

A CROSS-SECTIONAL STUDY ON THE QUALITY OF LIFE IN HIV INFECTED
GOLDMINERS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY IN AN
INDUSTRIAL SETTING IN SOUTH AFRICA

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Declaration: I, Kathryn Therese Mngadi, declare that this dissertation is my own work. It is being submitted in partial fulfillment of the requirements for the degree of Masters in Philosophy in Palliative Medicine at the University of Cape Town. It has not been submitted before for any degree or examination at this or any other University.

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ABSTRACT

This study set out to document quality of life in the industrialized setting of HIV infected South African gold miners who are on highly-active anti-retroviral therapy, by administering the MOS SF-36, and to determine which categorical variables impact on QOL in this study cohort. It also intended to promote routine quality of life measurements, as an index of programme performance, and to strengthen the case for widened access to antiretroviral treatment. A cross sectional survey of 202 outpatients was carried out at the central clinic at the health service hospital owned by AngloGold in the Northwest Province. Scores on eight scales of the MOS SF-36 measuring different aspects of quality of life were calculated. Demographic and laboratory data were collected from a separate case report form and the clinic database, as part of the categorical variables. Results showed that more than 59% of all respondents achieved scores of 100 for all subscale domains, and that the only categorical variable that showed statistically significant impact was age, with QOL scores on the physical function domains decreasing with age. This decrease in function was thought to be more attributable to age, than HIV status, stage or progression. The sample population was noted to have a high level of health care,

and exhibited both the well-worker and survival cohort effect, as a result of a stringent pre-employment selection, on-going occupational fitness assessments and medical boarding in the case of sub-standard fitness. The conclusion reached was that the MOS SF-36, the QOL assessment tool used in this population, whilst validated in the general South African population, was not a sensitive enough tool for use in this population. The cross sectional design of the study was not able to assess differences in QOL over time, and the lack of a control cohort exacerbated this problem. The recommendations are to validate the tool in this population and then to repeat the study in the same cohort (provided the tool is validated) to obtain longitudinal data, to validate other quality of life tools in this population, and to link the QOL assessment scores more closely with clinical and laboratory data. The routine use of a validated tool to assess programme performance would also strengthen the advocacy for widened access to HAART, provided the outcome was positive.

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HIV infected, drug toxicities, developing countries, industrialized setting , Medical

outcomes survey short form 36 (MOS-SF36)

Research term: palliative care

I .INTRODUCTION

Human Immuno Deficiency Syndrome (HIV) is a global emergency. UNAIDS estimates the total number of adults living with HIV at 37.2 million, with 4.9 million new adult infections, and 2.6 million adult deaths for 2004 ¹. Adult HIV prevalence has been roughly stable in recent years, but this does not mean that the epidemic is slowing, but rather that the worst phase of the epidemic is evident – when equally large numbers of people are being newly infected with HIV as those who are dying from AIDS ¹.

The emergency is even more evident in Sub Saharan Africa, a developing region only recently experiencing expanding access to antiretroviral therapy, which remains the worst affected subregion in the world. 10% of the world's population lives in Sub-Saharan Africa, yet 60% of all people living with HIV call this region home. In 2004, 2.3 million adult and child deaths due to AIDS occurred in this region ¹.

On a national level, South Africa continues to have the highest number of people living with HIV globally, estimated at 5.3 million at the end –2003, with no sign of decline in the epidemic². The latest data show an increasing prevalence in all age groups, except pregnant women older than 40 years of age¹. A population-based survey among young South Africans (Reproductive Health, Research unit, Medical Research Council, 2004) shows significant regional variation, based on antenatal data¹. In addition, very high prevalence is still being recorded in four other countries in the Sub Saharan African region: Botswana, Lesotho, Namibia and Swaziland. Of note these countries serve as labour sending sources for the gold mines of the Northwest Province where this study was conducted. More people in Africa succumb to HIV-related illnesses and its accompanying reduced quality of life, or even die from HIV. Life expectancy has decreased, and the risk of dying from AIDS for men in South Africa peaks among men aged 30 – 44 years¹. The majority of participants in this trial are black males drawn from the countries detailed above.

HIV is also an emergency in the mining industry itself. A population based survey conducted in 2000 – 2001 found that within workforces, miners had the highest level of infection ³. Contract, unskilled and semi-skilled workers are more likely to be infected than skilled workers, and migrant workers are more likely to be less skilled and to frequent sex workers, and a high level of HIV was evident among workers older than 49 years ³. Of note the data collected in this study, confirms that gold miners are an ageing workforce. Migrant mine workers are at particular risk of HIV infection. In a survey conducted in 2001 in Welkom, South Africa, the prevalence of HIV infection among the general population of mineworkers was 29% ⁴. In a similar survey conducted in August 2003 , 30% of a 40 000 strong workforce of gold miners were found to be infected with HIV, with an estimated financial impact of 1.9% or R71.9 million to the company's payroll ⁵ . The risk among migrant workers is thought to be higher because of long periods of separation from regular partners and relatively easy access to sex workers ⁵. This survey also suggests that HIV causes lower labour productivity and increased absenteeism. This would result in decreased earnings for the individual and the community, and impact on the economic aspect of quality of life (QOL).

It is vital that access to antiretroviral therapy becomes a priority for Sub Saharan people infected with HIV, experiencing an epidemic that impacts negatively on quality of health.

IMPACT OF HIV/AIDS AND HAART ON QUALITY OF LIFE

Before highly active anti-retroviral treatment (HAART) became widely available, AIDS was a rapidly fatal disease, characterized by a swift decline, involving multiple opportunistic infections and cancers, culminating in death, often within months of diagnosis⁶. The overall quality of life among AIDS sufferers, prior to the advent of HAART, was low.

The advent of disease specific treatments has resulted in a variable trajectory of disease, with a return to full health and function for some, and a “conversion from death to disability “for others⁶. Likewise, impact on quality of life for the HIV infected with access to treatment, is not uniform.

The individual experience of the disease, and the consequent perception of quality of life, is in part determined by the person’s access to care, including access to ARVs (the level of which is highly variable in Sub Saharan Africa), the ability to adhere to those regimens that are effective e.g. highly active antiretroviral therapy

(HAART) , co-morbidity in the form of substance abuse and other psychiatric illnesses, progressive viral resistance despite treatment, and intolerable drug toxicities⁶. Even those who return to full health and function and live longer , are then at risk for disease related to age e.g. ischaemic heart disease , malignancy and arthritis, and the consequent negative impact on quality of life. HAART regimens prevent opportunistic infections and reduce the incidence of some HIV – associated malignancies, thereby improving the medical aspects related to quality of life. However, HAART regimens, especially those including protease inhibitors have been shown to cause, in a high proportion of HIV-infected patients, a metabolic syndrome (lipodystrophy/lipoatrophy, dyslipidemia, type 2 diabetes mellitus, insulin resistance) that may be associated with an increased risk of cardiovascular disease (approximately 1.4 cardiac events per 1000 years of therapy)⁷.

