DETERMINANTS OF HEALTH RELATED QUALITY OF LIFE (HRQoL) OF ADULTS IN A PUBLIC SECTOR HAART PROGRAM IN BOTSWANA

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of requirements of the degree of Master of Science in Medicine in Epidemiology and Biostatistics.

MSc (Med) Epidemiology and Biostatistics

School of Public Health

Mr Edmore Marinda

30 May, 2008

DECLARATION

I, Evans Muhavani Buliva, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine in the branch of Epidemiology and Biostatistics in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university or college, and that all the sources I have quoted or used have been indicated and acknowledged as complete references.

Signature: ___Evans M. Buliva_________

___30_____ Day of ___May____, 2008.
DEDICATION

Dedicated to my wife Anyes,
my source of encouragement,
and to my small guys Mike, Angie, and Paul,
my true supporters.
ABSTRACT

Introduction

The advent of potent anti-retroviral agents for HIV treatment has resulted in marked decrease in deaths. Health workers now have to ensure that their patient’s physical, social, and psychological well-being is optimized. This study used a validated tool to measure Health Related Quality of Life concepts amongst HIV patients in a public treatment program. The main objective of this research was to establish factors that are associated with poor quality of life of these patients with the purpose of using this information as a basis for determining who would require individualized medical care and attention.

Materials and methods

The study is set at Bontleng Clinic in Gaborone, Botswana. The study questionnaire consisted of two parts: part one for collecting data on socio-demographic, illness and treatment related factors, and part two was the Medical Outcomes Study - Short Form tool used to obtain data on quality of life concepts. Two groups of participants were interviewed: ART-Naïve (n=90) and ART-Experienced (n=110). The study protocol had ethical approval from both the University of the Witwatersrand, Johannesburg and the Ministry of Health in Botswana.
**Results**

A smaller proportion of ART-experienced participants reported various disease symptoms as compared to those participants who were ART-naïve. Statistically significant differences were noted for: weight loss (25% vs 77%), diarrhoea (3% vs 11%), cough (19% vs 39%), and night sweats (24% vs 43%) for ART experienced and ART Naïve patients respectively. CD4 counts and HB levels were also significantly higher in patients on HAART. The overall QoL summary score was significantly higher (better) in the ART-experienced (mean score 53 out of 100) compared to the ART-naïve group (mean score 47 out of 100). Therefore being on ART favoured a higher QoL score. However, changes in the three laboratory indices of CD4 count, Hb level, and viral load had no statistical significant association with HRQoL scores. Multiple regression identified only five factors as being associated with better QoL scores. These factors were to do with the absence of the following disease symptoms: weight loss, diarrhoea, night sweats, and feet pains; as well as absence of recent hospitalisation.

**Discussion**

The study patients do respond well to HAART with significant improvements in all dimensions of QoL. This is in keeping with findings from other populations. In assessing these patients at the initiation of HAART, and at subsequent visits, one must take into account any history of recent hospital admission, history of weight loss, and most importantly presence/absence of various disease symptoms.
Conclusions and recommendations

Symptoms, regardless of the underlying cause: be it due to HIV disease itself or drug side effects; greatly impact patients’ quality of life. Efforts should be made to include the assessment of symptoms in the continuum of care of HIV patients. The introduction of newer potent anti-retroviral agents with fewer side effects should also favour the beneficial impact of HAART.
ACKNOWLEDGEMENTS

Foremost I would like to thank all the patients at Bontleng Council Clinic in Gaborone, Botswana who agreed to participate in this study. Your courage will never cease to amaze.

I also acknowledge all the nursing staff at the same clinic for their support.

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Bobgoti: thank you so much for your advice and for editing the document.

I cannot forget Lawrence Mpinga for shepherding my protocol through the university committees.
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<td>-------------</td>
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<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>ART</td>
<td>Anti-Retroviral Treatment</td>
</tr>
<tr>
<td>ARV</td>
<td>Anti-Retroviral</td>
</tr>
<tr>
<td>HAART</td>
<td>Highly Active Anti-Retroviral Therapy</td>
</tr>
<tr>
<td>Hb</td>
<td>Haemoglobin</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-Related Quality of Life</td>
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<tr>
<td>IDCC</td>
<td>Infectious Disease Care Clinic</td>
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<tr>
<td>IPT</td>
<td>Isoniazid Preventive Therapy</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>JHSPH</td>
<td>Johns Hopkins School of Public Health</td>
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<td>MHS</td>
<td>Mental Health Score</td>
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<tr>
<td>MOS-SF</td>
<td>Medical Outcomes Study for HIV - Short Form</td>
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<td>OTC</td>
<td>Over The Counter</td>
</tr>
<tr>
<td>PHS</td>
<td>Physical Health Score</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>UCSF</td>
<td>University of California, Santa Fe</td>
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<tr>
<td>VL</td>
<td>Viral Load</td>
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</table>
Introduction

Definition of Quality of Life:

Last (22) gives a straightforward definition of Quality of Life as the degree to which persons perceive themselves able to function physically, emotionally, (and) socially.

Mallory et al (4) has a more detailed definition of Health Related Quality of Life as a ‘multi-dimensional construct that refers to how well an individual functions in daily life and perceptions of how health status influences his or her life.

Quantitative assessments of Quality of life (QoL) are commonly used in clinical trials that compare different study arms. QoL measurements in such studies help identify and compare toxicities, or side effects of the competing therapies or interventions. Outside the scope of clinical trials, information on quality of life can also be useful in determining who amongst a large group of patients in a treatment program (e.g. for HIV) would require individualized attention and tailored treatment options for optimal response. This later goal is the focus of this research paper.

Factors previously identified as affecting QoL for HIV patients include: low CD4 count, hospitalization before enrollment, presence of symptoms, and dissatisfaction with information given by care giver(1). Some factors associated with improved QoL are: short length of time since HIV diagnosis, undetectable
viral load after 12 months of being on ARVs, and a low number of reported symptoms(2).

It is vital to identify factors and characteristics that play a role in determining the overall quality of life among HIV patients, as these factors will ultimately influence the uptake, adherence, and ultimately response to ARV therapy.

**Background**

Health Related Quality of Life (HRQoL) in the context of HIV/AIDS patients refers to how a person living with HIV/AIDS is satisfied with his or her life as a whole (3). The aim of this rapidly expanding branch of medical science is to use specific indicators to measure, compare and ultimately optimize the physical, social and psychological wellbeing of patients on different therapies or interventions.

HIV therapies are complex with many associated side effects as the disease follows a protracted course. The need to incorporate HRQoL in the assessment of these therapies, as is being done with therapies for other chronic illnesses such as cancer and arthritis, is now well recognized (5).

In January 2002 the Government of Botswana instituted the *Masa* (*Setswana* for ‘dawn’ of a new day) Program whose aim is to provide free antiretroviral
treatment to all qualifying citizens. By July 2004 the program had registered over 17000 patients. To enroll in this program one has to be HIV-positive with a CD4 cell count of ≤ 200/µL or with an AIDS defining illness (24). Currently there are more than 20 sites country-wide where this program is being implemented.

Universally access to ARV treatment is all but inevitable under this rapidly expanding program. Currently patient survival rate is the routine measure of success of the program. This researcher believes that quality of life data should now also be routinely obtained and used to monitor and evaluate the Masa program.

Literature Review

The 2005 official Botswana Government statistics (7) put the HIV prevalence at 33.4% of all pregnant women seeking ante-natal services. It is estimated that over 250,000 adults in Botswana are HIV positive (7), and these people will require Highly Active Antiretroviral Treatment (HAART) in the next few years.

Studies in Botswana have documented excellent clinical and virological response to HAART in HIV patients, though with high rates of toxicity with certain anti-retroviral drug regimens (8). Unfortunately very few studies have been performed in Africa to assess health-related quality of life amongst people living with HIV/AIDS, and very little is documented on how ARV therapy impacts on patient’s
quality of life as measured from the patient’s own perspective. Studies on HRQoL will help in advancing the additional treatment goals of avoiding drug related toxicity and improving adherence in the long term (9).

R. Murri et al (1) looked at a cohort of Italian HIV patients in a multi-center study and identified the following:

At baseline the predictors of poor HRQoL were:

- Low CD4 count,
- Hospitalization during the past three months and,
- Presence of symptoms.

At six months the predictors of HRQoL were:

- Stage of HIV infection,
- Baseline CD4 count and,
- Symptom score.

Current guidelines on anti-retroviral therapy (10) are based on the principle of aggressive initial treatment to reduce viral load which is then followed by long term treatment to suppress viral replication. The issues of side effects during long term use of ARVs is coming to the fore as we move from rescuing patients from the brink of death to long-term maintenance with an expectation of high quality of life (9).
As previously noted, use of ARVs in the public domain is now well established in Botswana; however drug toxicity, especially peripheral neuropathy, is a noted feature in some patients. One study (8) reported that close to 24% of Botswana patients experience severe toxicities before the end of the first year on ARVs. The issue of drug side-effects significantly affecting patient’s quality of life has been noted in several studies (4) (5) (11).

