -129.23773

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 330.78425

gllamm model

log likelihood = -129.23773

------------------------------------------------------------------------------
        ttoc |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0002237   .0018596     0.12   0.904     -.003421    .0038684
         sex |  -.0735179   .0404551    -1.82   0.069    -.1528084    .0057727
        feel |   .1942668   .0922781     2.11   0.035     .0134051    .3751284
       _cons |   .3250923   .1129799     2.88   0.004     .1036558    .5465288
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .11283283 (.00803901)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 3.282e-16 (5.334e-09)
------------------------------------------------------------------------------
```

```
Table 13
gllamm sga age sex feel if group==1 & sga~=., i(idno)

Iteration 0:   log likelihood = -387.39296
Iteration 1:   log likelihood = -312.01201
Iteration 6:   log likelihood = -261.60419

number of level 1 units = 743
number of level 2 units = 265

Condition Number = 288.85672

gllamm model

log likelihood = -261.60419

------------------------------------------------------------------------------
         sga |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0008683   .0019018     0.46   0.648    -.0028591    .0045957
         sex |    .055341   .0294303     1.88   0.060    -.0023414    .1130234
        feel |  -.1760062   .0678454    -2.59   0.009    -.3089807   -.0430316
       _cons |   .4840653   .1007638     4.80   0.000     .2865719    .6815586
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .10805685 (.00694124)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .01131279 (.00494255)
------------------------------------------------------------------------------


Table 14
gllamm sga age sex feel if group==0 & sga~=., i(idno)

Iteration 0:   log likelihood = -230.27485
Iteration 5:   log likelihood = -165.17233

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 272.61163

gllamm model

log likelihood = -165.17233

------------------------------------------------------------------------------
         sga |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.0002771   .0021475    -0.13   0.897    -.0044862    .0039319
         sex |  -.0125778   .0466932    -0.27   0.788    -.1040949    .0789392
        feel |  -.2171626   .1023838    -2.12   0.034    -.4178312   -.0164941
       _cons |    .639947   .1297073     4.93   0.000     .3857255    .8941686
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .12777788 (.01139872)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00804615 (.00764897)
------------------------------------------------------------------------------
```

```
Table 15
gllamm sgb age sex feel if group==1 & sgb~=., i(idno)

Iteration 0:   log likelihood = -306.24696
Iteration 6:   log likelihood = -134.98603

number of level 1 units = 743
number of level 2 units = 265

Condition Number = 288.95878

gllamm model

log likelihood = -134.98603

------------------------------------------------------------------------------
         sgb |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   .0008385    .001601     0.52   0.600    -.0022994    .0039765
         sex |    .026067   .0247727     1.05   0.293    -.0224866    .0746206
        feel |   .0687686    .057294     1.20   0.230    -.0435256    .1810628
       _cons |   .2300482   .0848173     2.71   0.007     .0638094     .396287
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .07699524 (.00495883)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .0078691 (.00353286)
------------------------------------------------------------------------------


Table 16
gllamm sgb age sex feel if group==0 & sgb~=., i(idno)

Iteration 0:   log likelihood = -199.46972  (not concave)
Iteration 9:   log likelihood =  -103.0324

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 276.90927

gllamm model

log likelihood = -103.0324

------------------------------------------------------------------------------
         sgb |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |   -.001657   .0017399    -0.95   0.341    -.0050672    .0017532
         sex |  -.0142413   .0378519    -0.38   0.707    -.0884297    .0599471
        feel |   .1499129   .0863402     1.74   0.083    -.0193108    .3191365
       _cons |   .3430836   .1057099     3.25   0.001      .135896    .5502712
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  .09877903 (.00703771)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 7.930e-22 (3.965e-12)
------------------------------------------------------------------------------
```

```
Table 17
gllamm sgc age sex feel if group==1 & sgc~=., i(idno)

Iteration 0:   log likelihood = -322.09642
Iteration 7:   log likelihood = -134.77749

number of level 1 units = 743
number of level 2 units = 265

Condition Number = 297.31857

gllamm model

log likelihood = -134.77749
```

| sgc | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | .000596 | .0014852 | 0.40 | 0.688 | -.002315 | .003507 |
| sex | -.0017057 | .0229773 | -0.07 | 0.941 | -.0467403 | .043329 |
| feel | .2710494 | .0575301 | 4.71 | 0.000 | .1582926 | .3838063 |
| _cons | .0769445 | .0795688 | 0.97 | 0.334 | -.0790075 | .2328964 |

```
Variance at level 1
------------------------------------------------------------------------------