Research has proven that HIV also impacts negatively on psychological and social aspects of quality of life especially in patients with advanced disease⁸. Factors such as older age, black race/ethnicity, lower education and income, lower CD4

counts and a lack of private health insurance, have also been shown to contribute to lower QOL in HIV ⁹. HIV affects individual and community QOL, by eroding the family structure due to multiple deaths. The stigma generated by the disease also erodes traditions surrounding burial, preventing those affected from grieving openly, as whole communities deny the existence of AIDS ¹⁰. HIV has even impacted on the ethics of clinical trials, where safeguarding the health and well-being of participants is a cornerstone ¹¹. Concerns have been raised about exploitation, standards of care and the informed consent process ¹¹. HIV infected people are considered a vulnerable population in research, as willingness to participate in trials, may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, e.g. receipt of free HAART ¹¹. The health care needs of a population must therefore dictate the study design (in South Africa where HIV prevalence is high there is a need for research on this topic), whilst shortcomings in overprotecting the participants must also be recognized ¹¹ (people living with HIV are a vulnerable research community, but protection should not be such that vital research projects of benefit to these communities are not

conducted at all). Blind assumptions that first world standard of care is the gold standard universally, can ultimately compromise those it is intended to help ¹¹

HIV also affects the economy of a country, which in turn affects the QOL of its inhabitants. It affects mostly the young and productive, and also generates cost to the government to combat the disease, increasing social and health expenditure.

Macroeconomically it raises costs, lowers worker efficiency, and reduces company and individual savings and profits ¹². Microeconomically, already severely stretched household budgets are affected further by illness and death, and economic hardship in turn, leads to a behavioral change that makes people susceptible to infection ¹².

HIV infected patients generally demonstrate a lower quality of life than the general population, and even a lower quality of life than those with other illnesses, e.g. cancer or depression ¹³. Quality of life in HIV infected persons can be negatively affected by ¹³:

- symptoms associated with HIV infection (weight loss, chronic diarrhoea, anaemia and consequent fatigue and pain)

- HIV medication side effects (nausea, anxiety, confusion, visual problems, sexual dysfunction, anorexia, insomnia, taste perversion and abnormal fat distribution)
- Diseases associated with extended life-span (arthritis, ischaemic heart disease, arthritis)
- Psychosocial factors, e.g. the diagnosis itself can result in discontinuation of employment, limitations in social activity, and dependence on others; limited social support and poor coping skills are other factors
- Sociodemographic factors e.g. older age, female gender, unemployment and low income
- Psychological factors e.g. disclosure, decision making regarding privacy issues negotiations for safer sex, and fear of violence secondary to disclosure
- Existential/spiritual distress

Of interest, the degree of limitation of physical function appears to predict clinical depression better than disease severity ¹³. HIV is thus a disease affecting the QOL of every aspect of individual and community existence.

PALLIATIVE CARE, QOL, AND HIV

The HIV/AIDS Bureau, through its working group on Palliative Care in HIV, has set forth the following working definition, quoted here in part:

“Palliative care is patient – and family – centered care. It optimizes quality of life by active anticipation, prevention, and treatment of suffering. Palliative care addresses physical, intellectual, emotional, social, and spiritual needs.”¹⁴

Clinicians and researchers agree that improvement of quality of life is the ultimate goal in palliative care ¹⁵. The World Health Organisation (WHO) takes a similar approach defining palliative care as:

“Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual “.

Physical symptoms, psychological distress, social and financial issues are all related to spiritual or existential problems and form the core elements of the concept of quality of life ¹⁶. To comprehensively assess quality of life, a systematic collection of information about patients' subjective health is paramount ¹⁵.

Improvement of quality of life is a cornerstone of palliative medicine. Palliative care is complementary, not alternative, and should not be provided only when disease-directed therapy fails or is unavailable, but should be used at all points along the course of HIV, from diagnosis through to death ¹⁷. Reflections on the pain experienced at initial diagnosis, or the psychological and spiritual suffering that are the basis of behaviors exposing individuals to HIV, further emphasise the importance of palliative care principles(including improvement in quality of life) being applied at all points along the course of the disease ¹⁷. Even in the era of highly active antiretroviral therapy (HAART), AIDS remains an important cause of morbidity and mortality in many adult populations, and attention to palliative care and end of life issues is an essential aspect of clinical care ¹⁷, in order to improve quality of life. Even populations with access to HAART experience problems with adherence and subsequent treatment failure, or overwhelming toxicities that

demand withdrawal of treatment, or concurrent opportunistic infections or immune reconstitution inflammatory syndrome, requiring medication and leading to drug interactions with antiretrovirals that may necessitate withdrawal of treatment. As a result AIDS remains a leading cause of serious illness, reduced quality of life and death for young adults. This may result from the chronic nature of the disease; the cumulative HIV related morbidity and treatment related toxic effects, uncertainties about prognosis and limitations of rapidly evolving therapies impacting on decision making about end of life issues ¹⁸. HAART exhibits the potential to both improve and reduce the quality of life for HIV infected people. It addresses the reversal of the immune depletion that is part of HIV, resulting in an increased CD4 count and a reduced viral load. Patient knowledge of an improvement in these laboratory parameters have been shown to improve the psychological aspects of HIV related quality of life ¹⁹. HAART also decreases the likelihood of opportunistic infection in a patient with a good immunological response. It also results in increased life expectancy and therefore increases opportunities to be more productive, thus increasing economic aspects of quality of life, but the well-documented adverse events may mitigate against an improvement in quality of life.

Adherence to medication is central to stabilizing the disease, but other factors e.g. socio-economic and personal characteristics can be equally important ¹⁴. As HAART does not provide a cure for HIV, but does improve immunity and in so doing, reduce the risk for opportunistic infection and improve longevity, it would also improve the quality of life and provide palliation for the disease itself. Adverse treatment effects, which are well documented with HAART, can then be weighed against the value of the desired clinical response ¹³. This can help patients and their carers to choose drug regimens that are both effective and well tolerated. Development of adverse effects can worsen QOL and lead to poor adherence.

HOLISTIC APPROACH OF QUALITY OF LIFE ASSESSMENTS

Quality of life has emerged as a significant medical outcome measure and its enhancement as an important goal. Quality of life has been described as congruence between one's dreams, hopes for the future, ambitions, present lifestyle and experience ²⁰. Quality of life assessments have practical implications in health care: one can measure changes in health brought about by medical interventions ⁸. Predictors of health related quality of life might eventually

contribute to the development of multiple entry points for interventions in promoting quality of life ²¹.

Personal burden of illness cannot be described fully by measures of disease status alone e.g. in the case of HIV, viral load and CD4 count. Psychosocial factors such as pain, apprehension, restricted mobility and other functional impairments, difficulty fulfilling personal and family roles, financial burden and diminished cognition must also be included ²². Health related quality of life research moves beyond direct manifestations of illness to study the patient's personal morbidity – that is, the effects that illnesses and treatments have on daily life and life satisfaction ²². Subjective well-being may be affected by a host of psychological and social factors ²². Many tools have been developed to measure QOL, an important outcome in most clinical trials on HIV. These tools are often developed through a process of item creation, focus group discussions, pilot tests and field tests ²³. The tool then aims to provide a measurement of quality of life across various domains, viz. physical, occupational and interpersonal ²².