HRQoL measurements are now being utilized in greater frequency in clinical trials and in quality of care studies. Many different tools have been developed to measure HRQoL. In this study the researcher will utilize the MOS-SF survey tool which has been utilized in several studies (12) (13) (5) and found to be a reliable and valid measure of quality of life for patients with HIV infection.

Below is a summary of results of two studies on HRQoL to serve as a comparator to this study. The first study is located in a developed country (United States of America), and the second one is a recent study in a developing country (South Africa).

U.S.A*: Factors associated with lower HRQoL in HIV infected persons (20).

- Older age
- Female sex
- Black or Hispanic race/ethnicity
- Injection drug use
- Lower education and income
• No private health insurance
• Lower CD4 count.

**South Africa**: Comparing HAART and Non-HAART HIV positive patients (21):

• HAART patients were twice more likely to have a higher HRQoL index than non-HAART patients.
• Employed respondents were more likely to have a higher HRQoL than unemployed respondents (though this was not statistically significant).

**Study Aim**

The study had the following aims:

• To identify socio-demographic and laboratory factors that are associated with poor or high health-related quality of life in patients enrolling for anti-retroviral therapy in Botswana.
• To investigate if anti-retroviral therapy has any association with improved quality of life.
• To demonstrate and promote the use of HRQoL instruments in the initial work-up and subsequent follow-up of patients in public ARV therapy programs in Africa.

* Taking antiretroviral medication was not associated with differences in HRQoL regardless of CD4 count. Median age of study participants was 37 years.

** 75% of the South African interviewees were aged below 45 years, with twice as many women than men.
Study Objectives

The objectives of the study are:

1. To describe two groups of patients: those about to go on ART, and those who have been on treatment in terms of:
   a. Socio-demographic factors, and
   b. HIV disease markers (CD4 count, Viral load, hemoglobin level)

2. To measure HRQoL in a sample of patients as they start ARV treatment ('ART Naïve'), as well as a sample of patients who have been on treatment for at least six months ('ART Experienced'), at a public HIV treatment site in Gaborone, Botswana.

3. To determine factors associated with HRQoL by comparing treatment status, socio-demographic characteristics and disease markers (latest available laboratory HIV monitoring data) with HRQoL scores.

4. To investigate any association between HRQoL and the following HIV patient factors: patient satisfaction, illness-related factors, disease-related factors, and symptoms
METHODS

A. Study design

This was a cross-sectional comparative study involving simultaneous primary data collection of explanatory and outcome variables in two distinct groups of participants.

HRQoL (outcome) and data on various predictor (explanatory) factors was measured in the following two groups of participants:

1. **ART Naïve Group**: This group consisted of participants who were eligible for Anti-Retroviral Treatment but had not yet commenced the treatment. This group were still undergoing administrative processes before starting HIV treatment.

2. **ART Experienced Group**: This group consisted of participants who had been on ARV medications for 6 or more months by the date the researcher was conducting the HRQoL interview.

B. Study population

The study population consisted of adult Botswana citizen HIV positive patients attending a public HIV treatment site in the city of Gaborone, Botswana.

Study participants would either be new patients qualifying for, and presenting themselves for the first time for ARV treatment, OR old patients already taking
ARV treatment for 6 or more months at the time the researcher was undertaking this study.

**C: Principles of HRQoL Measurement (6)**

HRQoL measurements objectively document issues like treatment toxicity and psychological aspects of illness such as anxiety or depression, ability to cope with illness, and satisfaction with life. Many generic instruments have been developed to measure HRQoL, and all use fairly simple forms of scoring.

Examples of QoL measurement tools include (6): Nottingham Health Profile (NHP), EuroQol (EQ-5D), Functional Assessment of Cancer Therapy (FACT-G), Quality of Life in Epilepsy (QOLIE-89), and the McGill Pain Questionnaire (MPQ). In general a change of 5 - 10 points on a 100-point scale is regarded as significant and likely to be noticed by the patients.

HRQoL is essentially measured by interviewing only the patient. This is because observers such as relatives or health care workers are known to dwell on obvious symptoms while under-estimating the impact of psychological aspects of a disease on the patient. Conventional clinical outcomes also correlate poorly with patients’ own assessment of their quality of life.

The Medical Outcomes Study for HIV Short Form (MOS-SF) health survey instrument that is used in this study consists of patient self-ratings on 20 items
measuring 6 health concepts (see Appendix B-2): Physical functioning, Role functioning, Social functioning, Mental health, Health perceptions, and Pain.

Table 1 below gives a brief description, in terms of meaning, of the 6 Medical Outcomes Study construct scales.

**Table 1. Summary of MOS-HIV Survey Concepts**

<table>
<thead>
<tr>
<th>Concept</th>
<th>No. of Items in Questionnaire</th>
<th>Meaning of a Low score</th>
<th>Meaning of a High score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>6</td>
<td>Very limited in performing physical activities due to poor health including eating, dressing, bathing or using the toilet</td>
<td>Performs all types of physical activities due to poor health including vigorous or strenuous activities without limitations</td>
</tr>
<tr>
<td>Role Functioning</td>
<td>2</td>
<td>As a result of physical health, experiences problems with work or daily activities</td>
<td>No problems with work or other daily activities as a result of health</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>1</td>
<td>Social activities limited due to health</td>
<td>No limitations on social activities as a result of health</td>
</tr>
<tr>
<td>Mental Health</td>
<td>5</td>
<td>Feels nervous and depressed all of the time</td>
<td>Feels calm, peaceful and happy all of the time</td>
</tr>
<tr>
<td>General Health Perceptions</td>
<td>5</td>
<td>Views personal health as poor</td>
<td>Views personal health as excellent</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td>Very severe and limiting pain</td>
<td>No pain or limitations due to pain</td>
</tr>
</tbody>
</table>

*Note: Adapted from “The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual framework and item selection” by J.E. Ware and C.D. Sherbourne, 1992, Medical Care, 30: 473-483.*

Two summary scores are then obtained by use of formulae (see Appendix A):

1. **PHS - Physical Health Summary score and**

2. **MHS - Mental Health Summary score,**

For purpose of this study we will examine only the PHS.
D. Sample size calculation

Sample size calculation (14)

It was important to do a sample size calculation for this study so that if in actual fact there was a difference in HRQoL in our two study groups, this study should have been able to detect that difference and that the analysis would be statistically significant.

The researcher did the actual sample size calculation using STATA® computer statistical program.

The variables of interest were:

1. The desired power i.e the probability that the null hypothesis will be correctly rejected. A power of 90% was set.
2. The desired significance level i.e the cut-off point for the p-value below which the null hypothesis would be rejected. This level was set at 5%.
3. Size of difference of HRQoL scores of clinical importance = 5 points
4. The standard deviation of HRQoL was estimated at 10 points
5. The primary outcome variable was HRQoL scores summarized by means

.sampsi 45 50, p(0.9) r(1) sd1(10) sd2(10)

Estimated sample size for two-sample comparison of means
The Null hypothesis was that mean HRQoL in ART-Naïve patients = mean HRQoL in ART-Experienced patients.

Assumptions:

\[
\begin{align*}
\text{alpha} & = 0.0500 \text{ (two-sided)} \\
\text{power} & = 0.9000 \\
\text{m1} & = 45 \text{ (estimated mean QoL score for ART-naïve group)} \\
\text{m2} & = 50 \text{ (estimated mean QoL score for ART-experienced group)} \\
\text{sd1} & = 10 \text{ (estimated standard dev for ART-naïve group)} \\
\text{sd2} & = 10 \text{ (estimated standard dev for ART-experienced group)} \\
\frac{n2}{n1} & = 1.00 \text{ (ratio of participants in experienced to naive)}
\end{align*}
\]

Estimated required sample sizes:

\[
\begin{align*}
\text{n1} & = 85 \text{ (sample size in ART-naïve group)} \\
\text{n2} & = 85 \text{ (sample size in ART-experienced group)}
\end{align*}
\]

Thus minimum sample size per group = 85 per group, 170 in total.

The researcher decided to increase this number by 18% to 200 participants to cover for any participants who might otherwise withdraw their consent or drop out once enrolled.
**E. Sampling method**

The ART clinic attends patients on a first come first served basis. Clinic staff ensure patients are seated in a waiting area in their order of arrival. The clinic operates only weekday mornings. Patients arrive early morning (almost as a group), and by midday they have all been attended to and gone.

The research assistant would first give an overview presentation of the study to all patients seated in the waiting room. She would then invite anyone interested in the study to see her (one by one in order of the clinic queue) in a side room just adjacent to the general waiting area.

She would explain the study in more detail to those who were interested and had come in to see her. She would politely decline to interview those who did not meet this study’s selection criteria. All interviews went well and did not take much of the patients’ time as they were all able to regain their spots on the original clinic queue.