  .08326198 (.00537694)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): .00090312 (.00326839)
------------------------------------------------------------------------------


Table 18
gllamm sgc age sex feel if group==0 & sgc~=., i(idno)

Iteration 0:   log likelihood =  -185.3882  (not concave)
Iteration 8:   log likelihood = -78.973129

number of level 1 units = 394
number of level 2 units = 150

Condition Number = 276.90924

gllamm model

log likelihood = -78.973129
```

| sgc | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age | -.0009807 | .0016369 | -0.60 | 0.549 | -.0041889 | .0022275 |
| sex | -.0201198 | .0356097 | -0.57 | 0.572 | -.0899135 | .0496739 |
| feel | .4079828 | .0812257 | 5.02 | 0.000 | .2487835 | .5671822 |
| _cons | .0970473 | .0994479 | 0.98 | 0.329 | -.0978671 | .2919617 |

```
Variance at level 1
------------------------------------------------------------------------------

  .08742288 (.00622862)

Variances and covariances of random effects
------------------------------------------------------------------------------


***level 2 (idno)

    var(1): 1.795e-15 (6.410e-09)
------------------------------------------------------------------------------
```

**APPENDIX XIII**

## Means and Standard Deviations MOS-HIV, WHOQOL-HIV BREF and SQOLI-HIV

**Table 1** **MOS-HIV scales and mean scores for ART DART group -** *at baseline, six and twelve months*

| Scale | Baseline n=276 | Six months n=251 | Twelve months n=246 |
|---|---|---|---|
| **Perceived health** Mean -SD | 34.7 ± 20.9 | 54.6 ± 28.7 | 55.4 ± 25.1 |
| **Physical functioning** Mean (SD) | 57.1 ± 26.4 | 75.0 ± 24.2 | 78.3 ± 22.2 |
| **Role functioning** Mean -SD | 32.8 ± 36.7 | 49.0 ± 43.9 | 55.7 ± 41.5 |
| **Social functioning** Mean -SD | 65.7 ± 33.6 | 88.8 ± 27.1 | 93.8 ± 20.4 |
| **Cognitive functioning** Mean -SD | 58.3 ± 23.2 | 63.0 ± 25.3 | 61.8 ± 22.9 |
| **Bodily pain** Mean -SD | 37.9 ± 23.1 | 60.6 ± 31.1 | 66.2 ± 30.5 |
| **Mental health** Mean -SD | 57.8 ± 17.4 | 69.3 ± 18.6 | 72.8 ± 16.0 |
| **Vitality** Mean -SD | 43.4 ± 19.4 | 65.8 ± 19.0 | 69.6 ± 17.1 |
| **Health distress** Mean -SD | 67.0 ± 22.2 | 88.4 ± 15.8 | 90.8 ± 12.9 |
| **Quality of life** Mean -SD | 46.8 ± 19.8 | 60.7 ± 18.1 | 57.2 ± 18.9 |
| **Health transition** Mean -SD | 69.4 ± 22.9 | 67.7 ± 24.4 | 68.0 ± 21.4 |

**Table 2** **MOS-HIV scales and mean scores for Non ART EC group** - *at baseline, six and twelve months*

| Scale | Baseline N = 159 | Six months n = 142 | Twelve months n =121 |
|---|---|---|---|
| **Perceived health** Mean -SD | 34.1 ± 34.4 | 46.0 ± 23.7 | 54.9 ± 23.4 |
| **Physical functioning** Mean (SD) | 73.8 ± 25.5 | 59.3 ± 28.7 | 76.1 ± 24.4 |
| **Role functioning** Mean -SD | 49.0 ± 47.4 | 51.8 ± 35.9 | 69.0 ± 41.5 |
| **Social functioning** Mean -SD | 81.6 ± 35.5 | 90.8 ± 18.7 | 93.7 ± 18.4 |
| **Cognitive functioning** Mean -SD | 69.0 ± 27.4 | 46.8 ± 19.0 | 58.6 ± 18.0 |
