PREVALENCE OF AND FACTORS ASSOCIATED WITH PAIN IN AMBULATORY HIV AND AIDS PATIENTS AT THE TWO TEACHING AND REFERRAL HOSPITALS IN UGANDA

NAMISANGO EVE (PGD STATISTICS)

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DECLARATION

I hereby declare that all the work in this dissertation is original unless otherwise acknowledged and has not been submitted for another degree in this or any other university or institution of higher learning.

Signature

_____ _____

Eve Namisango Date

(Candidate)

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;DEDICATION

This book is dedicated to all those people whose lives have been devastated by the deadly Human Immunodeficiency Virus. Hope was born at the very foundations of the world; with the same hope, a cure will some day be found.

ACKNOWLEDGEMENTS

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Abstract

Background: Pain is a clinically significant problem contributing greatly to psychological and functional morbidity in HIV/AIDS patients. Limited research has been done on the magnitude, diversity and medical correlates of pain in HIV patients in developing countries. This underscores the need for increased clinical focus on identifying the presence of pain and adequate treatment of pain in all stages of HIV disease. This study aimed at estimating the prevalence of and factors associated with pain in the ambulatory HIV/AIDS patients.

Methods: This was a cross-sectional study with both descriptive and analytic components employing quantitative methods of data collection. It was conducted at the AIDS outpatient clinics of Mulago and Mbarara Teaching and referral hospitals between January and May, 2008. Patients were selected using systematic sampling method and a total of 302 patients were recruited over the study period.

Measurements included: Socio-demographics: age, gender, religion, education level, marital status, employment status, previous use of alcohol, drugs and smoking habits. **Clinical**: CD 4 count, viral load, WHO clinical disease stage, use of HAART, prevalence of symptoms, function performance, and previous treatment for pain. The dependent variables were presence/absence of pain and pain intensity.

Measures : The *Karnofsky* Performance scale- measure of functional performance. The Brief pain Inventory (BPI) – for pain, Memorial Symptom Assessment Scale (MSAS)-intensity, frequency and distress associated with physical and psychological symptoms and the MOS HIV – for measuring Quality of Life. The inclusion criteria was all ambulatory HIV/AIDS patients aged 18 years and above attending AIDS outpatient clinics at the two study sites and consented to take part were in the study. Patients too ill to complete the questionnaires and those who could not comprehend English and or Luganda were excluded from the study.

Data was analysed using STATA software: To determine whether socio-demographic variables are predictive of pain scores, socio-demographic groups were compared using ANOVA one way between groups using the F test. To establish the factors associated with presence of pain logistic regression analysis was used. Multiple regression analysis was used to determine the most parsimonious set of variables that predicted pain intensity

Results: The mean age of the study population was 37 years and majority were female 64.24(n=194). Of the 302 patients recruited, 143 (47%) reported having had pain other than other than everyday kinds of pain like minor headaches, sprains and toothaches; one week prior to the study . Demographic variables were not associated with presence of or intensity of pain. 9+ number of symptoms reported was associated with 3 fold increase in the odds of pain as compared to 4-8 (OR = 3.3, CI (1.68-652), p = 0.001) . Physical symptom distress was also associated with a 4 fold increase in the odds of presence pain (OR = 3.6, CI 1.86-7.06, P<0.001). Single Marital status and physical symptom distress were associated with increasing pain intensity (beta = 1.31, P< 0.001, beta = 0.96, P = 0.023). Presence of pain was also associated with greater functional impairment t (df(300) =11.206, p <0.001) .

Conclusions: Results demonstrate high levels of pain and pain related functional impairment among HIV and AIDS patients. The presence and intensity of pain are associated with demographic factors (single marital status) as well as a high symptom burden which may be a more proxy marker for disease progression.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
MSAS	Memorial Symptoms Assessment Schedule
QOL	Quality of Life
BPI	Brief pain Inventory
WHO	World Health Organization
MOS-HIV	Medical outcome scale - HIV

CHAPTER ONE

1.1 Introduction

HIV continues to be a major public health concern world wide. In 2007, 33.2 million people were estimated to be living with HIV, 2.5 million people became newly infected and 2.1 million people died of AIDS. There was an estimated 1.7 million new infections in sub-Saharan Africa in 2007, a significant reduction since 2001. An estimated 22.5 million people are living with HIV which accounts for 68% of the global total [(1).] In Uganda, the prevalence is estimated to be about 6.7%, which is high as compared to that in developed countries[(2)] .

Surveys of HIV infected patients have established that pain is highly prevalent, diverse in presentation and associated with significant psychological and functional morbidity [(3)]. Estimates of the prevalence of pain have ranged from 25% to 80%, a range that reflects differences in the populations evaluated and methodologies used for pain assessment [(3-5)]. It is widely believed that pain has a profound effect on a person's quality of life and many measures that are designed for use in health care include an assessment of pain as part of the evaluation(6) . In addition, the growing recognition that acquired immune deficiency syndrome (AIDS) is a chronic illness, the management of which is largely palliative has heightened awareness of quality of life outcomes[(7)].

Although previous research conducted on pain in HIV in the western world broadly highlights the scope of the problem , it offers little detail the characteristics in AIDS patients and impact on patient health related quality of life especially in the African context [(8)]. More so, interpretation of some of the data is hampered by methodological limitations, including use of small or idiosyncratic patient samples, reliance on retrospective or chart review and use of vague or overly broad criteria for determining the presence of pain. Some findings on pain are from the pre-HAART era, and certainly the contribution of specific opportunistic infections to pain syndromes has diminished over time as the incidence of such infections

declined. However, it should be noted that in some instances, the incidence and or prevalence of pain may have actually increased over time. As is often the case with AIDS, the irony of decreased mortality rates is that by surviving longer some patients may thus be vulnerable to new complications and pain as in the observed increasing prevalence of peripheral pain neuropathy which occurred with longer survival according to a multi-centre AIDS cohort study [(9)].

This study thus sought to provide a more reliable and detailed assessment of HIV-related pain and its associated factors in the ambulatory HIV/AIDS patients in the Ugandan context.

1.2 Problem Statement

There is growing concern that services are neglecting one of the most common HIV related symptom of pain. Incidentally, limited research has been undertaken on the magnitude, diversity and medical correlates of pain in HIV patients in Uganda [8]. This underscores the need for increased clinical focus on identifying the presence of pain and adequate treatment of pain in all stages of HIV disease. Pain in AIDS even in this era of protease inhibitors and decreased AIDS death rates, is a clinically significant problem contributing greatly to psychological and functional morbidity[10] . More so much as pain has a significant impact on patients' quality of life, the components of quality life that are significantly affected have not been identified in Uganda and the structure of quality of life and the place of pain within it is not well understood and this is what this study sought to address.