This was thus a non-random sampling procedure as only interested and self-selecting consecutive persons participated. Thus those who consented to participate were included into the study until the required numbers were reached (15).
ART-naïve patients’ first attendance to the clinic is without appointment, and the researcher interviewed them before they got registered into the clinics’ computer database. The researcher thus did not have a sampling frame by which random sampling would have been achieved.

**F. Data collection**

Training:
The researcher trained one research assistant on principles of health research and on use of a structured questionnaire for data collection, with emphasis on ethical considerations. Specific training was then done on the nature and reason of the study, and how to collect the data, including questionnaire administration (both questionnaires in Appendices B-1 and B-2 were administered) and examination of a participant’s clinic records for information on CD4 count, Hb level, and VL.

Pilot testing:
This was conducted on 5 members of the community. It was done to ensure the research assistant understood the purpose and meaning of each item in the questionnaire so that she could be able to elicit meaningful responses from respondents. Piloting also tested the flow of the questionnaire and clarity of each question.
Interviews:

These were conducted at Bontleng Clinic from April 2007 to June 2007. As noted earlier, the research assistant would first give a short presentation about the study to potential participants as they sat in the waiting room of the clinic. Interested participants would then present themselves one at a time into a quiet side room where the interviewer was seated and their privacy was assured.

The purpose of the study, and how the interview was going to be conducted, would then be further explained. At this stage all participants who consented to being interviewed would then be asked to sign the informed consent form before proceeding with the interview. Interviews took about 20 minutes to complete with the research assistant reading out the structured questionnaire and filling it in as per responses received. Clinic staff then availed the research assistant with the participant’s file for extraction of latest recorded laboratory data.

At the time this study was conducted public ART services in Gaborone were only being offered at the City’s main Government hospital (Princess Marina Hospital) and at Bontleng Council Clinic. Thus at that time these patients did reflect a fair representation of the city residents who accessed public ART programmes. Currently (2008) ARV services in the City have been expanded and three other public clinics in the City of Gaborone do offer ART services.
G. Data management and quality

The researcher actively supervised data collection and did sit in on some interviews for quality checks.

Completed questionnaires were reviewed daily by the researcher and discussed with the research assistant to ensure responses had been accurately, completely, and correctly captured. There was thus no incident of missed data. The following amendments were made:

1. Q3 length of time on ARVs was converted into total time in months.
2. Q4 on employment status was re-coded to two variables only:
   Unemployed or Employed (to include all those having regular jobs or temporary jobs or are self employed), as it proved difficult to get accurate responses for the initial 4 response sub-categories.
3. Q9 on education level was re-coded into the following four categories:
   none/primary/secondary/tertiary.
4. Q10 the research assistant found it difficult to convert a respondent’s work/vocation into a skill level, she thus just wrote down the exact vocation and the researcher then later converted these entries into a skill level.
5. Q11 asks about number of years since HIV diagnosis, we converted the question and the responses to obtain number of months instead of years.
6. Q25 on disease symptoms is ‘none of the above’, we converted this to ‘Other symptoms’ as participants mentioned many other symptoms such as dizziness, back pains, headache, chest pains, body itchiness, etc.

7. An unexpected finding was that all ART-naïve patients did not have record of their Viral Load as that test had not been done. We coded and entered this into the database using the word ‘blank’ rather than numerical ‘0’ which would have caused confusion. In general, after a period of being on ART, Viral Load levels are expected to decrease as compared to baseline levels. This researcher would have liked to find out if any changes in VL are associated with changes in HRQoL in this population. However, a review of other studies (22) shows that presence (or paucity) of VL data was unlikely to affect the outcome of this study.

The researcher then went through each questionnaire and coded the responses by writing the corresponding code in pencil next to each response.

The researcher then created an Excel® spreadsheet that contained all the variables in the questionnaire. Double data entry was done with the research assistant doing initial entry, while the researcher did the second verification entry.

Visual inspection of the entered data was done. Range checks for consistency were also done using the Excel® software. Data cleaning was then done by re-checking inconsistent data with what was in the questionnaire.
Formulae (as detailed in Appendix A) obtained from Dr A. Wu’s handbook (16) were then entered into the Excel® database and executed to obtain scores for all the six QoL constructs, as well as to obtain the final summary PHS values for each participant.

The process of obtaining item scores essentially transforms and averages each item to a 0 - 100 range of lowest to highest possible scores. The six items are then aggregated and weighted using the PHS formula to obtain a single summary QoL score.

The data was then imported for statistical analysis into STATA® Version 9 using Stattransfer® software. Variable labels where created for each variable in STATA® in order to ease understanding during analysis.

**H. Data Analysis**

The outcome variable measured in this study is health-related quality of life as indicated by the summary value Physical Health Score (PHS). Data analysis was done based on the objectives of the study. Table 2 on the following page gives a summary of variables investigated.
Table 2: Summary of study variables

<table>
<thead>
<tr>
<th>Variable Type</th>
<th>Variable Category</th>
<th>Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-economic factors</td>
<td>Gender</td>
<td>Age, Marital status, Work skills, Employment status, Education level</td>
</tr>
<tr>
<td></td>
<td>Illness related factors</td>
<td>Time (months) on ART, Concurrent TB treatment, Using isoniazid tabs (IPT), Prior TB treatment, Relation to home care, Recent hospitalization, Time from HIV diagnosis, Self OTC supplements</td>
</tr>
<tr>
<td></td>
<td>Patient satisfaction</td>
<td>With info given, With care given</td>
</tr>
<tr>
<td></td>
<td>Disease symptoms</td>
<td>Weight loss, Diarrhea, Cough, Difficulty in breathing, Night sweats, Feet pains, Fever or chills, Other symptoms</td>
</tr>
<tr>
<td></td>
<td>Laboratory markers</td>
<td>Hemoglobin level, CD4 cell count, Viral Load</td>
</tr>
<tr>
<td>Health-related Quality of Life</td>
<td>(numerical continuous variable)</td>
<td>Physical fx, Role fx, Social fx, Mental hlth, Hlth perc’p. Pain, PHS - Physical Health Score (derived summary)</td>
</tr>
</tbody>
</table>

During statistical analysis a significance level of $p < 0.05$ was used throughout.
**Data analysis sequence**

The following sequence was used during data analysis:

1. Frequency tabulations was obtained for the following categorical variables:
   Marital status, work skills level, employment status, education level,
   presence of a caregiver, satisfaction levels for information and care, and
   presence of symptoms.

2. Means, medians and ranges of the following numerical continuous
   variables obtained:
   Time on ARVs, time since HIV diagnosis, Viral Load levels, CD4 levels, Hb
   level, summary HRQoL scores.

3. The above two were used to give descriptive statistics of the data. These
   are shown in tables 3, 4, 5, 6, and upper part of table 7.

4. Un-paired t-tests were done to compare numerical continuous data of the
   two study groups. These are shown in lower part of table 7, and table 8.

5. Chi-square tests to compare proportions of categorical variables of the two
   study groups. P-values obtained are shown in tables 3, 4, 6, and upper 7.

6. Prior to using parametric tests to analyse the summary Physical Health
   Score (PHS). The distribution of this score was thus investigated for
   normality by visual inspection of its Histogram, Box Plot, and of its
   Normality plot (**pnorm** in Stata). The assumptions of normality were met.
7. Univariate analysis was then done on each variable, with the use of ‘dummy’ variables during the Univariate analysis of categorical variables. Results are indicated in tables 9, 10, 11 and 12.

8. Variables that were statistically significantly associated with QoL on Univariate analysis were then considered for inclusion in the multivariate model.

9. Stepwise multivariate regression was then done using the method of least squares, starting with an empty model and adding significant Univariate variables one by one. The purpose of this was to obtain a model that would best explained QoL scores in these participants. This is shown in table 13.

I. Ethical Considerations

Approval
The study protocol was reviewed and approved by both the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg (Protocol Clearance Certificate Number M060541), and the Health Research & Development Committee of the Ministry of Health, Botswana (Reference No. PPM&E 13/18 PS Vol I (13) of February 21, 2006 and (55) of March 20, 2007). Further permission to collect the data at Bontleng clinic was obtained from the Chief Medical Officer, Gaborone City Council Clinics Department. Copies of these documents are available at Appendices D, E-1, and E-2.
Consent

Patients were not coerced to participate in the study, and they were neither promised nor given any incentives. Signed informed consent was obtained from the participants before they were interviewed. Interviews were conducted in total privacy and anonymity was assured. Questionnaires were identified only by numbers and responses were kept confidential and not provided even to the clinic staff.

Feedback

Some participants did request for feedback of the study findings. Once the study is over the researcher and his assistant will go back and do presentations of the study findings to the patients at Bontleng Clinic.

RESULTS

Response rate

This was low with the interviewer only managing to interview an average of 6 out of 50 eligible clinic attendees daily (12%). A total of 200 participants were interviewed. Accruing this number of participants took three months, from April to June 2007. Two reasons were given for refusal to participate:

- Previous researchers from other studies did not provide them with feedback, so they did not see the need to assist this researcher.
- They were just not interested in participating this study.