| **Bodily pain** Mean -SD | 48.0 ± 32.4 | 44.0 ± 26.5 | 62.5 ± 31.9 |
| **Mental health** Mean -SD | 57.9 ± 23.4 | 64.8 ± 17.9 | 74.8 ± 15.0 |
| **Vitality** Mean -SD | 59.1 ± 23.4 | 60.1 ± 18.5 | 70.5 ± 15.4 |
| **Health distress** Mean -SD | 79.2 ± 29.0 | 81.7 ± 15.5 | 91.3 ± 11.0 |
| **Quality of life** Mean -SD | 48.6 ± 23.7 | 53.0 ± 17.7 | 56.2 ± 17.8 |
| **Health transition** Mean -SD | 57.3 ± 17.9 | 71.5 ± 19.7 | 65.9 ± 20.4 |

**Table 3** **WHOQOL-HIV BREF scales and mean scores for ART DART group** - *at baseline, six and twelve months*

| Scale | Baseline N = 120 | Six months n = 107 | Twelve months n =104 |
|---|---|---|---|
| **Physical** Mean -SD | 11.10 (2.4) | 14.2 (3.6) | 15.0 (3.3) |
| **Psychological** Mean (SD) | 11.9 (2.0) | 14.1 (2.3) | 14.2 (2.4) |
| **Level of independence** Mean -SD | 10.8 (1.9) | 12.6 (2.8) | 12.8 (2.5) |
| **Social relationships** Mean -SD | 12.2 (2.8) | 14.1 (3.0) | 14.3 (2.4) |
| **Environment** Mean -SD | 10.9 (2.0) | 11.9 (4.7) | 11.4 (2.0) |
| **Spirituality** Mean -SD | 14.8 (2.3) | 16.3 (2.8) | 16.9 (2.4) |

**Table 4** **WHOQOL-HIV BREF scales and mean scores for Non ART EC group** - *at baseline, six and twelve months*

| Scale | Baseline N = 159 | Six months n = 141 | Twelve months n =121 |
|---|---|---|---|
| **Physical** Mean -SD | 14.0 (2.0) | 12.9 (3.2) | 14.4 (3.1) |
| **Psychological** Mean (SD) | 12.8 (2.9) | 13.2 (2.0) | 13.8 (2.3) |
| **Level of independence** Mean -SD | 13.0 (3.5) | 11.7 (2.3) | 12.7 (2.3) |
| **Social relationships** Mean -SD | 14.5 (2.7) | 12.8 (2.4) | 14.4 (2.3) |
| **Environment** Mean -SD | 11.8 (2.0) | 10.5 (2.0) | 10.6 (2.1) |
| **Spirituality** Mean -SD | 16.2 (2.8) | 16.3 (5.1) | 17.3 (2.0) |

**Table 5** **SQoLI-HIV scales and mean scores for ART DART** *group - at baseline, six and twelve months*

| Scale | Baseline N = 155 | Six months n = 144 | Twelve months n =142 |
|---|---|---|---|
| **Physical** Mean -SD | 10.7 (2.7) | 8.7 (2.6) | 8.4 (3.1) |
| **Psychological** Mean (SD) | 11.2 (1.7) | 10.5 (2.2) | 9.8 (2.3) |
| **Level of independence** Mean -SD | 11.7 (4.2) | 7.4 (5.0) | 5.7 (3.9) |
| **Social relationships** Mean -SD | 10.8 (2.6) | 9.7 (2.8) | 10.0 (2.5) |
| **Environment** Mean -SD | 9.7 (1.7) | 9.6 (2.1) | 9.0 (1.9) |
| **Spirituality** Mean -SD | 9.5 (1.8) | 10.1 (1.9) | 10.2 (1.7) |

**Table 6** **SQoLI-HIV scales and mean scores for Non ART EC** *group - at baseline, six and twelve months*

| Scale | Baseline N = 159 | Six months n = 142 | Twelve months n =121 |
|---|---|---|---|
| **Physical** Mean -SD | 9.3 (2.9) | 9.5 (7.3) | 8.8 (2.3) |
| **Psychological** Mean (SD) | 12.2 (1.9) | 10.4 (2.0) | 9.7 (1.9) |
| **Level of independence** Mean -SD | 7.9 (5.2) | 4.9 (2.7) | 5.4 (3.9) |
| **Social relationships** Mean -SD | 9.8 (2.3) | 10.8 (2.5) | 10.2 (2.1) |
| **Environment** Mean -SD | 10.0 (1.7) | 8.6 (1.5) | 8.4 (1.5) |
| **Spirituality** Mean -SD | 9.3 (1.7) | 10.1 (1.5) | 9.8 (1.3) |

## APPENDIX XIV

## MOS-HIV ANALYSIS