1.5 Objectives of the Study

1.5.1 General objective

The general objective of this study was to determine the prevalence of and factors associated with pain in ambulatory HIV/AIDS patients in Mulago and Mbarara hospitals.

1.5.2 Specific Objectives

1. To determine the prevalence of pain in ambulatory HIV/AIDS patients in Mulago and Mbarara hospitals

2. To determine the clinical factors associated with pain in ambulatory HIV/AIDS patients in Mulago and Mbarara hospitals.

3. To establish the socio-demographic factors associated with pain in ambulatory HIV/AIDS patients in Mulago and Mbarara hospitals.

4. To assess the relationship between pain and health-related quality of life in ambulatory HIV/AIDS patients in Mulago and Mbarara hospitals.

1.5.3 Hypotheses

1. There is no association between of pain socio-demographic factors.

2. There is no association between pain and clinical factors.

3. There is no association between pain and quality of life

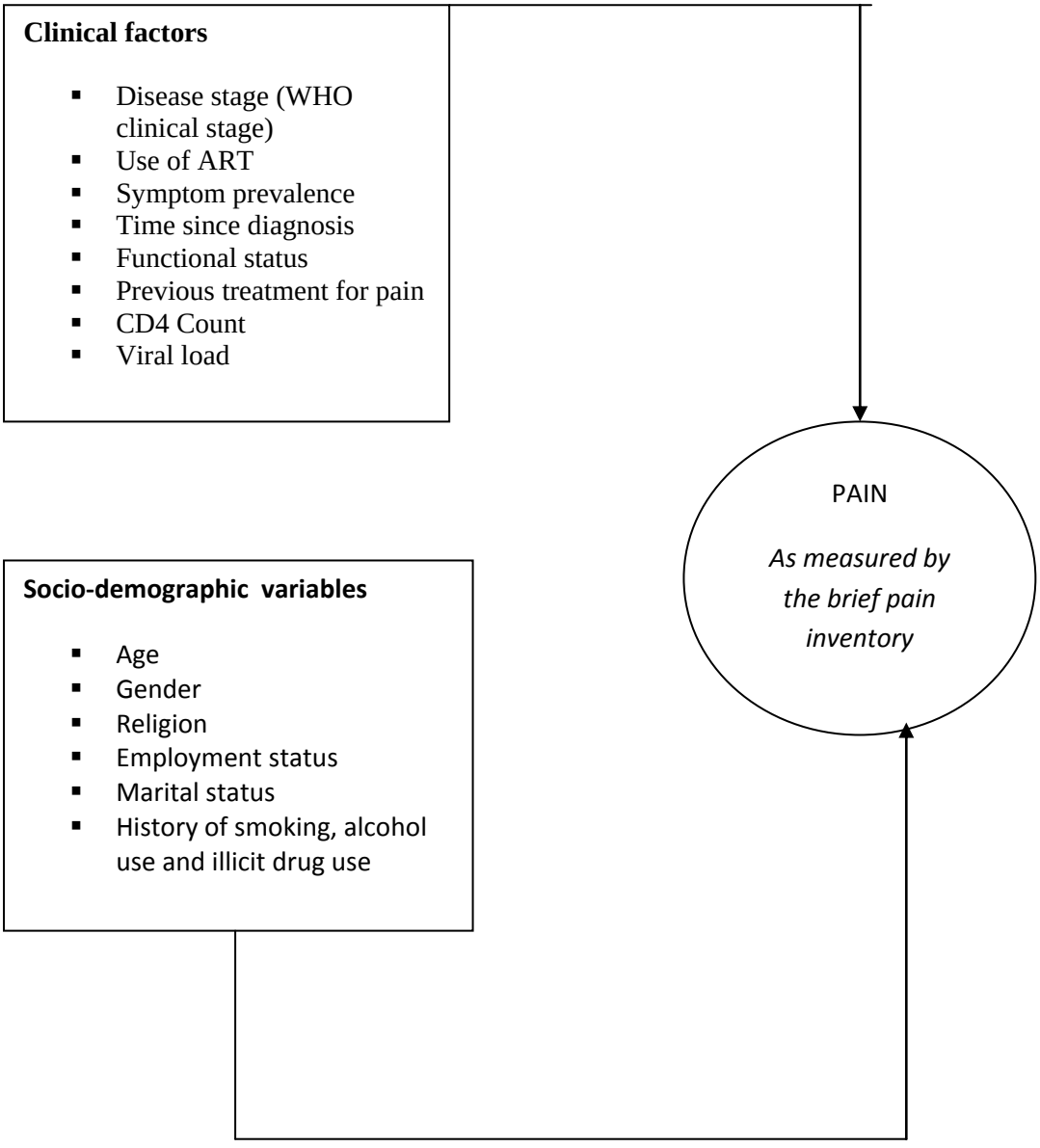
1.3 Significance

Surveys of HIV infected patients conducted else where have established that pain is highly prevalent, diverse in presentation, and is associated with significant psychosocial and functional morbidity [3]. In Uganda, there is limited information on pain in HIV infected patients, its diversity on presentation and impact has not been well studied, a challenge which this study will attempt to address. Findings will thus provide specific disease related markers for pain and establish the magnitude of the problem which is an important step in improving patient care and quality of life. Identifying components of quality of life that are significantly affected by presence of pain will be of great clinical value and worth targeting during treatment.

1.4 Conceptual framework

The conceptual framework below shows some of the predictors of pain in ambulatory AIDS patients. The factors range from socio-demographic to clinical.

Figure 1.1: CONCEPTUAL FRAMEWORK



CHAPTER TWO: LITERATURE REVIEW

Pain is an unpleasant sensory or emotional experience associated with actual or potential tissue damage or an experience described in terms of such damage.[11] Pain is classified in two major categories, nociceptive and neuropathic pain. Nociceptive pain derives from the stimulation of intact 'nociceptors' or pain receptors in afferent nerves and is further subdivided into somatic pain (involving skin, soft tissue, muscle and bone) and visceral pain (involving internal organs and hollow viscera). Noinceptive pain may be well-localized or more diffuse (common in visceral pain), and may be sharp, dull, aching, gnawing, throbbing, constant or spasmodic, with varying intensity. [19]

2.1 Prevalence of Pain in ambulatory AIDS Patients

Estimates of the prevalence of pain in AIDS generally range from 30 to 90 percent, with prevalence of pain increasing as the disease progresses[4]. A survey of ambulatory HIV-infected patients found that 38% prevalence of pain lasting a minimum of 2 weeks duration[12] .