The researcher did not collect information of socio-demographics of those who refused to participate in this study.
### A. Descriptive Tables

**Table 3:** Socio-Demographics of ART-naïve and ART-experienced patients in a QoL study in Botswana.

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>ART Naïve n (%)</th>
<th>ART Experienced n (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41 (46)</td>
<td>39 (35)</td>
<td>0.147</td>
</tr>
<tr>
<td>Female</td>
<td>49 (54)</td>
<td>71 (65)</td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>35</td>
<td>36</td>
<td>0.3266</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>9 (10)</td>
<td>16 (15)</td>
<td>0.213</td>
</tr>
<tr>
<td>Co-habiting</td>
<td>27 (30)</td>
<td>21 (19)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>49 (54)</td>
<td>65 (59)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (6)</td>
<td>8 (7)</td>
<td></td>
</tr>
<tr>
<td><strong>Work skills</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>65 (56)</td>
<td>67 (61)</td>
<td>0.409</td>
</tr>
<tr>
<td>Semi-skilled</td>
<td>15 (23)</td>
<td>25 (23)</td>
<td></td>
</tr>
<tr>
<td>Trade skill</td>
<td>8 (14)</td>
<td>15 (14)</td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>2 (4)</td>
<td>3 (3)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>47 (52)</td>
<td>81 (74)</td>
<td>0.002</td>
</tr>
<tr>
<td>Unemployed</td>
<td>43 (48)</td>
<td>29 (26)</td>
<td></td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12 (13)</td>
<td>9 (8)</td>
<td>0.467</td>
</tr>
<tr>
<td>Primary</td>
<td>36 (40)</td>
<td>39 (35)</td>
<td></td>
</tr>
<tr>
<td>Secondary</td>
<td>37 (41)</td>
<td>56 (51)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>5 (6)</td>
<td>6 (5)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3 above shows that the mean age is mid-thirties for both ART-experienced and ART-naïve groups. The greater proportion in both groups are either single (54%, 59%) or cohabiting (30%, 19%). Most respondents do not have any work skills (56%, 61%). There is a statistically significant association between the two variables (treatment and employment status) as the proportion of those on treatment who are working is (74%) compared to those not on treatment (52%).
Table 4: Comparison of Illness related factors

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>ART Naïve n(%)</th>
<th>ART Experienced n(%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (months) on ARV treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0</td>
<td>20</td>
<td>-</td>
</tr>
<tr>
<td>Median</td>
<td>0</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0</td>
<td>6 - 149</td>
<td></td>
</tr>
<tr>
<td>If currently on TB treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18(20)</td>
<td>28(25)</td>
<td>0.362</td>
</tr>
<tr>
<td>No</td>
<td>72(80)</td>
<td>82(75)</td>
<td></td>
</tr>
<tr>
<td>If currently on TB prevention treatment (IPT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>52(58)</td>
<td>74(67)</td>
<td>0.166</td>
</tr>
<tr>
<td>No</td>
<td>38(42)</td>
<td>36(33)</td>
<td></td>
</tr>
<tr>
<td>If previous history of TB treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11(12)</td>
<td>13(12)</td>
<td>0.930</td>
</tr>
<tr>
<td>No</td>
<td>79(88)</td>
<td>97(88)</td>
<td></td>
</tr>
<tr>
<td>Caregiver (treatment buddy)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Close family</td>
<td>50(56)</td>
<td>76(69)</td>
<td>0.024</td>
</tr>
<tr>
<td>Other relative</td>
<td>21(23)</td>
<td>26(24)</td>
<td></td>
</tr>
<tr>
<td>Friend</td>
<td>13(14)</td>
<td>8(7)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4(4)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>2(2)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Hospitalisation in past 3 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12(13)</td>
<td>14(13)</td>
<td>0.899</td>
</tr>
<tr>
<td>No</td>
<td>78(87)</td>
<td>96(87)</td>
<td></td>
</tr>
<tr>
<td>Time (months) from Diagnosis to starting ARVs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>7.5</td>
<td>26</td>
<td>-</td>
</tr>
<tr>
<td>Range</td>
<td>0 - 93</td>
<td>2 - 149</td>
<td></td>
</tr>
<tr>
<td>If uses other 'supplementary' products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13(14)</td>
<td>8(7)</td>
<td>0.100</td>
</tr>
<tr>
<td>No</td>
<td>77(86)</td>
<td>102(93)</td>
<td></td>
</tr>
</tbody>
</table>

*Supplementary products*: are self-prescribed over the counter nutritional, herbal, or vitamin products that patients purchase by themselves.

Table 4 above shows there is no statistical association between the two variables cross tabulated (being on ART and being on TB treatment) as there is no
difference in proportions of those currently taking tuberculosis treatment between the two groups (20% vs 25% for ART-experienced and ART-naïve patients respectively). The exact same proportion (12%) in the two groups has previously been on TB treatment. Significantly, more patients in the ART-experienced group have a close family member as a caregiver (treatment supporter) (69%), compared to 56% in the ART-naïve group. Surprisingly, exactly the same proportion in the two groups (13%) has been hospitalized in the previous three months. Very few patients report use of ‘supplementary products’ (14% and 7% for ART-experienced and ART-naïve groups respectively).

**Table 5**: OTC Supplements being used by ART-naïve and ART-experienced groups.

<table>
<thead>
<tr>
<th>ART naïve group</th>
<th>ART experienced group</th>
</tr>
</thead>
<tbody>
<tr>
<td>African Potato</td>
<td>African Potato</td>
</tr>
<tr>
<td>B-Immune Meal</td>
<td>Bio-viusid</td>
</tr>
<tr>
<td>Cannova Drops</td>
<td>Calcivita</td>
</tr>
<tr>
<td>Go-for-Health</td>
<td>Chinese Tea</td>
</tr>
<tr>
<td>Green Tea</td>
<td>Go-for-Health</td>
</tr>
<tr>
<td>Nutri Powder</td>
<td>Golden Products</td>
</tr>
<tr>
<td>Selenium</td>
<td>Green Tea</td>
</tr>
<tr>
<td>Tesly Tablets</td>
<td>Selenium</td>
</tr>
</tbody>
</table>

Table 5 above shows that the range of over the counter supplementary products used by participants appears to be the same in the two groups.
Table 6: Patient satisfaction with information and care in ART-naïve and ART-experienced patients.

<table>
<thead>
<tr>
<th>Satisfaction Level</th>
<th>ART Naïve n(%)</th>
<th>ART Experienced n(%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total= 90</td>
<td>Total = 110</td>
<td></td>
</tr>
<tr>
<td>Information given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not satisfied</td>
<td>0 (0)</td>
<td>2(2)</td>
<td>0.004</td>
</tr>
<tr>
<td>Low satisfaction</td>
<td>3 (3)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Mod. satisfaction</td>
<td>30(33)</td>
<td>18(16)</td>
<td></td>
</tr>
<tr>
<td>High. Satisfaction</td>
<td>57(63)</td>
<td>90(82)</td>
<td></td>
</tr>
<tr>
<td>Care given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not satisfied</td>
<td>1(1)</td>
<td>1(1)</td>
<td>0.640</td>
</tr>
<tr>
<td>Low satisfaction</td>
<td>1(1)</td>
<td>3(3)</td>
<td></td>
</tr>
<tr>
<td>Mod. satisfaction</td>
<td>20(22)</td>
<td>18(16)</td>
<td></td>
</tr>
<tr>
<td>High. Satisfaction</td>
<td>68(76)</td>
<td>88(80)</td>
<td></td>
</tr>
</tbody>
</table>

*Information given* refers to if and how health care workers give information to patients about their illness, *Care given* refers to the full treatment package received including counselling, lab work, medicines, etc.

Table 6 above shows that most patients are highly satisfied with the information and care they receive from the clinic. A statistically significant association is noted between the cross tabulated variables (being on ART and reporting high satisfaction with information) as a higher proportion of ART-experienced reports high satisfaction with information given (82%) compared to ART Naïve group (63%).
Table 7: Comparison of disease symptoms and disease markers between ART-experienced patients and ART-naive patients.