```
Table 1
gllamm HSS ihss1 i1age i1sex i1gp i1fup2 i1fup3 i1gpfup2 i1gpfup3 ihss2 i2age i2sex
i2gp i2fup2 i2fup3 i2gpfup2 i2gpfup3, f(gaussian) l(identity) nocons eq(line) i(idno)
adapt


number of level 1 units = 2384
number of level 2 units = 434

Condition Number = 151.64654

gllamm model

log likelihood = -8830.3402
------------------------------------------------------------------------------
         HSS |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
       ihss1 |   49.16556   1.620993    30.33   0.000     45.98847    52.34265
       i1age |  -.0656103   .0448076    -1.46   0.143    -.1534316    .0222109
       i1sex |   .6006486   .7895881     0.76   0.447    -.9469156    2.148213
        i1gp |  -.3018651   1.049974    -0.29   0.774    -2.359777    1.756047
      i1fup2 |  -.2721729   1.086629    -0.25   0.802    -2.401927    1.857581
      i1fup3 |  -.0165479    1.14351    -0.01   0.988    -2.257787    2.224691
    i1gpfup2 |     .27718     1.3622     0.20   0.839    -2.392683    2.947043
    i1gpfup3 |   .0342569   1.411284     0.02   0.981    -2.731808    2.800322
       ihss2 |   46.56263    1.29727    35.89   0.000     44.02003    49.10524
       i2age |  -.0154772   .0342859    -0.45   0.652    -.0826763    .0517218
       i2sex |    .792562   .6033224     1.31   0.189    -.3899282    1.975052
        i2gp |  -3.858521   .9372636    -4.12   0.000    -5.695524   -2.021518
      i2fup2 |   2.055474   1.080612     1.90   0.057    -.0624853    4.173434
      i2fup3 |   2.124088    1.13022     1.88   0.060    -.0911026    4.339279
    i2gpfup2 |   3.912464   1.355109     2.89   0.004     1.256499    6.568428
    i2gpfup3 |   3.887532   1.397758     2.78   0.005     1.147977    6.627087
------------------------------------------------------------------------------

Variance at level 1
------------------------------------------------------------------------------

  87.545519 (2.8008569)

Variances and covariances of random effects
------------------------------------------------------------------------------

***level 2 (idno)

    var(1): 22.585965 (3.853622)

    loadings for random effect 1
    ihss1: 1 (fixed)
    ihss2: .13481565 (.09485043)
------------------------------------------------------------------------------
```

## APPENDIX XV
## WHOQOL-HIV BREF ANALYSIS

**Table 1**

```
gllamm domain dom1 d1age d1sex d1gp d1fup2 d1fup3 d1gpfup2 d1gpfup3 dom2 d2age d2sex
d2gp d2fup2 d2fup3 d2gpfup2 d2gpfup3 dom3 d3age d3sex d3gp d3fup2 d3fup3 d3gpfup2
d3gpfup3 dom4 d4age d4sex d4gp d4fup2 d4fup3 d4gpfup2 d4gpfup3 dom5 d5age  d5sex d5gp
d5fup2 d5fup3 d5gpfup2 d5gpfup3 dom6 d6age d6sex d6gp d6fup2 d6fup3 d6gpfup2 d6gpfup3,
f(gaussian) l(identity) nocons eq(line) i(idno) adapt