In a study conducted in ambulatory HIV infected men, 28% asymptomatic seropositive men reported at least one painful symptom during the previous 6 months compared to 56% of patients diagnosed with AIDS- related complex and 80% of patients with AIDS. Most of the studies above relied on chart-review data and use of criteria for determining the presence of pain that are vague or overly broad. To redress these and provide a valid and detailed assessment of HIV-related pain in ambulatory setting this study will use validated measures of pain, functional status and symptoms.

2.2 Factors Associated With Pain in Ambulatory AIDS Patients

2.2.1 Pain and disease stage

The prevalence of pain has been found to increase with advancing disease. In a longitudinal study conducted in USA, it was found that pain was more likely to occur in later stages of HIV disease. The presence of pain was significantly associated with indices of disease progression including CDC category, antiretroviral therapy, and number of AIDS-related symptoms[4]. The study population was however strictly full blown AIDS and may not bring out a clear picture on pain prevalence in early stages of disease trajectory.

2.2.2 Pain and Functional Status

In a longitudinal study conducted in USA among ambulatory AIDS patients, subjects who reported two or more pains were significantly more disabled (81.9+-14.5) as measured by the *karnofsky* score, than subjects who reported one pain (91.4 +- 14.4) or no pain (95.9+-8.3 9 (p= 0.001)([4, 8]. This finding suggests a positive relationship between pain intensity and functional ability. The study was however conducted in a culturally different setting, thus findings may not blindly be extrapolated to the Ugandan setting given the role of culture in pain science.

2.2.3 Pain and Socio-demographic factors

Several patient characteristics have been identified through previous research as correlates of under treatment and thus intensity of pain in AIDS patients.

One study has suggested that women with HIV experience pain more frequently than men with HIV disease and reported somewhat higher levels of pain intensity, [13, 14]. A study conducted in USA showed that women and minority ethnic groups tend to report significantly

higher levels of pain intensity than men and other non-minority groups. It could be that they experience distinct patterns of HIV-related symptoms and illnesses or differential treatment of pain across the subject groups[8].

Although concerns are frequently raised that patients with a history of substance abuse may be prone to pain exaggeration, findings from previous research suggest that the concerns raised by clinicians treating pain in patients with a history of substance abuse may be over stated and need empirical verification [8]. There is thus needs for more evidence on the relationship between substance abuse and pain in HIV to inform clinical practice from an evidence based point of view.

2.2.4 Symptom prevalence in HIV/AIDS

The strongest indicator of impaired global quality of life in HIV-infected patients is the presence of various symptoms. A longitudinal study conducted in USA found a high prevalence (over 28% in the asymptomatic group, 56% AIDS-related complex group and 80% full blown AIDS group) of painful symptoms in a sample of HIV-positive volunteers suggesting a positive association between pain and symptom prevalence[4] . There is therefore evidence to suggest that the higher the number of symptoms, the greater the experience of distress and pain. Vogl et al explored 504 ambulatory patients with AIDS to assess symptom prevalence, characteristics and distress [7]. In this group, of the 32 symptoms assessed using the memorial symptom assessment short form, the mean number of symptoms reported was 16.7. Given the fundamental role of culture in symptom definition and reporting, the latter findings may not be directly extrapolated to different cultural settings thus the need for similar studies in our local context.

2.2.5 Pain and Quality of Life

Quality of life is now claimed to be one of the most important contemporary measures in health care [15] . While improvements in quality of life are often said to be associated with successful treatment for chronic and acute pain, the structure of quality of life in the place of pain has not be explored[6] . More so if this is the case that pain has a significant impact on quality of life generally, then this raises questions about whether some or all other components of quality of life are significantly affected by presence of pain. Identification of these areas could have a heuristic clinical value in targeting then during treatment.

CHAPTER THREE: METHODOLOGY

3.1 Study design

This was a cross-sectional study with both descriptive and analytic components employing quantitative methods of data collection.

3.2 Study setting

The study was conducted at two sites of AIDS outpatient clinics of Mulago National Referral Hospital, and Mbarara Regional referral Hospital between March and May, 2008. The Mulago National referral hospital is located approximately 2 kilometres from Kampala city centre. The patients who attend this clinic come from all over Uganda but the majority come from the Central region of Uganda. Mbarara Regional Hospital is located in Western Uganda about 3 kilometres from Mbarara town and it is the teaching hospital for Mabarara University of science and Technology medical school. Majority of the patients who attend this clinic come from the Western region of the country. Some of the patients who attend these clinics have been referred from other health units but others use it as their first point of contact with the health service. The Mulago Hospital clinic runs once a week on Friday and an average of 40 patients is seen on a typical clinic day, while the Mbarara Regional Hospital clinic runs 5 times a week and an average of 100 patients is seen on a typical day. The hospitals were chosen for this research because of their diverse patient population.

3.3 Population

The target population of this study was all ambulatory HIV/AIDS patients in Uganda. The accessible population of this study was all ambulatory HIV/AIDS patients attending the AIDS outpatient clinic in Mulago or Mbarara teaching and referral Hospitals between March and May 2008. The study population was all ambulatory HIV/AIDS patients attending the AIDS outpatient clinics that fulfilled the eligibility criteria and consented to take part in the study.

3.4 Eligibility Criteria

3.4.1 Inclusion criteria

All ambulatory HIV/AIDS patients aged 18 years and above attending Mulago or Mbarara Hospital AIDS outpatient clinics and consented to take part were included in the study.

3.4.2 Exclusion Criteria

Patients too ill to complete the questionnaires and those who could not comprehend English, Runyakitara or Luganda were excluded from the study.

3.5 Sampling Procedure

Study subjects from the AIDS clinic were selected using systematic sampling method by selecting every fourth patient after taking a random start.

3.6 Sample Size estimation

Sample size was estimated using the formula for prevalence studies

$$N = \frac{Z^2 * P(1 - P)}{D^2}$$

Where:

$Z_{\alpha/2}$ = was standard normal value corresponding to 95% confidence interval =1.96,

P = Estimated prevalence of pain in ambulatory HIV/AIDS patients (P= 0.35)

D = was the tolerable sampling error in the study (0.05)

N = Total number of subjects

Sample size after substitution = 350

3.7 Variables and Measurements

3.7.1 Independent variables

Socio-demographic: age, gender, previous use of alcohol / drugs and smoking habits

Clinical: CD 4 count, viral load, WHO clinical disease stage, use of HAART, prevalence of symptoms, function performance, and previous treatment for pain

3.7.2 Dependent variable

The dependent variable in this study was pain which was treated as a binary outcome to establish the factors associated with its presence and as a continuous outcome to establish the factors associated with pain intensity in the study population.