<table>
<thead>
<tr>
<th>Symptom / Marker</th>
<th>ART Naïve n(%)</th>
<th>ART Experienced n(%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total = 90</td>
<td>Total = 110</td>
<td></td>
</tr>
<tr>
<td>Loss of weight</td>
<td>69 (77)</td>
<td>27 (25)</td>
<td>0.000</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>10 (11)</td>
<td>3 (3)</td>
<td>0.017</td>
</tr>
<tr>
<td>Cough</td>
<td>35 (39)</td>
<td>21 (19)</td>
<td>0.002</td>
</tr>
<tr>
<td>Difficulty in breathing</td>
<td>22 (24)</td>
<td>17 (15)</td>
<td>0.110</td>
</tr>
<tr>
<td>Night sweats</td>
<td>39 (43)</td>
<td>26 (24)</td>
<td>0.003</td>
</tr>
<tr>
<td>Feet pains</td>
<td>50 (56)</td>
<td>52 (47)</td>
<td>0.244</td>
</tr>
<tr>
<td>Fever or chills</td>
<td>31 (34)</td>
<td>32 (29)</td>
<td>0.372</td>
</tr>
<tr>
<td>Other symptoms</td>
<td>37 (41)</td>
<td>39 (35)</td>
<td>0.366</td>
</tr>
<tr>
<td>Viral Load (copies/ml)</td>
<td>No data</td>
<td>11397</td>
<td>-</td>
</tr>
<tr>
<td>Mean</td>
<td>No data</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>No data</td>
<td>400 - 750,000</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>No data</td>
<td>75295</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>No data</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CD4 (cells/ml)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>114</td>
<td>276</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>Hemoglobin (g/dl)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>8.9</td>
<td>10.9</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table 7 above shows statistically significant higher proportions of ART-naïve patients report having loss of weight (77% to 25%), diarrhea (11% to 3%), cough (39% to 19%), and night sweats (43% to 24%) for ART-naive and ART-experienced patients respectively. There is no data on VL in the ART-naïve group. The ART experienced group has a median VL of 400 copies/ml. Mean CD4 counts and Hb levels were significantly higher in ART-experienced individuals compared to ART-naïve individuals.
### TABLE 8: Scores for HRQoL constructs and overall PHS summary

[note: higher score indicates a more favorable quality of life]

<table>
<thead>
<tr>
<th>Quality of Life Construct</th>
<th>ART Naïve group Mean Score (%)</th>
<th>ART Experienced group Mean score (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>80</td>
<td>89</td>
<td>0.0002</td>
</tr>
<tr>
<td>Role Functioning</td>
<td>82</td>
<td>87</td>
<td>0.1361</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>84</td>
<td>91</td>
<td>0.0440</td>
</tr>
<tr>
<td>Mental Health</td>
<td>67</td>
<td>72</td>
<td>0.0110</td>
</tr>
<tr>
<td>Health Perception</td>
<td>45</td>
<td>60</td>
<td>0.0000</td>
</tr>
<tr>
<td>Pain</td>
<td>43</td>
<td>63</td>
<td>0.0016</td>
</tr>
<tr>
<td><strong>SUMMARY SCORE</strong> (PHS - Physical Health Summary)</td>
<td><strong>47</strong></td>
<td><strong>53</strong></td>
<td><strong>0.000</strong></td>
</tr>
</tbody>
</table>

Table 8 shows the ART-experienced group scores are statistically significantly higher (better) for all HRQoL constructs except for Role Functioning where the score for ART Experienced is still higher (87% compared to 82%) but not significantly so. Overall summary score is statistically significantly higher in ART Experienced patients (63% compared to 47%).

It is interesting that ART-experienced patients score high on all constructs except for Role Functioning (problems with work or daily activities). This effect may be real, or perceived as a result of being on chronic medication. An alternate explanation may be that this construct is probably only affected by extremely debilitating disease or a late stage of untreated HIV disease.
B. Univariate and Multivariate Models

Table 9: Univariate and multivariate regression models for baseline Sociodemographic factors associated with QoL for HIV patients in Gaborone

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>Univariate Model Coeff. (95% CI)</th>
<th>p-value</th>
<th>Multivariate Model adjusted for Treatment Group Coeff. (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Female</td>
<td>1.93 (-0.64 - 4.51)</td>
<td>0.140</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.11 (-0.27 - 0.06)</td>
<td>0.212</td>
<td></td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-habitng</td>
<td>1.54 (-2.86 - 5.93)</td>
<td>0.491</td>
<td>Ref.</td>
<td>2.57 (-1.69 - 6.83)</td>
</tr>
<tr>
<td>Single</td>
<td>2.88 (-1.06 - 6.82)</td>
<td>0.150</td>
<td></td>
<td>3.24 (-0.56 - 7.02)</td>
</tr>
<tr>
<td>Separated</td>
<td>8.87 (0.77 - 16.97)</td>
<td>0.032</td>
<td></td>
<td>7.88 (0.07 - 15.70)</td>
</tr>
<tr>
<td>Work skills</td>
<td></td>
<td></td>
<td></td>
<td>Variable not significant</td>
</tr>
<tr>
<td>None</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-skilled</td>
<td>1.13 (-2.10 - 4.37)</td>
<td>0.491</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade skill</td>
<td>2.52 (-1.53 - 6.57)</td>
<td>0.222</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>4.14 (-4.03 - 12.30)</td>
<td>0.319</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Working</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>-1.75 (-4.38 - 0.88)</td>
<td>0.192</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>2.97 (-1.40 - 7.34)</td>
<td>0.182</td>
<td>Ref.</td>
<td>2.52 (-1.70 - 6.75)</td>
</tr>
<tr>
<td>Secondary</td>
<td>5.38 (1.10 - 9.66)</td>
<td>0.014</td>
<td></td>
<td>4.53 (0.38 - 8.68)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>4.74 (-1.86 - 11.33)</td>
<td>0.158</td>
<td></td>
<td>4.16 (-2.20 - 10.53)</td>
</tr>
<tr>
<td>Treatment Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART-naive</td>
<td>Ref.</td>
<td></td>
<td></td>
<td>Ref.</td>
</tr>
<tr>
<td>ART-experienced</td>
<td>5.22 (2.77 - 7.66)</td>
<td>0.000</td>
<td></td>
<td>5.22 (2.77 - 7.66)</td>
</tr>
</tbody>
</table>

Table 9 above indicates there was a statistically significant difference in QoL scores between married individuals and those who were separated - with separated individuals having 7.88 points higher QoL scores than individuals who were married. Participants who had some secondary education had QoL scores that were on average 4.53 points higher than those who never went to school.
Other factors: gender, age, work skills level and employment status were not statistically associated with QoL scores.

**Table 10:** Univariate and multivariate regression models for Illness related factors that are associated with QoL for patients on ART in Gaborone.

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>Univariate Model</th>
<th>Multivariate adjusted for Treatment Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coeff. (95% ci)</td>
<td>Coeff. (95% ci) p-value</td>
</tr>
<tr>
<td>Time on ART</td>
<td>0.075 (-0.00 - 0.16) 0.063</td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Presently on TB treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.07 (-1.94 - 4.08) 0.484</td>
<td></td>
</tr>
<tr>
<td>Presently on TB prevention (IPT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>-1.40 (-4.02 - 1.23) 0.295</td>
<td></td>
</tr>
<tr>
<td>Treated for TB before</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>-1.05 (-4.96 - 2.85) 0.595</td>
<td></td>
</tr>
<tr>
<td>Caregiver (treatment ‘buddy’)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Close family</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Other relative</td>
<td>-0.79 (-3.86 - 2.29) 0.615</td>
<td></td>
</tr>
<tr>
<td>Friend</td>
<td>0.93 (-3.30 - 5.16) 0.665</td>
<td></td>
</tr>
<tr>
<td>Hospitalisation in past 3 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3.77 (0.03 - 7.50) 0.048</td>
<td></td>
</tr>
<tr>
<td>Time (months) from Diagnosis to starting ARVs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.03 (-0.03 - 0.09) 0.346</td>
<td></td>
</tr>
<tr>
<td>If uses other supplementary products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2.72 (1.41 - 6.84) 0.195</td>
<td></td>
</tr>
<tr>
<td>Treatment Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART-naïve</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>ART-experienced</td>
<td>5.22 (2.77 - 7.66) 0.000</td>
<td></td>
</tr>
</tbody>
</table>
Table 10 above shows there was a statistically significant difference in QoL scores between participants who had had a hospital admission within the past three months and those who had not - with non-hospitalised individuals having 3.70 points higher QoL scores than individuals who had been hospitalised. Other factors: length of time on ART, being on tuberculosis treatment, being on tuberculosis prevention therapy, having been treated before for tuberculosis, the type of caregiver at home, time from HIV diagnosis to starting ARTs, and the use of self-prescribed supplementary products were not statistically associated with QoL scores.

**Table 11:** Univariate and multivariate regression models for QoL scores for variables on patient satisfaction with Information given, and satisfaction with Care given, for patients on ART in Gaborone.

<table>
<thead>
<tr>
<th>Satisfaction Level</th>
<th>Univariate Model</th>
<th>Multivariate Model</th>
<th>p-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group</td>
<td>Coeff. (95% cl)</td>
<td>Coeff. (95% cl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Information given</strong></td>
<td></td>
<td>Variable not significant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not satisfied</td>
<td>Ref</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low satisfaction</td>
<td>-0.06 (-16.44 - 16.31)</td>
<td>0.994</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mod. Satisfaction</td>
<td>-1.76 (-14.70 - 11.18)</td>
<td>0.789</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High satisfaction</td>
<td>0.57 (-12.20 - 13.34)</td>
<td>0.930</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Care given</strong></td>
<td>Ref.</td>
<td>Variable not significant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not satisfied</td>
<td>-11.58 (-27.05 - 3.89)</td>
<td>0.142</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low satisfaction</td>
<td>-5.00 (-18.96 - 6.96)</td>
<td>0.363</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mod. Satisfaction</td>
<td>-4.33 (-17.04 - 8.39)</td>
<td>0.503</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Group</strong></td>
<td>Ref.</td>
<td>5.22 (2.77 - 7.66)</td>
<td>0.000</td>
<td>5.22 (2.77 - 7.66)</td>
</tr>
<tr>
<td>ART-naïve</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART-experienced</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 11 the two factors of [the patient’s level of satisfaction with information given by health workers] and [the level of satisfaction with the care given by health workers] - were not statistically associated with QoL scores.
Table 12: Disease symptoms and lab. factors associated with QoL for patients on ART in Gaborone. Univariate and multivariate regression models for QoL.