The Case for Routine monitoring of QOL

Monitoring and optimization of QOL, may improve adherence to therapy, and also serve as tools to evaluate programs and services ¹³, which in turn may convince governments to expand access to care. Routine assessment of health related quality of life in persons with HIV, could potentially improve care by assessing and monitoring treatments effects, enhancing communication and tracking changes in functional status over time ¹³.

Variable political and industrial commitment, high costs of HIV care (laboratory and drugs); concerns about drug toxicities and uncertainty of benefits on quality of life remain impediments to large-scale implementation of HAART. The political history of AIDS care in South Africa alone, has been characterized by misunderstanding and controversy, with government support for “bogus” cures e.g. Virodene (which contains a toxic industrial solvent), a coal-derivative and a nutritional cocktail of garlic and vegetables, with a concomitant lack of support for antiretroviral drugs for rape survivors, prevention of mother-to-child transmission and treatment of AIDS

²⁴. The current political will to continue with the rollout of antiretrovirals is

challenged both provincially and nationally with differences in infrastructure, and capacity between sites ²⁴. The treatment plan needs to be a catalyst to strengthen the public health care system, and not weaken it, so the drug manufacturing industry's commitment to grant licences to generic manufacturers was also challenged ²⁴. Delays in the government tender process for procurement continues to cause unnecessary delays in reaching targets set out by the plan ²⁴. The fact that HAART does not cure and therefore needs to be sustained lifelong, with the inevitable prospect of treatment failure with successive regimens as a subsequence of viral mutation and consequent drug resistance, further adds to the burden of care.

Study Rationale

Whilst a wealth of quality of life studies have been carried out in developed countries, documenting improvement in general well – being in response to therapy, the same is not true for the developing world. Studies done locally tend to be on treatment naïve patients and document the decrease in the quality of life as the disease progresses. Minimal access to treatment results in few treatment experienced cohorts where quality of life studies can be done. Few QOL tools have

also been tested for validity and reliability in the developing world, further inhibiting the studies of this aspect of HIV care. No studies have been done exclusively in industrialized populations, on HAART in the developing world.

Given that HIV is almost exclusively a disease of young people, both in the biological and economically productive times of their lives, such a study in an industrialized setting, is of great value, to assess the impact of HAART on QOL and, as a result, on the potential of such people to remain economically productive, whilst living with, and being treated for the disease.

This study sets out to document quality of life in a cohort on HAART, in an industrialized setting, in an effort to identify the categorical values that are likely to impact on the quality of life in this population. An industrialised setting refers to a setting such as the mining environment, where the study population is gainfully employed, and do not experience the severe levels of poverty, malnutrition or economic problems that non-industrialised populations may be exposed to. In addition, migrant miners have basic shelter, nutrition, and above average health care provided free of charge, whilst employed by the mines. It is hoped that this

study will form a foundation for later longitudinal studies on the impact of HAART on quality of life, thereby providing documented evidence of improvement in quality of life on HAART, thus promoting routine use of QOL measurements to assess treatment programme performance, and ultimately impacting positively on political will to provide free access to treatment for all.

II. LITERATURE REVIEW

The literature review was conducted by means of an online search of relevant articles at Pubmed, using advanced keyword searches e.g. “quality of life in HIV” and “quality of life tools” , “impact of HIV /HAART on quality of life”, and from various textbooks and publications in the possession of the principal investigator.

Previous studies provide insights to the impact of HIV on all aspects of quality of life, and the variable effects of HAART on quality of life.

A prospective study of the emotional reactions to change in viral load in a cohort of 166 HIV positive people demonstrated meaningful reductions in depression, specifically the affective symptoms thereof, with decreasing viral load (Seth C, Karus D et al) .This was demonstrated after controlling for years of living with HIV,

age and HIV symptoms, and results suggested that emotional distress and perceptions of HIV treatments, change in parallel to markers of HIV disease (Seth C.; Karus D et al).

A study by Burgoyne RW and Saunders DS among urban outpatient HIV infected Canadians, using the MOS-SF 36 demonstrated quality of life ratings, both on physical and psychological functioning, that were lower than for the general population, especially among those patients with symptomatic HIV or AIDS.

Findings also suggested that whilst becoming symptomatic has a significant impact on the majority of dimensions of quality of life, being diagnosed with HIV affects well-being dimensions the most, and support for adjusting to diagnosis and symptom management is as important as viral suppression (Burgoyne RW, Saunders DS).

A multi-site study by Campsmith M et al to examine demographic and behavioural associations with self-reported quality of life among people with HIV, demonstrated that a lower CD4 count was the factor most consistently associated with lower

quality of life and that taking anti-retroviral medication was not associated with differences in quality of life.

Medical aspects of HIV also have an impact on quality of life. The presence, frequency and severity of constitutional symptoms (fatigue, anorexia, nausea and nightsweats), have a strong negative correlation with health related quality of life.

The presence of opportunistic infections, especially *Pneumocystis carinii* (jiroveci)

pneumonia was also associated with a lower quality of life. Hospitalisations,

particularly the frequency and length of stay thereof, also negatively affect quality

of life. Significant pain also has an independent negative effect, irrespective of the

treatment setting and stage of disease. Sexual dysfunction, a common complaint in

HIV seropositive men, leads to lower self-reported quality of life scores, and

hypogonadism may also lead to body cell mass depletion and a compromised

quality of life (Cunningham WE et al).

Initially, AIDS care was mostly palliative care, and the focus was on improving

quality of life. HAART has expanded the possibilities for active biomedical care, but

has also created uncertainties with regard to prognosis of HIV/AIDS, and the

promise and limitations of rapidly evolving therapies have made decision making

about advance care planning and end-of-life issues more complex and elusive than when the disease course was more uniform, predictable and rapid. Longer surviving patients with access to HAART may be in need of comprehensive symptom management, as well as psychosocial, family and planning support in order to improve quality of life. Palliative care must be integrated with the biomedical model for optimal care of patients and their families (Selwyn PA et al).

Palliative medicine focuses on quality of life for the patient and family from diagnosis through to death, and integrates biomedical, psychosocial and spiritual aspects into one holistic approach. This allows for active treatment with HAART, whilst counselling the patient and family on every aspect from acceptance of diagnosis, through to end-of-life planning, as well as assisting the patient and family with the spiritual aspects of the disease.

Palliative medicine, with its focus on quality of life, has much to offer to HIV care, by enhancing adherence to HAART and other therapies, and addressing the complicated psychosocial issues faced by patients and their families (Selwyn P). In the developed world, physicians face difficult decisions about withdrawal of care, goals of therapy, and acceptance of treatment failure and death in the age of

HAART. Palliation of symptoms related to HIV and HAART will improve quality of life and help to promote adherence. The possibility of pharmacological interactions between HIV medications and palliative medications makes it essential to coordinate care, in order to improve the quality of life. Home and community based care for patients with advanced illness can provide benefits in quality of life (Selwyn P). Palliative care could also teach the new generation of HIV care providers to attend to psychosocial issues involved with end-of-life care, which may not be as familiar as when death was inescapable (Selwyn P). The science and evidence base of palliative medicine have much to offer for improvement of quality of life, relief of suffering, enhancement of disease specific therapy, expert end-of-life care, and coping with chronic progressive illness for patients and their loved ones (Selwyn P).