3.8 Measures

3.8.1 The Karnofsky Performance scale

This is an observer rated- scale used to report a patient's level of physical functioning ability. Patients are rated on a scale of 0-100, with 0 corresponding to no functioning ability (i.e. death) and 100 corresponding to complete, independent functioning.

3.8.2 Brief pain Inventory (BPI)

A self-report measure of pain intensity and pain-related interference that has been validated in AIDS populations(16). The BPI asks the patients to rate their pain intensity during the past week using a series of 11-ponit (0-10) numerical rating scales corresponding to current pain, pain "at its worst", pain "at its least" and pain "on average". Patients are also asked to rate using a familiar format the extent to which their pain interferes with seven aspects of their functioning (general activity, mood, walking ability, sleep, relations with others and enjoyment of life). The latter scales were summed to form an overall index of pain-related interferences.

3.8.3 Memorial Symptom Assessment Scale (MSAS)

This is a symptom checklist that elicits information about the intensity, frequency and distress associated with 32 physical and psychological symptoms. It has been validated for use in AIDS patients and generates an index of overall symptom distress (the global Distress Index or GDI), as well as two subscales that correspond to physical symptom distress and psychological symptom distress[(17).]

3.8.4 The Medical Outcome Scale –HIV (MOS-HIV)

The MOS-HIV instrument consists of 35 questions which assess 10 dimensions of health related quality of life including general perceptions, physical functioning, role functioning, pain, social functioning, mental health, energy, health distress, cognitive functioning, overall quality of life. In addition one item assesses health transition. The subscales of the MOS-HIV were scored as summated rating scales on a 0-100 scale where higher scores indicate better health. The MOS-HIV was developed in USA and is the most widely used HIV-targeted questionnaire(18). The MOS-HIV has been adapted and validated in Uganda and it has been found to be a valid and reliable quality of life measure in HIV patients (α>0.7) for all domains[19] .

3.9 Data collection

Data was collected by the PI with the help of 3 trained research assistants (health care workers) using standard measurement tools and according to guidelines laid out in the operations manual. Each health care worker recruited a maximum of 10 patients per day and thus data collection lasted three months. Written informed consent was obtained from each client before conducting the interview. To identify the sub group likely to have clinically significant pain, patients were asked whether during the past 7 days they had experienced persistent or frequent pain of any type. Those who answered yes affirmatively were given the BPI and then the other patients with or without pain were requested to complete all the other tools. After the interview, each questionnaire was crosschecked for any omissions and errors by a trained senior medical personnel. To avoid re-enrolment, the clients' code numbers were recorded and the lists were referred to each time a new client presented at the clinics. Also, self-report by clients was used to avoid re-enrolment.

3.10 Management

Questionnaires were checked at the end of each day for completeness and correctness. All data were edited, and double entered into Epi data version 7, alidated, cleaned then exported to STATA version 10 exported for analysis. All completed questionnaires will be stored under lock and key by the principal investigator for 7 years.

3.11 Data analysis

The MSAS and MOS-HIV data were scored according to appropriate scoring instructions before formal data analysis. 11 items on the MOS-HIV were accordingly so that higher scores indicate better health.

3.11.1 Univariate analysis

This was used to get the general description of the data. Categorical variables like gender, use of HAART were summarized into frequencies and percentages and displayed using bar graphs and pie chart. The continuous variables like, pain, quality of life, age, viral load and CD4 count were summarized into means, medians, standard deviation and ranges for description whereas histograms were used for display. The prevalence of pain was obtained by calculating the percentage of ambulatory HIV/AIDS patients who reported pain in the previous 7 days.

3.11.2 Bivariate analysis

3.11.2.1 Presence of pain and categorical variables

We assessed the association between presence of pain (pain and no pain) with each categorical independent variables using the chi-square statistic. The formula of the chi-square statistic is

$$\sum \sum \frac{\left(o_{ij} - e_{ij}\right)^2}{e_{ij}} \quad \text{.....3.1}$$

Where

o_{ij} is the observed frequency

e_{ij} is the expected frequency

Proportions were computed and variables that had p-values≤0.1 were entered into multivariate analysis. The t-test statistic was used to assess the association between pain and continuous variables like CD4 cell count and to compare symptom severity in pain and pain free groups.

Presence of pain and continuous variables

To assess the relationship between pain and continuous variables, single variable logistic regression analysis was performed and Odds ratios were used as the measure of association.

3.11.2.2 Pain intensity and categorical variables

To assess the association between pain intensity and each of the categorical variables, Analysis of Variance (ANOVA) was used. The analysis of variance takes the form;

$$y_{ij} = \mu + \alpha_i + \varepsilon_{ij} \quad \text{.....3.2}$$

Where

y_{ij} is the pain intensity

μ is the general mean

α_i is the pain intensity due to different levels of the factor

ε_{ij} is the error term

Means, F-statistic and p-values were computed and p≤0.05 was considered important at this level and entered into multivariate analysis.

Analysis of variance was further performed to assess the relationship between pain and quality of life, where the pain and pain free groups were compared across the various quality of life domains.

3.11.2.3: Correlates of pain intensity

To establish the functional correlates of pain intensity, correlation analysis was performed. The analysis was performed between pain intensity and other continuous variables like functional performance and a cut off of 0.5 was adopted to suggest strong linear relationship between the independent variable and pain intensity.

Correlation formula

$$r_{xy} = \frac{s_{xy}}{s_x s_y} \quad \text{.....3.3}$$

Where

s_{xy} is the covariance of continuous variable and pain intensity

s_x is the standard deviation of any of the continuous variable

s_y is the standard deviation of the pain intensity.

3.11.2.4 Relationship between pain and quality of life

Analysis of variance using the F test was further performed to assess the relationship between pain and quality of life, where pain and pain free groups were compared across the various quality of life domains.

3.12 Multivariate analysis

Logistic regression and stratified analysis were used where pain was treated as a binary outcome (presence/absence).

3.12.1. Assessment for interaction and confounding

Stratified analysis was used to assess for confounding and interaction and variables to be used in the stratified analysis were based on a review of relevant literature [8-11]. Factors with a difference in stratum specific odds ratios and with significant p-value for test of homogeneity were considered to interact. Factors for which there was no interaction were assessed for confounding. A difference of at least 10% between adjusted odds ratio and the crude odds ratio was considered confounding.