<table>
<thead>
<tr>
<th>Symptom / Marker</th>
<th>Univariate Model Coeff. (95% ci) p-value</th>
<th>Multivariate Model adjusted for Treatment Group Coeff. (95% ci) p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 6.50 (4.13 - 8.87) 0.000</td>
<td>5.20 (2.44 - 7.97) 0.000</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 11.60 (6.72 - 16.49) 0.000</td>
<td>10.11 (5.30 - 14.93) 0.000</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 4.55 (1.80 - 7.31) 0.001</td>
<td>3.45 (0.71 - 6.19) 0.014</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Difficulty in breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 6.68 (3.62 - 9.75) 0.000</td>
<td>6.02 (3.04 - 9.00) 0.000</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Night sweats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 7.19 (4.67 - 9.70) 0.000</td>
<td>6.30 (3.80 - 8.81) 0.000</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Feet pains</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 7.14 (4.80 - 9.47) 0.000</td>
<td>6.76 (4.50 - 9.01) 0.000</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Other symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Ref 1.73 (-0.87 - 4.33) 0.192</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td>Variable not significant</td>
</tr>
<tr>
<td>Viral Load (copies/ml)</td>
<td>-5.86e-07 (-0.000 - 0.000) 0.955</td>
<td>Variable not significant</td>
</tr>
<tr>
<td>CD4 (cells/ml)</td>
<td>0.01 (0.01 - 0.02) 0.004</td>
<td>0.00 (-0.01 - 0.02) 0.637</td>
</tr>
<tr>
<td>Hemoglobin (g/dl)</td>
<td>0.64 (0.16 - 1.12) 0.009</td>
<td>0.30 (-0.21 - 0.81) 0.246</td>
</tr>
<tr>
<td>Treatment Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART-naive</td>
<td>Ref 5.22 (2.77 - 7.66) 0.000</td>
<td>5.22 (2.77 - 7.66) 0.000</td>
</tr>
<tr>
<td>ART-experienced</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
From table 12 on previous page we note the following statistically significant observations: Those who did not experience weight loss having 5.20 points higher QoL scores, participants without diarrhoea had 10.11 points higher QoL scores, those without cough had 3.45 points higher QoL scores, those without difficulty in breathing had 6.02 points higher QoL scores, those without night sweats had 6.30 points higher QoL scores, and those without feet pains had 6.76 higher QoL scores.

**Laboratory disease markers:** Changes in CD4 cell count, Haemoglobin level, and Viral do not have any statistically significant impact on QoL in multivariate model.

**Study Group:** Being on ART results in a statistically significant 5.22 point improvement in HRQoL scores compared to those participants not on ART.

**‘Super’ Multivariate Regression Model**

From above multivariate models the following 9 statistically significant factors were selected to be run in a ‘super’ (non-stepwise) multivariate model:

1. Marital status
2. Education level
3. Study group
4. (No) Recent hospitalisation
5. (No) Loss of weight
6. (No) Diarrhoea
7. (No) Cough
8. (No) Difficulty in breathing
9. (No) Night sweats
10. (No) Feet pains
Table 13: Factors identified as predictors of QoL of HIV patients in Gaborone.

<table>
<thead>
<tr>
<th>Predictor factor</th>
<th>Univariate Coeff. (95% ci) p-value</th>
<th>Multivariate Coeff. (95% ci) p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence of recent hospitalisation</td>
<td>3.77 (0.03 - 7.50) 0.048</td>
<td>3.31 (0.26 - 6.36) 0.033</td>
</tr>
<tr>
<td>Absence of loss-of-weight</td>
<td>6.50 (4.13 - 8.87) 0.000</td>
<td>2.29 (-0.19 - 4.76) 0.070</td>
</tr>
<tr>
<td>Absence of diarrhoea</td>
<td>11.60 (6.72 - 16.49) 0.000</td>
<td>8.73 (4.43 - 13.04) 0.000</td>
</tr>
<tr>
<td>Absence of night sweats</td>
<td>7.19 (4.67 - 9.70) 0.000</td>
<td>3.91 (1.58 - 6.24) 0.001</td>
</tr>
<tr>
<td>Absence of feet pains</td>
<td>7.14 (4.80 - 9.47) 0.000</td>
<td>6.43 (4.35 - 8.51) 0.000</td>
</tr>
<tr>
<td>Being on ART</td>
<td>5.22 (2.77 - 7.66) 0.000</td>
<td>1.97 (-0.42 - 4.35) 0.106</td>
</tr>
</tbody>
</table>

From table 13 above we see the following by examining the coefficients: relief of diarrhoea gives the highest increase in QoL score, followed by relief of feet pains and night-sweats. Effect of ‘hospitalization’ and ‘feet pains’ remains almost constant whether on their own or when combined with other factors. Univariate effect of ‘weight-loss’ and ‘being on ART’ is almost halved when these two variables are combined with other variables.

**Discussion**

This study was able to successfully obtain data from 200 patients attending the Bontleng ARV clinic. Mean age of participants was 36 years with more than half being single. Unemployment rate was high at 36%, though 85% had some form of primary or secondary level education. Almost a quarter were on TB treatment. The overall QoL summary score was significantly higher in ART-experienced group, with ART-experienced patients reporting fewer disease symptoms as compared to the ART-naïve patients. Higher CD4 and Hb levels were also noted.
in ART-experienced patients. Multivariable regression model identified the absence of recent hospitalization, weight loss, diarrhea, night sweats, and feet pains are the best predictor of higher QoL.

This study was able to obtain current information on the socio-demographic characteristics of patients attending this ARV treatment site. We are thus able to provide a clear profile of the ‘typical’ patient attending these clinics.

There are more women than men attending this clinic. The highest age-specific HIV prevalence rate in Botswana is found in women aged 30 - 34 years. All available surveillance data indicate prevalence of over 40% in this group of women (7). Average age for participants starting treatment is 35 years, and that of participants already on treatment is 36 years. Of interest to note is that QoL of patients on HAART improves regardless of sex, age, work-skills level, or employment status.

In keeping with results of better HRQoL amongst participants established on ARVs, we notice higher employment levels amongst this group. From this study we cannot conclude the temporal sequence of these events: Does the improved general wellbeing of patients make them able to go out and find jobs, or does the fact of getting employment further improve their quality of life. The answer is probably a bit of both.
It is known that unequal and abusive relationships or lack of stable mature relationships play a role in the spread of HIV. Most respondents in this study are either single or co-habiting. For women many of these relations with the opposite sex are forged based on economic need and are thus frequently open to abuse with high incidence of concurrent partners, and therefore high rates of HIV transmission. There was no statistical difference in marital status between the two study groups, however, participants who reported to be separated tended to report a better QoL score. More studies are needed to investigate how social and interpersonal relationships impact treatment adherence and QoL in HIV patients.

In both study groups we notice education levels of either primary or secondary school for most respondents. We also note a general absence of work skills that can be used to acquire employment. In Botswana Primary school is free, while secondary school is highly subsidised by government. Thus general education to secondary level is the norm rather than the exception. Post secondary work skill acquisition is however the prerogative of the individual and the pressure to get an unskilled job is much higher than the desire to spend more years in training so as to acquire more skills.

All study participants were able to enrol for treatment with CD4 count results only. All treatment naïve participants interviewed did not have baseline Viral Load results. All treatment experienced participants however did have these results, with median VL being 400 copies/ml. Treatment guidelines aim for VL of < 400 copies/ml in 3 months, and undetectable ( < 50 copies/ml) in six months time of
ARV treatment (10). Laboratory results frequently report VL at 400 copies/ml, and not lower, after six months of treatment, as this is the thresh-hold of lab equipment detection.

ART-naïve patients had mean CD4 count of 114, compared to the much higher 276 for ART-experienced patients. HB levels are also on average higher in ART-experienced at 10.9 compared to 8.9 in ART-naïve. There is thus a strong association between improvement in these indices and the fact of being on ART.

This study showed that with an average of 20 months of HAART, HIV patients in Botswana showed significantly higher scores in all constructs of HRQoL (except for Role Functioning) as compared to those just starting HAART. This is in keeping with other findings in other populations (2). Summary overall score (PHS) is also higher in individuals established on HAART. Thus being on anti-retroviral treatment is associated with one having a higher QoL score for almost all QoL constructs, and having higher overall scores.