In a systematic review by Harding R, Karus D et al to appraise the models of palliative care on patient outcomes, the evidence demonstrated largely, that home palliative care and inpatient hospice care significantly improved patient outcomes in the domains of pain and symptom control, anxiety, insight and spiritual well-being, thus increasing quality of life.

A study was conducted by Carrieri P et al, to investigate the impact of the first year of HAART on health-related quality of life, using the MOS-SF 36 among 1053 patients; final data was available for 654, and showed that factors independently associated with a normal health-related quality of life at 12 months of HAART were: normal baseline QOL, baseline CD4 <500cells/mm³, time since diagnosis of HIV < 8 years, undetectable HIV RNA at 12 months, and lower number of self reported symptoms at 12 months.

Another study by Saunders DS and Burgoyne RW that looked at quality of life after 2 years of care in which most patients received HAART, showed non-significant changes in QOL ratings, irrespective of initial disease stage, or prior HAART exposure.

A study of patients on HAART conducted in a developed country by Carrieri P et al showed the following factors to be independently associated with a normal QOL:

- ❖ Normal baseline QOL
- ❖ Baseline CD4 <500 cells/mm
- ❖ Time since HIV diagnosis <8years

❖ Undetectable viral load at 1 year

A study by Brecht JR et al, demonstrated that HAART appears to have positive effects on CD4 counts, viral loads and measures of physical health, but less clear benefits on treatment of pain and symptom distress, and psychological well-being, and that HAART that is effective and tolerable has the potential to improve QOL with time (Nieuwkerk PT et al)

In developing countries, access to antiretrovirals is beginning to expand due to increased political commitment and funding. A QOL study conducted in South Africa on HIV infected treatment naïve populations by O'Keefe and Wood, demonstrated that HIV infection impacts early on all aspects of quality of life and that this impact is largely independent of ethnic origin. However this study was conducted in a referral clinic of a general hospital, and not exclusively in an industrialised setting. No studies have documented QOL among an industrialized ethnic population on HAART.

Quality of life studies recognize that the burden of illness cannot be measured by signs and laboratory indices alone (N.Paton et al). They should include

psychosocial factors, limitation of function or social activity, impairment of role responsibilities and financial aspects if possible (N.Paton et al). Measurement of quality of life provides important insights with regard to how the disease and its treatment affect the patients. These factors may affect adherence to, and efficacy of the treatment, as well as the durability of the response (N.Paton et al).

III. AIMS

To describe the quality of life of a cohort of HIV infected gold miners on HAART, in an industrialized setting in South Africa.

IV. OBJECTIVES

- To ascertain which construct variables have a significant impact on quality of life in a South African mining population
- To promote the integration of the quality of life aspect of HIV care, with the “curative” biomedical model of care
- To promote the routine use of QOL measures in HAART to assess treatment outcomes

- To form a foundation for further longitudinal studies on quality of life in the same cohort
- To assess whether HAART improves quality of life, impacting positively on political and industrial commitment, and thereby advocate for expansion of access to HAART

V. METHODOLOGY

CHOOSING A TOOL

QOL research seeks two kinds of information ²²:

- The functional status of the individual
- The individual's appraisal of health as it affects their quality of life

Assessment of objective functioning must be validated against measures of directly observed behavioral performance.

QOL tools can be either ²²:

- generic, providing a general overview of QOL in a variety of populations
- disease specific, designed to measure QOL in specific groups

QOL tools usually measure functional status and general well-being, and include assessments of the physical and mental domains. Tools are validated by criterion validity (where scores are compared to the best indicator of the disease), or by construct validity – which includes convergent validity (scores should correlate with self report data from established instruments measuring the same indices) and discriminant validity (there should be no correlation with factors unrelated to health)

22.

Examples of some generic instruments include:

- Sickness Impact Profile, a 136 question questionnaire that assesses physical, psychosocial and other domains, but has a disadvantage of emphasis on physical function and negative wording of items, which may lead to biased responses ¹³.
- Medical outcomes study short form-36 (MOS SF –36), derived from a prospective 4 – year observational study, covering 8 domains. These domains include: physical functioning, physical related role limitations,

social functioning, physically related role limitations, social functioning, pain, vitality, mental health, emotionally related role limitations and general health perceptions ¹³. It is short, but moderately comprehensive, with supported validity and reliability among HIV/AIDS patients, and has been culturally adapted and translated into more than 50 languages ¹³.

- Quality of well-being scale (QWB), examines 5 domains, but produces a single score that does not reflect the wide range of issues affecting QOL ¹³.

The domains included are: self-care, mobility, institutionalisation, social activities and symptoms/problems ¹³.

Examples of some HIV specific instruments are:

- MOS-HIV, specific to HIV assessing 10 domains and health transition, demonstrates sound psychometric properties in varied populations, including Afro- Americans and responsiveness to changes in clinical status, presence of adverse events and opportunistic infections. The domains included are: general health perceptions, pain, physical functioning, role functioning, social functioning, mental health, energy/fatigue, cognitive

function, health distress, and QOL ¹³. Disadvantages are that it does not cover somatic symptoms, sleep, sexual dysfunction, appetite and body image and ceiling and floor effects for some of the subscales ¹³.

- Multidimensional QOL questionnaire for HIV/AIDS (MQOL-HIV), evaluates 10 domains and is responsive to change, but is less reliable and less responsive to change than MOS-HIV ¹³
- HIV overview problems evaluation system (HOPES), an instrument derived from the Cancer Rehabilitation System that has demonstrated reliability and validity, but the length of the questionnaire is sub optimal and negative phrasing may result in response bias ¹³. The summary scales included are: physical, psychosocial, medical interaction, sexuality, and communication and interaction with partner.

Of note, an optimal tool for use in the clinical setting has not been identified from the numerous tools that do exist, all of which omit some key HIV related aspects relevant to QOL. An optimal tool would ideally include the following ¹³:

- Reliability and validity

- Be self-administered
- Be brief, yet comprehensive
- Evaluate the most relevant aspects of HIV related QOL
- Be appropriate for the entire spectrum of disease severity
- Be responsive to clinically important changes in health status over time
- Be easy to understand for all literacy levels
- Be sensitive to a wide range of cultural and ethnic backgrounds
- Be available in translated versions
- Have wide acceptance
- Allow for easy data collection, scoring and interpretation

Tools that are meaningful to both clinician and patient are also valuable, because of their focus on the item structure, and weighting of scores on each domain, as well as subjective wording that allows respondents to interpret measured elements according to their own experience ³⁴.