3.12.2 Factors associated with presence of pain

To assess the factors associated with presence of pain (pain and no pain) a logistic regression model was used. Odds ratios, confidence intervals and p-values were computed for each of the variables and a variable with $p \leq 0.05$ was considered important in explaining presence of pain. The backward elimination method – 'Likelihood ratio test was used to determine the final multivariate model with a removal level of significance of $p<0.10$. Sensitivity of the results was assessed for consistence using the forward selection method.

The formula of the logistic regression is represented below

$$\log\left(\frac{p_i}{1-p_i}\right) = b_0 + b_1 x_1 + b_2 x_2 + \ldots\ldots + b_k x_k + \varepsilon_i \quad \ldots\ldots\ldots\ldots 3.4$$

p_i is the probability of having pain

x_i is a particular explanatory variable

b_i is the coefficient for each variable above

ε_i is the error term

3.12.3 Diagnostic tests after the model

3.12.3.1 Specification Error

The –hat and -hatsq statistics were used as the predictors to rebuild the model. The variable –hat was used to test whether the variables in the model were statistically significant predictors of treatment outcome and –hatsq was used to establish whether there were, some relevant variables left out in the model.

3.12.3.3 Goodness -of –fit

The goodness of fit of the model was measured using Hosmer-Lemeshow goodness of fit statistic. The Hosmer-Lemeshow goodness of fit statistic was computed as the Pearson chi-square from a contingency table of observed frequencies and expected frequencies. The model was considered to be fitting the data well if the Hosmer- Lemeshow probability is large.

3.12.2 Predictors of pain intensity

To establish the factors associated with pain intensity a multiple linear regression analysis was performed . Dependent variables with p-values equal to or less than 0.2 at bivariate level were into a multiple linear regression model to determine the most parsimonious set of variables that predicted pain intensity. Beta coefficients, p-values and confidence intervals were computed for each of the predictors.

The formula of the multiple regression model is presented below

$$Y_{it} = b_o + b_1 x_1 + b_2 x_2 + \ldots\ldots + b_k x_k + \varepsilon_i \quad \ldots\ldots 3.5$$

Where:

y_i is the pain intensity

b_i are the coefficients to be estimated

x_i are the potential predictors

ε_i is the error term

Coefficients, p-values and confidence intervals were computed for each of the predictors and predictors with $p \leq 0.05$ were considered important in explaining pain intensity.

3.12 Quality control

The following procedures was undertaken by the principal investigator to ensure quality control: 1) Training of research assistants, 2) Pretesting and standardization of study instruments, 3) An operations manual was prepared and given to each research assistant, 4) Data entry on daily basis in Epi-data, 5) Data cleaning and editing, 6) Double entry and validation of data to minimize errors.

3.13 Ethical Considerations

Ethical approval was obtained from the Institute of Statistics and Applied Economics, Mulago Hospital Research and ethics committee and Mbarara Regional Hospital ethics committee. Permission to use the respective instruments was sought from the respective authorities for this study. Written informed consent was obtained from patients as they came to the out patient clinics.

CHAPTER FOUR: RESULTS

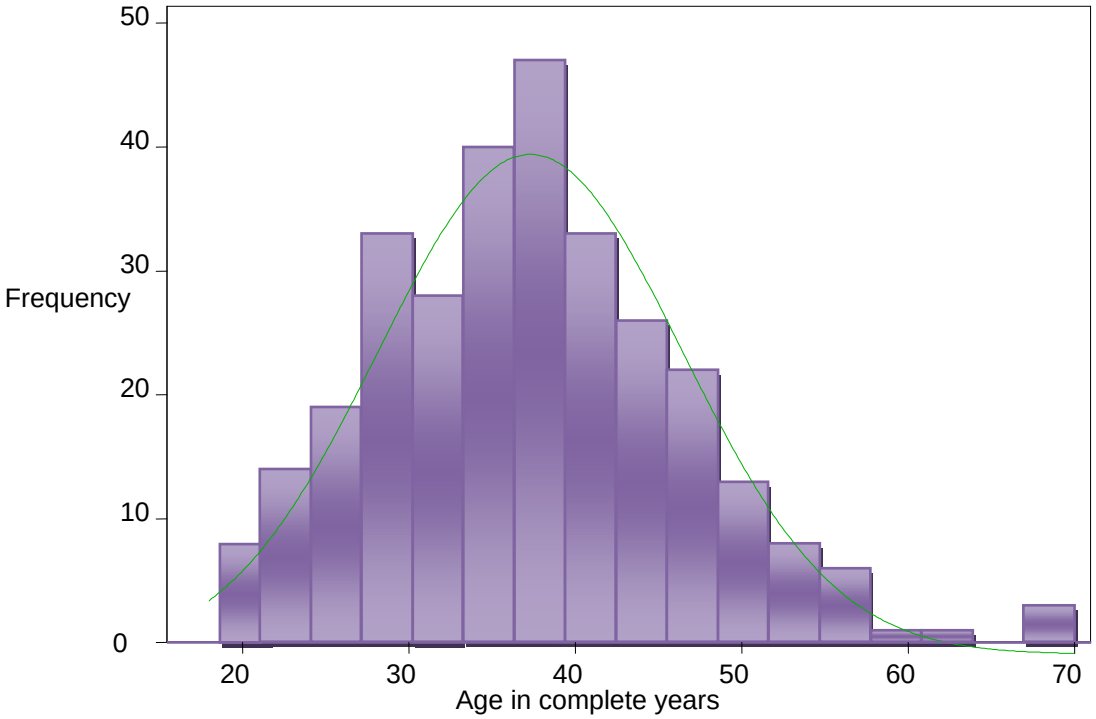
4.1 DESCRIPTION OF THE STUDY POPULATION

Between April and July 2008, a total of 302 ambulatory HIV/AIDS patients aged 18 years and above were interviewed to establish the prevalence of and factors associated with pain in ambulatory HIV/AIDS patients.

4.2 Socio-demographic characteristics

4.2.1 Age of Respondents

Figure 4.1: Age distribution of 302 ambulatory HIV/AIDS patients



The respondents were aged between 18-70 years and their age was normally distributed as shown in figure 4.1 above.

4.2.2 Gender of respondents

The majority of the respondents were female comprising 194 (64.2%) of the participants.

4.2.3 Marital status of the respondents

142(47.0%) of the respondents were married, those that were single comprised 30 (10.0%) of the study sample while 70 (23.0%) were widowed and 60 (20.0%) were divorced or separated.