It is thus very feasible to have these assessments incorporated in both the baseline and follow-up assessments of HIV patients attending treatment clinics. As demonstrated Hughes J et al (18) in their South African study on the use of HRQoL to inform health care providers about the potential use of rehabilitation interventions in the management of people living with HIV/AIDS, it is possible to do HRQoL studies in an African context and obtain valid results.
A systematic review of HRQoL studies (23) reveals that these scores do not always correlate with disease stage or health indices, and that disease symptoms have a greater impact on HRQoL than measured health indices. This study mirrors these same findings, in that although there were significant differences in CD4 cell count and Hb levels between treated and untreated patients, these indices have no statistical significant effect on HRQoL scores.

Impact of Symptoms

Higher QoL measurements are observed in:

a) Patients who did not report a recent hospital admission,

b) Those who did not experience weight loss, and

c) In those without certain disease symptoms (diarrhea, cough, difficulty in breathing, night sweats, and feet pains).

This study compares well with previous studies done elsewhere (17) (12) where adverse disease symptoms were significantly related to low HRQoL. Importantly for our study population these symptoms are amenable to clinical intervention. Thus any HRQoL assessments in these patients must always include details of all patient-reported symptoms.

This study shows that with or without use of ART, HIV patients in Gaborone, Botswana, respond very well in terms of improvement of measured HRQoL when certain disease symptoms are addressed and treated. Therefore clinicians in HIV treatment clinics in Botswana must devise strategies to make the management of symptoms a high priority.
Limitations

This study was conducted in an urban setting with generally high level of unemployment and other urban pressures impacting respondents. These factors will in themselves contribute to a low baseline QoL for respondents). This population may inherently be different from a rural population. The ARV program is being rolled out to the whole of Botswana, including rural areas, we thus cannot say with certainty that similar results as in this study will be seen in other areas of the country.

Due to time limits, logistical difficulty and lack of a sampling frame the researcher was unable to obtain a completely random sample of participants to interview. Though we also did not in any way ‘select’ those to interview, but relied on self-selected participants. Point of note is that those who volunteered may also in some way be quite different from other HIV patients (maybe more sick, or more health conscious, etc).

The design of the study could ideally been done using a ‘before’ and ‘after’ methodology, i.e interviewing the same participants after several months on HAART. But this was not feasible due to time constraints and a possible problem with retention of participants due to the researcher’s limited financial resources. The treatment-experienced group may have been over-represented by ‘hardier’ HIV survivors and not necessarily all patients on HAART. The researcher
however believes that the present design has also given us sufficient data to be able to comment with some degree of reliability.

The researcher did not attempt to do clinical staging of HIV disease amongst any of the participants due to capacity limitations. Thus the participants may all have been starting treatment at different stages of the disease, with some being more ill than others. Disease stage-ing would have allowed a more accurate statistical analysis of results based on initial disease category.

This was not a blinded study, and in the consenting process participants were clearly told what the study was about before they agreed to be interviewed. It is possible that the awareness that quality of life was being assessed may well have affected their responses.

In this cross-sectional study it is difficult to assess the temporal relationship between the explanatory variables and measured QoL scores. Thus we can only conclude on associations rather than causality.

**Conclusions and Recommendations**

This study concludes that it is feasible to conduct quality of life assessments in a health intervention program outside of pure clinical research settings. Reliable and valid results can be obtained, and these can be used to inform policy on the management of patients. Incorporation of these assessments in clinical programs should be seriously considered.
Death rates can no longer be the sole measurement of outcome for patients on ARVs (12). This is particularly the case in Africa, where with the advent and success of mass HAART programs, other outcomes such as HRQoL should become relevant, more so that validated tools are now readily available.

Symptoms in patients on HAART maybe due to HIV disease itself, or may be due to side effects of drugs. Regardless of underlying cause, these symptoms greatly impact on QoL.

This study showed that in this group of patients symptoms and previous hospitalisation are important determinants of physical health. The introduction of new antiretrovirals with fewer side effects, and the inclusion of a continuum of care that includes assessment of symptoms and socio-economic data should favour the beneficial impact of HAART on Health Related Quality of Life.

This researcher concurs with the commentary (19) of the HIV/AIDS palliative care workgroup which notes that HIV patients now have a long life expectation, and thus more effort must be directed at maximising their disease-free interval, with systematic research efforts to evaluate effectiveness of various supportive therapies.
Specific recommendations:

1. Quality of life assessments should be included in the regular follow-up of patients on HAART.

2. There should be clear tabulated documentation and management of symptoms of patients in ARV programs.

3. Standardised symptoms treatment guidelines should be developed and availed for all health personnel managing various HIV-related symptoms.

4. Aggressive management of illnesses in early stages should be done in order to reduce episodes of hospitalisation.

5. Introduction of newer antiretroviral therapies with fewer side effects should be pursued.

6. Adaptation of HRQoL instruments to suit local conditions in Africa.

7. Further research as outlined below is necessary.

Suggestions for further research

1. Operational research into methods of incorporating deliberate symptom mitigation in the management of HIV patients.

2. Head to head comparison of the impact of various HAART regimens on the QoL of HIV patients in Botswana.

3. Effect of other alternative therapies including traditional medicines on QoL of HIV patients.

4. To determine other social and cultural factors that influence adherence to HAART.
REFERENCES


APPENDIX A
Item Scoring

Item Scoring, Calibration and Summing (16)

Step 1:
Data Cleaning, checking for any missing values, and reconciling from the questionnaire.

Step 2:
Re-calibration of one item (Q15 under Health Perceptions). In the MOS it was decided that the distance between responses was unequal and they should be adjusted in scoring the item, and then re-coding it by reversal so that high scores reflect favourable health. Thus 1 → 5, 2 → 4.36, 3 → 3.43, 4 → 1.99, 5 → 1.

Step 3:
All questions and items are scored so that a high score defines a more favourable health state. Some items thus needed to be reverse scored (Questions 11, 13, 15, 16, 17, and 21). This facilitates consistent comparison.

Step 4:
Transforming each item linearly to a 0 → 100 possible range. The lowest and highest scores were thus set at 0 and 100 respectively. Transformation formulas were used for this.

Step 5:
Deriving the final score per scale by simply averaging scores for items in the same scale as all items in a given scale have roughly equivalent relationships to the underlying HRQL concept being measured.

Thus:
1. Physical Functioning: average scores for questions 1 → 6.
2. Role Functioning (work): average scores for questions 7 → 8.
4. Mental Health Index: average scores for questions 10 → 14.

Summary Scores

PHS Formulae

\[ \text{PHS} = [ ( ( \text{mh} - 69.2284314)/18.8444325 )^* - .13017 ) + ( ( \text{pf} - 80.4395425)/24.2176719 )^* .34370 ) + ( ( \text{pn} - 64.7941176)/28.8807702 )^* .31854 ) + ( ( \text{rf} - 73.1371549)/40.7722411 )^* .29617 ) + ( ( \text{sf} - 84.6862745)/21.2559432 )^* .22165 ) + ( ( \text{gh} - 56.792402)/24.550145 )^* .17829 ) ] \]
APPENDIX B - 1

Questionnaire

Questionnaire Number: __________  Date of Interview: ______________

1. Respondents: Sex: Male □  Female □

2. Respondents: Age: ______________________________

3. Length of time on ARVs: ___________years and _______months

4. Employment status:
   - Yes (regular job) □
   - Yes (temporary jobs) □
   - No (not working) □
   - Self Employed □

5. If currently on full TB treatment:
   - Yes □
   - No □
   - Don’t Know □

6. If currently on TB prevention (IPT) medicines:
   - Yes □
   - No □
   - Don’t know □

7. Marital status:  Married □
   - Living with partner □
   - Single □
   - Separated □
   - Widowed/widower □
   - Divorced □
8. Closest caregiver (treatment buddy or ‘mompati’)
   
   Immediate family member  □
   Other relative  □
   Friend  □
   Other (specify) □___________________
   None  □

9. Education level (highest): write actual level (e.g. std 6) ________________

10. Work skills level
    
    Not skilled  □
    Semi-skilled  □
    Full trade skill  □
    Professional  □

11. Number of years since HIV diagnosis: ________________

12. Any Hospitalisation during the past 3 months?
    Yes  □
    No  □

13. Previous history of TB treatment
    Yes  □
    No  □
    Don’t know  □

14. Level of satisfaction with information from health care providers

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15. Level of satisfaction with treatment provided at this clinic.

|------------------|---------------------|-------------------------|---------------------|

**FOOD SUPPLEMENTS**

16. Are you taking any other nutritional supplements, vitamins or “immune boosters”

Yes □ (if yes go to Q 16) No □ (if no jump Q16, go to Q 17)

17. Give names of supplements/“immune booster” you have been using:

________________________________________________

**SYMPTOMS:** Which of the following problems do you have at present:

18. Loss of weight □
19. Diarrhoea □
20. Cough □
21. Difficulty in breathing □
22. Sweating at night □
23. Feet pains and/or numbness □
24. Fever or Chills (feeling cold) □
25. None of the above □

**OBTAIN FROM MEDICAL RECORDS**

26. Last recorded HIV Viral Load: _____________________

27. Last recorded CD4 count: _______________________  

28. Last recorded Hb (haemoglobin) level: ______________
APPENDIX B - 2
MOS-HIV Short Form Questionnaire

**Physical Functioning (Physical Health)**
These questions concern some problems you may have to deal with because of your illness.