number of level 1 units = 4493
number of level 2 units = 279

Condition Number = 75.368126

gllamm model
log likelihood = -10199.873
```

| domain | Coef. | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| dom1 | 13.5407 | .3517384 | 38.50 | 0.000 | 12.8513 | 14.23009 |
| d1age | .0038018 | .0176261 | 0.22 | 0.829 | -.0307447 | .0383482 |
| d1sex | .7539416 | .3394574 | 2.22 | 0.026 | .0886173 | 1.419266 |
| d1gp | -2.942991 | .3680732 | -8.00 | 0.000 | -3.664401 | -2.221581 |
| d1fup2 | -1.388205 | .257698 | -5.39 | 0.000 | -1.893284 | -.8831267 |
| d1fup3 | .282514 | .2704618 | 1.04 | 0.296 | -.2475813 | .8126093 |
| d1gpfup2 | 4.37817 | .3937042 | 11.12 | 0.000 | 3.606523 | 5.149816 |
| d1gpfup3 | 3.48727 | .404174 | 8.63 | 0.000 | 2.695104 | 4.279437 |
| dom2 | 12.5422 | .2806225 | 44.69 | 0.000 | 11.99219 | 13.09221 |
| d2age | .0190964 | .0132978 | 1.44 | 0.151 | -.0069669 | .0451596 |
| d2sex | .3205293 | .2559685 | 1.25 | 0.210 | -.1811597 | .8222183 |
| d2gp | -.8481576 | .3103864 | -2.73 | 0.006 | -1.456504 | -.2398116 |
| d2fup2 | .3440873 | .2565011 | 1.34 | 0.180 | -.1586456 | .8468203 |
| d2fup3 | .9795576 | .2683242 | 3.65 | 0.000 | .4536517 | 1.505463 |
| d2gpfup2 | 1.797518 | .3918258 | 4.59 | 0.000 | 1.029554 | 2.565483 |
| d2gpfup3 | 1.276788 | .4009245 | 3.18 | 0.001 | .4909904 | 2.062586 |
| dom3 | 12.74246 | .2998592 | 42.49 | 0.000 | 12.15474 | 13.33017 |
| d3age | -.0100457 | .0145182 | -0.69 | 0.489 | -.0385008 | .0184095 |
| d3sex | .4084872 | .2790731 | 1.46 | 0.143 | -.1384859 | .9554604 |
| d3gp | -2.273688 | .3254844 | -6.99 | 0.000 | -2.911626 | -1.63575 |
| d3fup2 | -1.47263 | .2578356 | -5.71 | 0.000 | -1.977978 | -.9672816 |
| d3fup3 | -.3570647 | .2688644 | -1.33 | 0.184 | -.8840293 | .1698999 |
| d3gpfup2 | 3.265695 | .3924001 | 8.32 | 0.000 | 2.496605 | 4.034785 |
| d3gpfup3 | 2.391242 | .4015977 | 5.95 | 0.000 | 1.604125 | 3.178359 |
| dom4 | 14.16611 | .2529848 | 56.00 | 0.000 | 13.67027 | 14.66196 |
| d4age | .0022812 | .011527 | 0.20 | 0.843 | -.0203114 | .0248737 |
| d4sex | .4107977 | .2218811 | 1.85 | 0.064 | -.0240814 | .8456767 |
| d4gp | -2.220878 | .2891759 | -7.68 | 0.000 | -2.787653 | -1.654104 |
| d4fup2 | -1.765162 | .2561238 | -6.89 | 0.000 | -2.267156 | -1.263169 |
| d4fup3 | -.0582225 | .2676168 | -0.22 | 0.828 | -.5827418 | .4662967 |
| d4gpfup2 | 3.598462 | .3911936 | 9.20 | 0.000 | 2.831737 | 4.365187 |
| d4gpfup3 | 2.138888 | .4000186 | 5.35 | 0.000 | 1.354866 | 2.92291 |
| dom5 | 11.46263 | .2563836 | 44.71 | 0.000 | 10.96012 | 11.96513 |
| d5age | .0028411 | .0117464 | 0.24 | 0.809 | -.0201814 | .0258636 |
| d5sex | .4594221 | .2261675 | 2.03 | 0.042 | .016142 | .9027022 |
| d5gp | -.8704784 | .2917261 | -2.98 | 0.003 | -1.442251 | -.2987058 |
| d5fup2 | -1.429768 | .2561596 | -5.58 | 0.000 | -1.931832 | -.9277049 |
| d5fup3 | -1.243442 | .2676958 | -4.64 | 0.000 | -1.768116 | -.7187678 |
| d5gpfup2 | 2.402311 | .3918553 | 6.13 | 0.000 | 1.634288 | 3.170333 |
| d5gpfup3 | 1.710018 | .4001286 | 4.27 | 0.000 | .92578 | 2.494255 |
| dom6 | 16.11216 | .2440581 | 66.02 | 0.000 | 15.63382 | 16.59051 |
| d6age | .0395982 | .0109398 | 3.62 | 0.000 | .0181565 | .0610399 |
| d6sex | .1340969 | .210515 | 0.64 | 0.524 | -.2785048 | .5466987 |
| d6gp | -1.425945 | .2825139 | -5.05 | 0.000 | -1.979662 | -.8722279 |
| d6fup2 | -.005255 | .256028 | -0.02 | 0.984 | -.5070605 | .4965506 |
| d6fup3 | .983626 | .2674069 | 3.68 | 0.000 | .4595182 | 1.507734 |
| d6gpfup2 | 1.556239 | .3904328 | 3.99 | 0.000 | .7910049 | 2.321473 |
| d6gpfup3 | 1.130326 | .399748 | 2.83 | 0.005 | .3468345 | 1.913818 |

```
Variance at level 1
------------------------------------------------------------------------------
  4.8822329 (.10635843)
Variances and covariances of random effects
------------------------------------------------------------------------------
 ***level 2 (idno)

    var(1): 4.2730404 (.51387433)
     loadings for random effect 1
    dom1: 1 (fixed)
    dom2: .62321007 (.04866391)
    dom3: .73484207 (.05101339)
    dom4: .43310888 (.04794875)
    dom5: .45931619 (.04709678)
    dom6: .35699604 (.04676651)
```

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