4.2.4 Highest level of Education

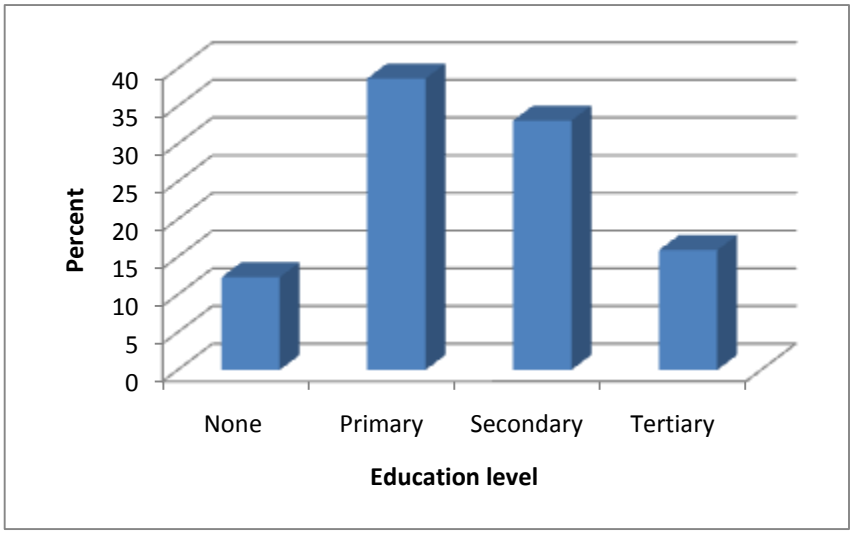


Figure 4.2 Highest education level attained by respondents

Respondents with primary education as the highest level of education attained comprised the 117(38.7%) of the study population 117 (38.7%) while only 48 (15.9%) had attained tertiary education. Highest education level attained by respondents is summarised in figure 4.2.

4.2.5 Current smoking status of the respondents

The majority of the respondents were non-current smokers 285 (94.4%).

4.2.6 Use of alcohol status

Non current users of alcohol comprised the biggest proportion of the study population 264(87.4%).

4.2.7 Religion

Of the 302 respondents recruited into the study, 166(55.0%) were Anglican, 75(24.8%) were Roman Catholic, 38(12.6%) were Muslim while 23(7.6%) were Pentecostals.

4.2.8 Current Occupation of respondents

Respondents who reported no having an occupation comprised 138 (45.7%) of the study sample while 47 (15.7%) were involved in business. Salaried employees were 71 (23.5%) and non-professionals were 46(15.2%).

4.3 Clinical characteristics

4.3.1 CD4 count

Of the 302 respondents recruited into the study, 147 (48.7%) had CD4 counts ranging between 201-499cell per mm^3, 75(24.8%) had CD4 counts less than 200 and 57(18.9%) had CD4 counts above 500 cells per mm^3. 23(7.6%) did not know their most recent CD4 count.

4.3.2 *Karnofsky* performance score

Majority of the respondents had *karnofsky* performance scores above 70%, 264(87.4%).

4.3.3 Use of ARVs

The majority of the respondents were on ARVs comprising 224(74.2%) of the study participants.

4.3.4 WHO clinical Stage

164(54.3%) the respondents were in clinical stage three, 69 (22.9%) were in WHO clinical stage two while 53 (17.6%) were in stage four and 16(5.3%) in clinical stage one.

4.4 Prevalence of pain

Of the 302 ambulatory HIV/AIDS patients interviewed, 143 reported having had pain other than everyday kinds of pain like minor headaches, sprains and toothaches. Thus the prevalence of pain was 47%. Of those reporting pain 13.9% reported having pain on the head, 19.1% chest, 17.8% abdomen, 12.1% back, 10.4% legs, arms/hands 6.1%, thighs 6.5% feet 3.5%, thorax 3.0%, anogenital/pelvic 5.2% neck 2.6%.

4.5 Characteristics of pain

The following descriptive data is based on the sub-sample of 143 that reported pain in the previous seven days prior to the study. On the 0-10 numeric scale rating, the mean ratings for pain on average, at its least and its worst were 5.01, 4.41 and 7.23 respectively, Table 4.1).

Table 4.1: Pain and pain interference scores

Score description	Mean	SD	Range
Pain intensity on average	5.01	1.72	2-10
Pain intensity at its least	4.41	1.72	1-10
Pain intensity at its worst	7.23	1.91	2-10
Pain intensity right now	4.47	2.39	0-9
Pain interference scores on;			
General activity	6.57	2.39	0-10
Mood	5.07	2.50	0-10
Walking ability	5.63	3.10	0-10
Normal Work	5.90	2.74	0-10
Relations with other people	3.20	3.30	0-10
Sleep	4.13	3.89	0-10
Enjoyment of life	5.41	3.47	0-10
Broad domain Interference scale scores			
Pain-related functional interference	5.18	2.57	0.43-9.60
Pain related Activity interference	6.03	2.47	0-10
Pain related Mood interference	4.61	2.82	0-10

4.5.1 pain intensity ‘on average’ and seven different domains of pain related functional interference

Using ‘on average’ pain ratings to classify pain intensity into mild (rating of 0-4), ‘moderate’ (5-6), and ‘severe’ (7-10) categories, figure 4.3 demonstrates the relationship between pain interference items on the BPI and pain intensity.

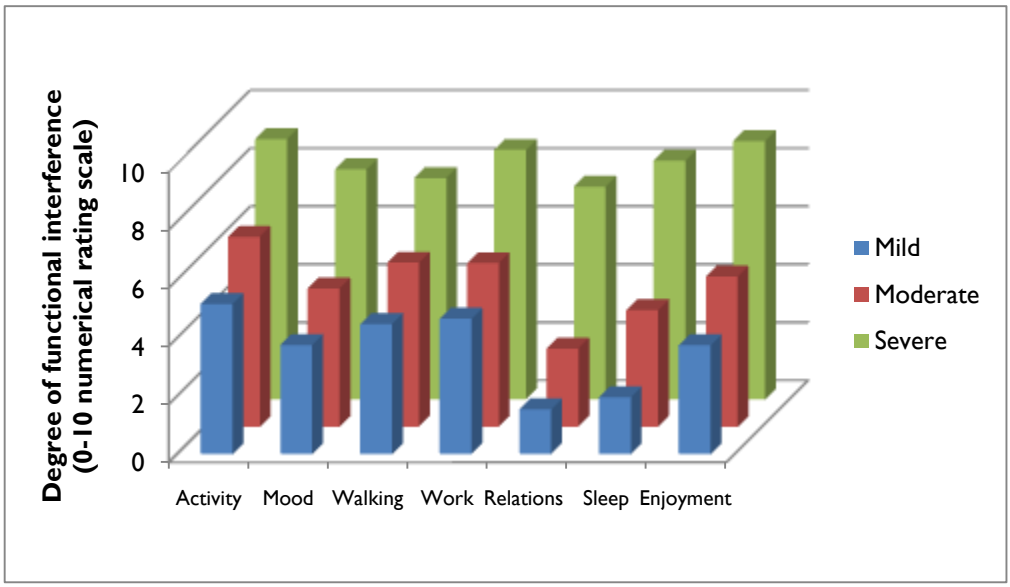


Figure4.3: Relationship between pain intensity on average and domains of the pain interference function

4.5.2 ‘Mild’ pain interference and Brief pain inventory functional interference subscales

Patients with mild pain (number of observations is 52) reported mean pain interference scores ranging from 1.54-5.17. For these patients with ‘mild’ pain, pain interfered most with general activity (mean 5.17, SD 2.31) and normal work (mean 4.48 SD 2.99) (Table 4.2).