Does your illness limit you in these activities?

**INSTRUCTIONS:** For Q1 to Q8, insert clearly either [1] or [2] or [3] in the box where;

- [1] = Yes. Limited a lot.
- [3] = No. Not limited at all

**ACTIVITIES**

1. Vigorous activities such as running, lifting heavy objects, sports activities?

2. Moderate activities like moving a table or carrying two full bags of groceries?

3. Walking uphill or climbing 10 steps without resting?

4. Bending, Kneeling, or stooping?

5. Walking from your house to nearest taxi/combi stop?

6. Eating, dressing, bathing or using the toilet?

**Role Functioning (Daily Activities)**
These questions are about your regular daily activities.

7. Does your health keep you from working at a job, doing work around the house or going to school?
8. Have you been unable to do certain kinds or amounts of work, housework or schoolwork because of your health?

☐

**Social Functioning (Social Activities)**

The next question asks about your social activities.

9. How much of the time, during the past one month has your health limited your social activities (for example: visiting friends, relatives, etc)?

(Circle one)

- All of the time......................................................... 1
- Most of the time..................................................... 2
- A good bit of the time............................................. 3
- Some of the time.................................................. 4
- A little of the time............................................... 5
- None of the time.................................................. 6

**Mental Health (Your Feelings).**

10. How much of the time, during the past month, have you been a very nervous person?

(Circle one)

- All of the time......................................................... 1
- Most of the time..................................................... 2
- A good bit of the time............................................. 3
- Some of the time.................................................. 4
- A little of the time............................................... 5
- None of the time.................................................. 6
11. During the past month, how much of the time have you felt calm and peaceful?

(Circle one)

All of the time.........................................................1
Most of the time...................................................  2
A good bit of the time.................................        3
Some of the time.................................................  4
A little of the time.................................................  5
None of the time.................................................  6

12. How much of the time, during the past month, have you felt downhearted and blue?

(Circle one)

All of the time.........................................................1
Most of the time...................................................  2
A good bit of the time.................................        3
Some of the time.................................................  4
A little of the time.................................................  5
None of the time.................................................  6

13. During the past month how much of the time have you been a happy person?

(Circle one)

All of the time.........................................................1
Most of the time...................................................  2
A good bit of the time.................................        3
Some of the time.................................................  4
A little of the time.................................................  5
None of the time.................................................  6
14. How much of the time, during the past month, have you felt so down in the dumps that nothing could cheer you up?

(Circle one)

All of the time.................................................................1
Most of the time.......................................................... 2
A good bit of the time...................................................... 3
Some of the time.............................................................. 4
A little of the time.......................................................... 5
None of the time.............................................................. 6

Health Perceptions (Your Health)
Next are some general questions about your health and health-related matters.

15. In general would you say your health is:

(Circle one)

Excellent................................................................. 1
Very good................................................................. 2
Good................................................................. 3
Fair................................................................. 4
Poor................................................................. 5

16. Your health is excellent...

(Circle one)

Definitely true............................................................. 1
Mostly true.............................................................. 2
Not sure.............................................................. 3
Mostly false............................................................. 4
17. You are as healthy as anybody you know

(Circle one)

Definitely true................................................................. 1
Mostly true................................................................. 2
Not sure................................................................. 3
Mostly false................................................................. 4
Definitely false................................................................. 5

18. You are somewhat ill

(Circle one)

Definitely true................................................................. 1
Mostly true................................................................. 2
Not sure................................................................. 3
Mostly false................................................................. 4
Definitely false................................................................. 5

19. You have been feeling bad lately.

(Circle one)

Definitely true................................................................. 1
Mostly true................................................................. 2
Not sure................................................................. 3
Mostly false................................................................. 4
Definitely false................................................................. 5
20. In the past month, have you had any bodily pain?

(Circle one)

Yes.................................................................1
No.................................................................2

If yes, was the pain:

(Circle one)

Very Mild.........................................................1
Mild...............................................................2
Moderate.........................................................3
Severe...........................................................4
Dumelang! Good day to you Sir / Madam. I am Dr. Evans Buliva from the Medical School of the University of the Witwatersrand in South Africa. I am doing a study to find out how people who are sick with HIV are coping with their illness.

I will give you an outline of how the study will be done. I do request and invite you to consider participating in the study.

For the study I will need approximately 30 minutes of your time. I will ask you about 40 simple questions following the list of questions that I have with me. I will also ask to see your medical cards so as to obtain your last recorded laboratory results of CD4 count and amount of virus in the blood.

I will require nothing else from you apart from your time to answer simple questions which I will read out to you. In case I notice something seriously wrong with your health I shall immediately refer you to the attending doctors at the clinic. If you require any more information you may contact me (Dr. Buliva) at cell 71319225.

The Information you provide me is strictly confidential, and the personal answers you provide to me will not be shared even with the clinic staff. On your questionnaire will be recorded a number only and nobody will be able to identify your answers with you personally.

This study is completely voluntary and you may withdraw at any time without having to give a reason. There is absolutely no risk or penalty for withdrawing from the study and you will continue receiving assistance from this clinic as usual.

Some of the questions are sensitive and require personal answers from you. If you are disturbed by any question you have the choice not to answer, and you are free to stop the interview at any time.

If you are happy and willing and accept to take part in the study please read and sign the attached consent form. Thank you.
CONSENT FORM

I agree to participate in the study as outlined in the information sheet.

Questionnaire No.________________________

Signature:______________________________

Date:__________________________________
APPENDIX D
Wits ethics & Research committee certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Buliva

CLEARANCE CERTIFICATE

PROJECT
Determinants of Health Related Quality of Life (HRQL) of Adults in a Public Sector Highly Active Antiretroviral Treatment (HAART)...

INVESTIGATORS
Dr EM Buliva

DEPARTMENT
School of Public Health

DATE CONSIDERED
06.05.28

DECISION OF THE COMMITTEE*
APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06.07.06

CHAIRPERSON (Professor M Vorster)

*Guidelines for written ‘informed consent’ attached where applicable

cc: Supervisor : Mr E Marinda

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/We undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES
APPENDIX E - 1
Botswana Ministry of health ethics certificate

REFERENCE No: PPM&E 13/18 PS Vol I (13) February 21, 2006

Evans Buliva

Research Permit: “Determinants of Health Related Quality of Life Assessment of Adults in a Public Sector HAART Program in Botswana”

Your application for a research permit for the above stated research protocol refers. We note that you have satisfactorily revised the protocol as per our suggestions. Permission is therefore granted to conduct the above-mentioned study. This approval is valid for a period of 1 year, effective February 21, 2006.

This permit does not however give you authority to collect data from the selected facility without prior approval from the concerned facility. Similarly, consent should also be sought from all participants.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal will need to be resubmitted to the Health Research Unit in the Ministry of Health.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research Unit, Ministry of Health within 3 months of completion of the study. Copies should also be sent to relevant authorities.

Approval is for academic fulfillment only.

Thank you,

S. El-Halabi
For Permanent Secretary Ministry of Health
CONTINUING REVIEW PERMIT: "DETERMINANTS OF HEALTH RELATED QUALITY OF LIFE ASSESSMENT OF ADULTS IN A PUBLIC SECTOR HAART PROGRAM IN BOTSWANA"

Reference is made to the continuing review application submitted for the above titled study. Initial approval for one year was granted effective February 21, 2006. We have gone through your request and note that data collection is still underway.

The revised protocol is approved for a period of one year effective 21 February, 2007. The permit will expire on the 20th February, 2008.

The conditions outlined in our initial approval letter still stand.

Thank you.

S. El-Hajabi
For Permanent Secretary Ministry of Health
APPENDIX F
Permission letter from Gaborone City Council Health Dept

GABORONE CITY COUNCIL

To: Dr. Evans Buliva
    P.O.Box 20630
    GABORONE

Dear Sir,

PERMISSION TO CONDUCT HEALTH RESEARCH AT BONTLENG CLINIC

We are glad to grant you permission to conduct your research in Bontleng clinic, as we believe your research is safe to the research population, and has good potential to inform policy.

Thank you

Yours Faithfully

Dr. George Sinyangwe
Chief Medical Officer

All correspondence should be addressed to the

CITY CLERK
Private Bag 0089
Telephones: 3657400
Tel. Add.: 'CIVIC'
GABORONE
BOTSWANA
Fax: 300141

Reference: RV/de/5297

Date: 8th April, 2006