The tool chosen was the MOS 36 – ITEM Short Form Health Survey (SF 36)

[Appendix 1]. It assesses the following eight parameters:

- Limitation in physical activity because of health problems /physical function (pf)
- Limitation in usual role activities because of health problems/role physical (rp)
- Bodily pain (bp)
- General health perceptions (gh)
- Vitality /energy and fatigue (vt)
- Limitation in social activities because of physical and emotional problems (sf)
- Limitation in usual role activities because of emotional problems /role emotional (re)
- Mental health psychological distress and well- being (mh)

This tool was chosen because:

- It can be self or interviewer - administered and takes 5-10 minutes to complete, with a moderately comprehensive scope ³⁵.
- It has been widely used and has developed significant levels of reliability and validity in diverse populations ³⁵

- A commentary comparing the use of the two tools in HIV, showed more ceiling and floor effects for MOS-HIV than for MOS SF 36, due to fewer items in the physical functioning domains. Also the MOS-HIV has been used in fewer populations and is specific only for HIV, and therefore less able to assess HIV-infected patients with other concomitant chronic diseases. The result was that there was insufficient evidence to justify recommendation of the MOS-HIV over the MOS-SF 36 even in patients with HIV ³⁵.

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The tool was translated into Sesotho and Xhosa and then back translated into English to verify the translation. A developmental license to use and translate this document was obtained from the Medical Outcomes Trust [appendix 16]. The instrument was administered by trained research nurses between November 2004 and April 2005, during routine clinic visits. The research nurses were trained on how to administer the questionnaire and the case report form (CRF), by the principal investigator, using a training manual devised by the investigator) [appendix 2]. The tool and the CRF [appendix 11] were administered by the

research staff; none of the participants were handed documents for self-completion. A CRF was used to capture demographic data and data on use of traditional medicines.

LIMITATIONS OF THE TOOL

In this study translations into SeSotho and Xhosa, the two predominant languages on site, were made. Limitations include:

- The tool was not devised to accommodate an industrialized, SeSotho or Xhosa setting .It has been validated in a South African, Xhosa speaking non-industrialised population ³². A study on culture and QOL tools, suggests that these tools are not culture free, thus implying certain limitations and hazards in applying a tool devised in one cultural context, to a different context. It also discusses the influence of the culture of the researchers themselves and suggests that they portray more about the researchers than the actual cohorts, and probably reflect the degree of similar perception between participants and researcher ³⁶.

STUDY DESIGN, SETTING AND SITE

A cross sectional study was conducted at a specialist HIV outpatient clinic operated by the health service of a single gold mining company in the Northwest province. This study was conducted at a specialist HIV outpatient clinic operated by the health service of a single gold mining company in the Northwest province that employs miners from South Africa, Botswana, Swaziland, Lesotho and Mozambique. Miners either live in the single sex hostel facilities provided by the mine (60%), or in the peri-mining community (40%). All mine employees have excellent access to health care, with the mining company providing primary care through peripheral clinics situated at the shafts and hostels, and secondary and tertiary care through a combination of a mining hospital and referrals to private facilities. The strenuous work required underground, necessitates a high level of fitness, with a pre-occupational screening for all employees and ongoing fitness monitoring when returning from annual leave. Miners with chronic illnesses are closely monitored by hospital and occupational health physicians, in combination with occupational functional work capacity assessments, to assess fitness for work.

In the event of suboptimal fitness, a miner would be offered medical boarding, temporary or permanent incapacitation, or terminal incapacitation, with home-based care provided by a contractor to the mining company, at the labour sending areas of origin.

HIV comprehensive care includes education and awareness programmes, voluntary counselling and testing (VCT) that is easily accessible and available, prophylaxis for latent TB and opportunistic infections, and HAART. The employee assistance programme (EAP) provides for psychosocial and spiritual care of employees and families that live in and around the mine itself. HIV care is done within the Wellness clinic. The anti-retroviral programme of this company was launched in November 2002 and uses standardised treatment regimens, data recording and monitoring. It is an extension of existing HIV prevention and care programmes and uses guidelines derived from local and international best practice, with HAART being recommended for individuals with:

- CD4 count below 250 cells/mm³
- WHO stage IV disease
- WHO stage III disease with a CD4 count between 250 and 350 cells/mm³.

The first line regimen includes Zidovudine, Lamivudine and Efavirenz. The second line regimen includes Didanosine, Abacavir and Lopinavir-Ritonavir. Prophylaxis against opportunistic infections is also offered routinely. Laboratory and pharmacy services, using named-patient dispensing, are centralised. Counsellors, nurses and doctors receive general and programme-specific training on HIV care. Doctors are supported by experienced HIV clinicians through telephone consultations and site visits.

Routine recordkeeping in the wellness clinic that assisted with data capture for this study include:

- Data capture onto the routine case-report forms and double entry into the password protected Wellness Clinic database.

Procedures for data capture and internal data quality assurance in the wellness clinic include:

- Training of health service and study nurses and clinicians in the completion of case report forms by the Aurum Institute of Health, a research company involved in health systems development, and who developed the system for the clinic

- Maintenance of subject master files with all original documentation for source document verification
- Case-report forms are checked by a professional nurse for completeness and accuracy. Any queries are resolved prior to the patient departing the clinic.
- Data forms are entered in duplicate. The original is kept in the patients wellness clinic file and the duplicate is sent to the central data management site for safe keeping and further verification
- Data is double entered by dedicated data encoders. Data queries are submitted to the health service Wellness Clinic doctor and study coordinator for resolution against source documentation.
- The database includes range and consistency checks and includes internal validation rules.
- Patients will be assigned a unique study number. Database files will be merged using this study number once personal identifiers have been stripped to ensure confidentiality is maintained.

- Master data files are password protected. Only the data manager is allowed to make changes to the database structure and tables.

SAMPLE POPULATION

The questionnaire was offered to a sequential sample of routine clinic visit attendees.

Inclusion criteria:

- over 18 years of age
- male
- known to be HIV infected
- anti-retroviral treatment experienced
- SeSotho, Xhosa and English speaking (these are the majority languages spoken on the mines)

Exclusion criteria:

- Less than 18 years old
- Females

- HIV status negative or unknown (the clinic provides prophylaxis against latent tuberculosis for silicotics as well)
- Antiretroviral treatment naïve (could be included later provided HAART was initiated)
- Speak languages other than SeSotho, Xhosa or English

VI. DATA MANAGEMENT

Data was entered into two identical databases that were password protected.

These databases were run against each other to generate queries that were resolved by the principal investigator. These databases were also run against the Wellness clinic database to extract information on WHO stage, CD4 count, viral load and Karnofsky score.

VII. STATISTICAL ANALYSIS

Scores for each MOS subscale were derived from the subjects responses on the SF-36 scale and transformed to a 0 – 100 scale. The higher scores represent a better level of functioning.

Stata 8 was used to examine the effect on MOS score of age, WHO clinical stage, viral load and CD4. It was also used to determine the number of participants in

each subscale who scored 100 for that subscale. WHO clinical stages were limited to stages 2, 3 and 4, as no participants with WHO stage 1 had been started on HAART. CD4 counts were grouped into <199, 200 – 349 and >350. Viral load grouping was as follows: <50, 51-9999 and >10000. Age was grouped as follows: <39, 40 – 49 and > 50.