Table 4.2: "Mild" Pain interference scores across the seven BPI items of function

Item	Mean score	SD	Range
General activity	5.17	2.31	0-10
Mood	3.75	2.21	0-9
Walking	4.48	2.29	0-10
Normal work	4.67	2.41	0-10
Relations with people	1.54	2.09	0-8
Sleep	1.96	3.03	0-9
Enjoyment of life	3.75	2.92	0-10

4.5.3 'Moderate' pain interference and Brief pain inventory functional interference subscales

Patients with 'moderate' pain (number of observations is 61) reported reasonably high levels of interference across each domain except relations with scores ranging from 4.02-6.54. For these patients, pain interfered most with general activity (mean 6.54) and walking ability (mean 5.66), Table 4.3.

Table 4.3: "Moderate" pain scores for pain interference across BPI items of function

Item	Mean score	SD	Range
General activity	6.54	1.68	3-10
Mood	4.77	1.99	0-9
Walking	5.66	2.69	0-10
Normal work	5.64	2.34	0-10
Relations with people	2.69	2.76	0-10
Sleep	4.02	3.53	0-10
Enjoyment of life	5.18	3.28	0-10

4.5.4 ‘Severe’ pain interference and Brief pain inventory functional interference subscales

Patients with ‘severe’ pain reported greater pain interference across all domains of functioning (range 7.33-8.97). For this group pain interfered most with general activity, enjoyment of life, working ability and sleep , means 8.97; 8.90, 8.60; and 8.23 respectively, (Table 4.4) (number of observations = 30).

Table 4.4: "Severe" pain interference across the seven BPI items of function

Item	Mean score	SD	Range
General activity	8.97	1.77	4-10
Mood	7.93	1.311	4-10
Walking	7.63	3.06	0-10
Normal work	8.60	2.13	1-10
Relations with people	7.33	2.35	0-10
Sleep	4.23	2.28	0-10
Enjoyment of life	8.90	1.86	4-10

4.6 Symptom prevalence

On average patients reported a mean 12.04 symptoms (SD 5.616, range 4-30). The most prevalent symptoms were worry, feeling sad, hunger and nervousness which were endorsed by 94.4%, 91.7% , 82.5% and 75.2% of the 302 patients respectively (Table 4.5). On the MSAS, patients rated their symptom distress (MSAS physical symptom distress subscale score) as 1.293 (SD 0.683, range 0.125-3.670). Pain was excluded from MSAS score computations.

Table 4. 5: Symptom prevalence

Symptom	Yes	Percentage
Physical symptoms		
Difficulty concentrating	136	45.0
Lack of energy	182	60.3
Cough	94	31.1
Changes in skin	67	22.2
Dry mouth	106	35.1
Nausea	69	22.8
Feeling drowsy/tired	187	61.9
Numbness in hands/feet	48	15.9
Difficulty sleeping	104	34.4
Feeling bloated	84	27.8
Problems Urinating	19	6.3
Vomiting	30	9.9
Shortness of breath	27	8.9
Diarrhoea	37	12.3
sweats	115	38.1
Mouth sores	40	13.2
Problems with sexual interest	86	28.5
Itching	82	27.2
Lack of appetite	126	41.7
Dizziness	92	30.5
Difficulty swallowing	33	10.9
Changes in way food tastes	67	22.2
Weight loss	88	29.1
Hair loss	31	10.3
constipation	63	20.9
Swelling of arms or legs	33	10.9
“I do not like myself”	75	24.8
Sores or lumps on private parts	18	6.0
Discharge from private parts	46	15.2
Bad smell/odour	26	8.6
Difficulty moving	46	15.2
Difficulty walking	88	29.1
Muscle aches	55	18.2
Difficult hearing well	26	8.6
Difficult seeing well	49	16.2
Hunger	249	82.5
Psychological symptoms		
Feeling sad	277	91.7
Worrying	285	94.4
Feeling irritable	134	44.4
Feeling nervous	227	75.2

4.7 Symptom distress indices among the pain and pain free groups

The mean scores for global distress, physical distress and psychological distress are shown in (Table 4.9),. Patients reporting pain in the previous seven days prior to the study reported more global, physical and psychological distress.

Table 4.6: symptom distress scores

	Mean(SD)	
Distress indices	**Pain (n=143)**	**No pain(n=159)**
Global distress	1.56(0.81)	1.06(0.42)
Physical distress	0.99(0.78)	0.522(0.30)
Psychological distress	1.62(0.97)	1.01(0.47)

4.8 Bivariate analysis

4.8.1 Association between pain and socio-demographic variables

More males reported pain as compared to females however the association between gender and presence/absence of pain does not achieve statistical significance (Table 4.7). Pain was also more prevalent among those who had attained secondary education and least among the uneducated although the relationship between education level of the patient and presence/absence of pain does not achieve statistical significance. Other details are shown in Table 4.7.

Table 4.7: Relationship between socio-demographic variables and presence/absence of pain

Variable	Pain n (%)	No pain n (%)	χ^2	p-value
Gender				
Female	87(44.9)	107(55.1)	1.366	0.242
Male	56(51.9)	52(48.1)		
Religion				
Anglican	79(47.6)	87(52.4)		
Catholic	36(48.0)	39(52.0)	0.123	0.989
Moslem	17(44.7)	21(55.3)		
Other	11(47.8)	12(52.2)		
Marital status				
Single	14(46.7)	16(52.3)		
Married	68(47.9)	74(52.1)	0.121	0.989
Widowed	32(45.7)	38(54.3)		
Separated	29(48.3)	31(51.7)		
Education level				
None	12(23.4)	25(67.6)		
Primary	58(49.6)	59(50.4)		
Secondary	54(54.0)	46(46.0)	6.469	0.091
Diploma/degree	19(39.6)	29(60.42)		
Current smoking status				
Smoker	11(64.7)	6(35.3)		
Non-smoker	132(46.3)	153(53.7)	2.17	0.21
Use of alcohol				
Yes	19 (50.0)	19(50.0)	0.122	0.73
No	124 (47.0)	140 (53.0)		
Age				
18-35	61 (45.9)	72(54.1)	0.211	0.646
36+	82(48.5)	87(51.5)		

4.8.2 Association between presence/absence of pain and categorical clinical factors

Pain was more prevalent among those in clinical stage 4 and least among those in clinical stage 2. The association between pain and WHO clinical stage achieved statistical significance (Table 4.8).