Due to a technical error in downloading the MOS SF from the website, question 5c was omitted. Two of the three questions needed to calculate the role emotional score were asked; the mean of the scores for these two questions were used to calculate the score for the third question, and to calculate the overall role emotional score.

VIII. ETHICAL CONSIDERATIONS

Strict confidentiality was maintained for all participants. Informed consent [appendix 6] was obtained in accordance with good clinical practice guidelines. No personal demographic data was captured on either the questionnaire, information sheet [appendix 5] or consent form. All health and research staff signs a confidentiality agreement as part of their terms of employment. Ethical approval for this study was been obtained from the Ethics Committee of the University of Cape

Town [appendix 14]. The manager of the health service facility belonging to the mine also authorized conducting of the study at the health service clinic [appendix 15]

IX. RESULTS

Two hundred and two HIV clinic attendees were approached between November 2004 and April 2005. Only one hundred and forty one were included in the final analysis, based on aforementioned inclusion/exclusion criteria. Sixty-one were excluded on the basis of HAART having been stopped more than a month before the study interview, or because data from the wellness database was unavailable at the time of compiling the report, or because they had not started HAART at the time the questionnaire was administered.

All interviews were conducted by a qualified, trained research nurse, proficient in the preferred language of the subject. 63.8 percent (%) completed the questionnaire in SeSotho, 34.8% completed the questionnaire in Xhosa and 1.4% completed the questionnaire in English

Demographics for the sample are depicted in Table 1

CHARACTERISTIC	NUMBER	%
<u>Country of origin</u>		
South Africa	73	51.8
Lesotho	41	29.1
Other	27	19.2
<u>Current job</u>		
Underground	121	85.8
Surface	20	14.2
<u>Level of Education</u>		
No formal education		
Primary (1-7 years)	13	9.2
High school	80	56.7
	48	34.0
<u>Age</u>		
<30	2	1.4
31-39	50	35.5
40-49	65	46.1
>50	24	17.0

Table 1: Demographic data for sample n = 141

Thirty participants (21.3%) were taking concomitant prescribed chronic medication;

10 (33.3%) were taking INH prophylaxis, 17 (56.7%) were taking treatment for

Tuberculosis and 3 (9.9%) were taking other concomitant chronic medications.

21 (14.9%) were taking concomitant traditional or over the counter medications,

the most commonly used of which was the "Traditional Mixture" in 14 (66.7%).

Traditional mixture is a traditional medication in liquid form, composed and

provided by traditional healers for a multitude of symptoms. The constituents and

effects are unknown.

Data from the wellness clinic database on the Karnofsky performance status scale

[appendix 13] scores was available for 112 (79.4%) of participants. 2 (1.8%)

scored 80 i.e. they were capable of normal activity with effort and showed some

signs or symptoms of disease, 19 (17.0%) scored ninety i.e. they were able to

carry on normal activity with minor signs or symptoms of disease, and 91 (81.2%)

scored one hundred i.e. normal function with no evidence of disease.

The median CD4 count was 281 cells / mm³ (lower and upper quartiles 163 and 397). The median difference in days between the CD4 count being taken and the study visit was 70 (lower and upper quartiles 14 and 103). CD4 counts were Available for 135 (95.7%) participants (see table 2). The median viral load was 50 cps/ml (lower and upper quartiles 50 and 1282); the median difference in days between the taking of a viral load and the study visit was 22days (lower and upper quartiles 5 and 91). VL results were available for 137(97.2%) see table 2

Data from the wellness clinic database on WHO stage was available for 111 (78.7%) participants and has been summarized together with clinical and laboratory parameters for the sample are depicted in Table 2

Parameter		N= 141	Percentage
Who stage ¹	1	nil	
	2	7	6.3%
	3	56	50.5%
	4	48	43.2%
CD4 group ²	<199cells/mm ³	43	31.8%
	200 – 349 cells/mm ³	45	33.3%
	>350 cells/mm ³	47	34.8%
VL group ³	<50cps/ml	90	65.7%
	51-9999cps/ml	20	14.6%
	>10000 cps/ml	27	19.7%

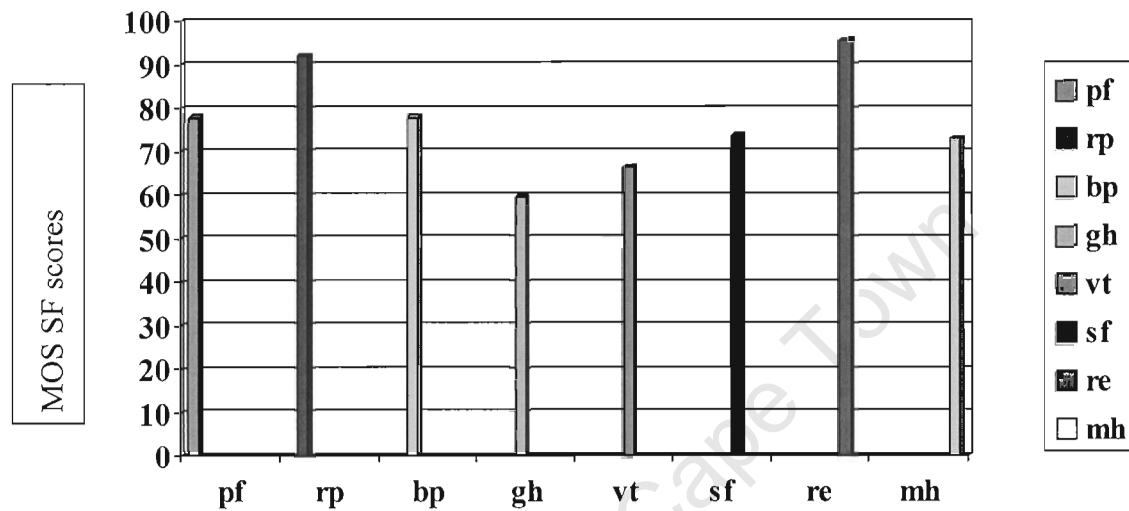
Table 2: Clinical and laboratory data for study participants.

¹ missing for n=30

² missing for n=6

³ missing for n=4

SF 36 scores were found to be =100 for more than 59% of participants on all eight subscales (see figure 1).



pf – physical functioning; rp – role physical; bp – bodily pain; gh – general health;

vt – vitality; sf – social functioning; re – role emotional; mh – mental health.

Figure 1: percentage of participants in each domain with a score of 100

All viral load groups scored a median of 100 for all 8 subscales. All CD4 groups scored a median of 100 on all subscales, as depicted in table 3.

Table 3: SF domain scores of 100 according to CD4, viral load and age groupings.

SF (score = 100)	Viral load group (copies /ml)			p value	CD4 group (cells/mm ³)			p value	Age group			p value
	<50	51- 9999	>10000		<199	200 –349	>350		<39	40-49	>50	
pf	18 (12%)	8 (5.7%)	3 (2.1%)	0.051	13 (9.2%)	9 (6.4%)	8 (5.7%)	0.292	5 (3.5%)	15 (10.6%)	11 (7.8%)	0.002
rp	5 (3.5%)	4 (2.8%)	2 (1.4%)	0.098	6 (4.3%)	1 (0.7%)	2 (1.4%)	0.063	1 (0.7%)	5 (3.5%)	5 (3.5%)	0.017
bp	20 (14.2%)	6 (4.3%)	4 (2.8%)	0.457	8 (5.7%)	6 (4.3%)	14 (9.9%)	0.138	9 (6.4%)	14 (9.9%)	8 (5.7%)	0.290
gh	35 (24.8%)	9 (6.4%)	11 (7.8%)	0.878	20 (14.2%)	16 (11.3%)	19 (13.5%)	0.578	17 (12.1%)	25 (17.7%)	5 (3.5%)	0.044
vt	30 (21.3%)	8 (5.7%)	7 (5.0%)	0.589	14 (9.9%)	13 (9.2%)	18 (12.0%)	0.627	15 (10.6%)	21 (14.9%)	11 (7.8%)	0.033
sf	24 (17.0%)	6 (4.3%)	6 (4.3%)	0.827	12 (8.5%)	12 (8.5%)	11 (7.8%)	0.880	9 (6.4%)	16 (11.3%)	12 (8.5%)	0.016
re	4 (2.8%)	1 (0.7%)	1 (0.7%)	0.976	2 (1.4%)	1 (0.7%)	2 (1.4%)	0.808	1 (0.7%)	3 (2.1%)	2 (1.4%)	0.429
mh	26 (18.4%)	4 (2.8%)	8 (5.7%)	0.703	9 (6.4%)	10 (7.1%)	18 (12.0%)	0.116	15 (10.6%)	13 (9.2%)	10 (7.1%)	0.115

X. DISCUSSION

The sample population chosen for this cross sectional research study consisted of black males over the age of eighteen, known to be HIV infected and antiretroviral treatment experienced, drawn from groups that speak either English, Xhosa or SeSotho in an industrialized setting. One hundred and forty one were included in the final analysis, of which 63.8 percent (%) spoke SeSotho, 34,8% Xhosa and 1.4% English. 93.7% were at WHO Stage 3 and 4 at baseline, with 63,1% being older than age 40. This study utilised MOS SF 36 in an outpatient setting. Length of time on antiretrovirals was not taken into consideration.

In comparison, a cross sectional study conducted in Cape Town on an HIV infected cohort made of up of males and females of all races from an outpatient clinic, one hundred and thirty four respondents were included, with 60.4% being at WHO Stages 3 & 4 at baseline, 43% speaking English, 34% speaking Afrikaans and 23% speaking Xhosa. The mean age was 32.5. This study also used the MOS SF 36. None of these subjects were on antiretroviral treatment ³².

A similar study in Singapore recruited HIV infected male and female patients from an outpatient clinic, with one hundred and sixty three being included in the final analysis. Of these 96% were male, with a mean age of 38.1 years. 58% had CDC Stage B&C disease at baseline, with 20.4% on treatment with three or more antiretrovirals, and 46.3% on dual therapy and 33.3% on no treatment at all. Subjects completed the questionnaire either in English or Chinese (no statistics recorded). This study was also cross sectional in design, and used the MOS HIV tool, derived from the MOS SF 36³³.

The primary aim of the latter two studies included the validation of the tool in that population^{32, 33}, and the results of these two studies will be compared to the results of this research study's population for each subscale domain.

Patient data in this study indicated no statistically significant differences in the different subscales of the tool, irrespective of WHO stage, CD4 count or viral load.

The only statistical significant difference was in relationship to increasing age with regard to physical function (pf), role physical (rp), general health (gh) and social functioning. This relationship to age, is thought to be more indicative of the effect of

age on function in this ageing workforce, rather than the effect of HAART on HIV.93,7% of all subjects were at WHO Stage 3 or 4 of HIV disease, yet 60% or more scored 100 in each domain, indicating a high level of quality of life despite advanced disease.

Physical function domain (pf)

For the physical functioning (pf) domain 78% scored 100, compared to an average score of 63 for the equivalent group in the Cape Town study ³². This was also the only subscale in that study to be affected by race and gender, in keeping with other MOS data, but researchers recognized that these scores could also be attributable to poorer socioeconomic status. In the environment of a mine, where the majority of employees live in hostels and have food and shelter provided, socioeconomic differences may be less overt and thus account for the high scores obtained in this study.

For a similar subgroup in the study conducted in Singapore, the physical function domain scores ranged between 54.0 and 61.5 ³³. This study indicated a strong relationship between most of the subscales and the overall burden of symptoms, using a local symptom score, indicating that the symptom score was the major

factor related to mental and physical health summary scores³³. The Karnofsky score in the study in this paper indicates that 79.4% of all subjects scored 80 or more, indicative of mild symptoms with minimal effort required to achieve normal effort. This indicates the low occurrence of symptoms in this population and could account for the high scores on the pf scale.

Role physical domain (rp)

The role physical (rp) subscale score in this study was 100 in 90% of subjects, in comparison to an average of 46 for the Cape Town³² study and a score of 61, 4 for the Singapore study³³. The findings in this study may also be attributable to the low occurrence of symptoms, as indicated by the Karnofsky score, as well as to the perceived equity in socioeconomic status among the group.

Bodily pain domain (bp)

The bodily pain (bp) subscale score in this study was 100 for 78% of subjects, with a score of 100 indicating no bodily pain. This was compared to an average of 58.5 in the Cape Town study³² and 69,05 in the Singapore study³³. This finding is in keeping with the low symptom score as per the Karnofsky performance scale

scores, and could account for the high overall scores in this group, given that symptoms impact negatively on quality of life.

General health domain (gh)

The general health subscale score for this study was 100 in 60% of subjects.

General health scores are partially dependant on presence of symptoms, and the high scores in this study, again indicate a low symptom presence in keeping with the Karnofsky scores. All aspects of quality of life are affected early in HIV disease, but impact is maximal on emotional and psychological factors in early disease, as opposed to physical function ³³.

Physical health subscale

These aforementioned four subscale scores are used to calculate the overall score on the physical subscale. The excellent physical function in this study group is borne out by the high scores in all physical domains, as well as the high scores on the Karnofsky scales. It is indicative of the high levels of physical function demanded for the strenuous mine work, as well as the excellent support in terms of HIV specific and general health care, and nutrition in the mines.

Mental health subscale

Mental health scores are a combination of vitality (vt), social functioning (sf), role emotional (re) and mental health (mh) domain scores.

Vitality domain (vt)

In this study 67% of all subjects obtained scores of 100 for the vitality subscale, compared to an average of 49 in the Cape Town study ³², and a score of 65,4 for this subscale in the Singapore study ³³. This subscale score represents the subjects' perception of energy levels and fatigue in respect of actual physical work and social interaction. Subjects in this study scored high, and this may indicate the high levels of energy necessary for the strenuous work done on a daily basis, as well as the high level of social interaction that is evident in the mining environment between hostel dwellers themselves, and between the hostel dwellers and surrounding community.

Social function domain (sf)

Social functioning scores in this study were 100 for 74% of subjects, compared to an average score of 60 in the Cape Town study ³², and 63.2 for the Singapore study ³³. The mining community has well defined social activities organized in

partnership with the mine management, with fully equipped recreational centers in the hostels for the hostel dwellers. In addition cultural activities are encouraged and in many cases subsidized by mine management e.g. choral activities and could account for the high scores on this subscale for this study.

Role emotional domain (re)

Role emotional scores for this study were 100 for 95% of the subjects, compared to scores of 48.5 in the Cape Town study ³², and 64.4 in the Singapore study ³³.

Role emotional scores comprise subscores reflecting the extent to which physical health or emotional problems interfered with normal social or work activities causing the individual to either cut down on activities or to accomplish less. High role emotional scores in this study population are in keeping with the Karnofsky score scales that indicate that 79,4% of subjects were able to do normal work with minimal effort, and is further borne out by the fact that employees have to pass biannual rigorous functional assessments as part of the occupational screening, in order to remain employed.

Mental health subscale

Mental health subscale scores in this study were 100 for 72% of subjects, compared to a score of 61 in the Cape Town study³², and scores ranging from 61.5 to 67.7 in the Singapore study³³. Mental health subscales reflect feelings of nervousness, depression, peacefulness, happiness and sadness, with higher scores reflecting overall better mental health. Subjects in this study scored high and this may indicate the calibre of the employee assistance program (EAP), run by a qualified team of psychiatrists, psychologists and social workers, employed by the mine. Workers and their families have access to these services at no expense for as long as these services are necessary. In addition, managers that detect problems in the workplace can refer workers for assessment and management. In-patient facilities with an extended pharmaceutical formulary is available for those admitted, including referral to outside specialists for consultation if needed. The difference in this subscale score between studies may indicate the differences in accessibility, availability and calibre of services available, between the mine health services, which are essentially private, and those of the state.

Summary

The data for this study population indicates an exceptional quality of life, which is in keeping with the correlation of the subscale scores and that of the Karnofsky scale.

This cohort was capable of normal activity with minimal effort, and showed minimal signs or symptoms of disease.

This may be indicative of the “well worker effect”, where such high levels of fitness are demanded by pre-occupational medical screening, that only those workers with high level of performance (even those with chronic diseases) may remain employed. This stringent screening may also result in employment of undiagnosed HIV infected workers that are at the early stages of HIV disease and are either asymptomatic or minimally symptomatic. Repeat stringent bi-annual occupational screening on return from leave would further screen out those employees whose health and quality of life may have deteriorated since initial employment, and leave only those workers with a high level of fitness remaining to attend the clinic.

Also, workers that are seriously ill with opportunistic infections, or became terminally ill as a result of HIV/AIDS were more likely to be admitted to the ward,

and therefore less likely to attend the clinic, designed for ambulant out-patients, from which the study population was drawn. This would also indicate that the study population was essentially drawn from the “survival cohort” of the mine employees – those that “survived” the repeated strenuous pre-employment and post leave screening.

The high level of health care offered to this population may also have added to these effects, in that the level of health education (part of pre-employment and post-leave screening) encourages miners to present early for treatment and care.

Free, easily accessible and available care also means early intervention for any illness or injury, without the individual having concerns for the cost of such care.

VCT is also freely available and accessible, with major marketing campaigns to increase the level of awareness and to encourage awareness of HIV status. This population may therefore be detected early during the course of HIV and be treated timeously and proactively with preventive therapy, and have the benefit of proactive screening for opportunistic infections, as well as access to antiretrovirals.

Antiretrovirals are also offered at CD4 counts that are higher than those recommended by the national programme for South Africa.

Expensive medication for the treatment of Cryptococcal meningitis and Cytomegalovirus infection are also freely available, so that the individual has no burden of cost and is not restricted by this when accessing care. Healthy, balanced meals devised by the company dietician are also provided free of charge to the miners living in the hostel, which ensures adequate nutrition and reduces the burden of socioeconomic and diet-related diseases. For those miners who choose to live in the peri-mining community, a living-out allowance to subsidise shelter and food is provided, and free access to mine health services is guaranteed.

The results could also indicate that the tool used is not sensitive enough to pick up statistically significant differences in an industrialized population with high levels of health care and fitness, because of limitations with the tool viz.:

- Lack of validation in an industrialised population
- Effect of culture on the tool devised for a westernized population. While this

tool has been validated among a Xhosa speaking population in the

Western Cape Province of South Africa, there were only 19% of

respondents in that study that were Xhosa speaking, as opposed to 34.8 %

of Xhosa speaking subjects in this study. This study also had 63.8% who were SeSotho speakers, for whom the tool has not been validated.

- Lack of a characteristically similar cohort infected with HIV, but not on HAART for comparison of subscales scores
- Tool may perform better in longitudinal as opposed to cross sectional study designs
- Lack of clinical data to collaborate subscale scores

Of interest there was no difference in subscale scores between patients using HAART and traditional medicines and those using HAART alone. Laboratory markers and symptoms of toxicity were not compared in the two cohorts, as the study was not designed to include this.

XI. CONCLUSION

The MOS SF 36 documented a high quality of life among miners on HAART, but only age was identified as a significant construct variable impacting on quality of life, and perhaps the tool was not useful for identifying which construct variables impact on QOL in this cohort using a cross-sectional study design. Identification of age as a statistically significant construct variable was thought to be due to the effects of ageing on the study population, and not progress of HIV disease or effects of HAART on HIV. The tool did enable establishment of a baseline assessment of QOL in this cohort, with high scores that could be attributable to HAART, the stringent selection criteria for employment, and the excellent level of health care offered to employees. This study has laid a foundation for future longitudinal quality of life studies in the same cohort, as workers are employed over long periods of time, attend the health service for the duration of their tenure and have records kept for their health care.

XI. RECOMMENDATIONS

The MOS SF-36 should be validated among an exclusively industrialized population with a high level of fitness and access to good health care, by conducting a test / retest method with a cohort approximately two weeks apart, and with a control cohort of healthy miners with similar demographics. The sample size should aim to power the study by at least 80%. Further cross sectional studies should be conducted in the same cohort using a validated MOS SF 36, to detect differences in quality of life in the same cohort over time. Other quality of life tools need to be validated in this specific population, using the test and retest method, in order to obtain a sensitive enough tool for this population. QOL scores must be aligned to clinical and laboratory parameters and monitored over a period of time, to see if changes in clinical and laboratory parameters, are in keeping with the quality of life subscale scores. The MOS SF 36 could be tested for sensitivity in this cohort over time, and could be tested against the performance of similar tools in this same cohort, controlling for time elapsed and response to HAART. The results of this study have shown a high quality of life for HIV infected gold miners on HAART, and could be used as part of an advocacy drive, to influence political

and industrial commitment to provide comprehensive wellness programmes, that ensure early access to HAART. These results would be further enhanced by a longitudinal study in the same sample population, as well as routine QOL measurements with a validated tool to allow for comprehensive programme performance monitoring.

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