Table 4.8: Association between categorical clinical variables and presence/absence of pain

Variable	Pain	No-pain	χ^2	p-value
WHO clinical stage				
1	7(43.7)	9(52.3)		
2	29(42.0)	40(58.0)	13.025	0.004*
3	70(42.7)	94(57.3)		
4	37(69.8)	16(30.2)		
Use of ARVs				
Yes	107(47.8)	117(52.2)		
No	36(46.1)	42(53.9)	0.061	0.806

*significant

4.8.3: Association between presence/absence of pain and continuous clinical factors

Increasing levels of psychological distress increased the odds of pain by 3.3 while increased physical symptom distress was also associated with 6 fold increase in the odds of pain. The presence of symptoms was associated with a 1.4 fold increase in the odds of pain (Table 4.9).

Table 4.9 : Single variable logistic regression analysis results for continuous factors and presence of pain

Variable	Odds ratio	p-value	95%CI
Time since diagnosis	0.998	0.311	0.993-1.000
Most recent CD4 count	0.999	0.240	0.998-1.000
Psychological distress	3.291	<0.001*	2.193-4.940
Physical symptom distress	5.933	<0.001*	3.199-11.004
Number of symptoms	1.356	<0.001	1.246-1.476

*significant p values

4.9 Correlates of pain intensity

Number of HIV-related symptoms was significantly associated with pain intensity, ($r = 0.63$, $p < 0.001$,) as was physical symptom distress (MSAS physical symptom distress subscale score, $r = 0.66$, $p<0.001$) as well as psychological distress. No correlation was observed between age and time since diagnosis and pain intensity (Table 4.10).

Table 4. 10: Correlation Analysis results for pain intensity and other independent variables

Variable	r	P value	Shared variance (%)
Age (years)	-0.06	0.435	0.36
# of symptoms	0.63	<0.001*	39.69
CD4 count($mm^{3)}$	0.14	0.095	1.96
Time since diagnosis(months)	0.08	0.344	0.64
Physical symptom distress	0.66	<0.001*	43.56
Psychological distress	0.62	<0.001*	38.44

*significant p- values

4.10 Factors associated with pain intensity

As illustrated in Table 4.11, use of ARVs, WHO clinical stage and marital status were significantly associated with pain intensity (Table 4. 11).

Table 4. 11: comparison of patients across pain intensity "on average" scores

Variable	Mean	F	p-value
Gender			
Female	5	0.19	0.59
Male	5		
Religion			
Anglican	5		
Catholic	5	2.27	0.082
Muslim	6		
Others	6		
Marital status			
Single	6		
Married	5	2.99	0.03*
Widowed	5		
Separated	5		
Education level			
None	5		
Primary	5	2.16	
Secondary	5		0.095
Diploma/degree	6		
Use of ARV			
Yes	5		
No	5	3.92	0.049*
WHO clinical stage			
1	4		
2	4		
3	5	8.56	<0.001*
4	6		

***significant p values

4.11 Relationship between pain and quality of life

Table 4.12 shows that the pain free group reported significantly higher scores on all domains of quality of life as compared to the pain group. The physical and role domains seem very important in discriminating between the pain and pain free groups as shown by the very big and significant F statistic values 103.46 and 101.75 respectively Table 4.12.

Table 4.12: Comparison of pain and pain free group across domains of quality of life

Quality of life domain	Group means		F	P value
	No Pain (n=159)	Pain (n=143)		
Overall well being	59.28	42.83	68.65	<0.001*
Physical function	90.67	61.94	103.46	<0.001*
Role	88.05	44.41	101.75	<0.001*
Social function	91.19	69.15	40.75	<0.001*
Mental Health	81.60	63.51	52.38	<0.001*
Energy	67.06	51.79	51.70	<0.001*
Health distress	77.83	63.53	28.07	<0.001*
Cognitive	76.76	61.35	43.93	<0.001*
General Health	46.80	50.41	4.8	0.029*
Health Transition	63.99	48.43	37.81	<0.001*

*significant p values

4.12 Functional correlates of pain and pain intensity

4.12.1 Functional correlates of pain

Patients with pain reported significantly lower functional performance as measured by the *karnofsky* performance scale than patients without pain t (df(300) =11.206, p <0.001) .

4.12.2 Functional correlates of pain intensity

Pain intensity on average significantly correlated with Functional performance (number of observations = 143, r= -0.659, p<0.001)**.** There was also significant correlation between pain intensity on average and pain related interference (number of observations =143 r=0.624, p<0.001), Table 13.

Table 4. 13: Correlation Analysis results for pain intensity and other independent variables

Variable	r	P value	Shared variance
Function	-0.659	<0.001*	0.434
BPI pain interference index	0.624	<0.001*	0.389
General activity	0.546	<0.001*	0.298
Mood	0.568	<0.001*	0.323
Walking ability	0.400	<0.001*	0.160
Normal work	0.500	<0.001*	0.250
Relations with people	0.599	<0.001*	0.359
Sleep	0.576	<0.001*	0.332
Enjoyment of life	0.533	<0.001*	0.284

*****significant p values

4.13 Results of Multivariate Analysis

After bivariate analysis, independent factors that had significant relationship with presence/absence of pain were considered for multivariate analysis. Stratified analysis and logistic regression were used for multivariate analysis in those instances where pain was looked at as binary outcome. In those instances where pain was analysed as a continuous variable in terms of intensity, multiple linear regression analysis was used for multivariate analysis.

4.13.1 Results of stratified analysis

There was significant interaction between number of symptoms reported and physical symptom distress as well as between gender and number of symptoms reported. The association between presence of pain and physical symptom distress was five times stronger among the group that reported 9+ symptoms as compared to those that had 0-8 symptoms, Table 4.14.

Table 4.14: Stratified analysis results with presence of pain as the outcome

Variable	Stratum 1 OR	Stratum 2 OR	*mOR	^cOR	H test ~p~ values	comment
Number of symptoms	**4-8**	**9+**				
Physical symptom distress	0.641	3.14		5.933	0.016	Interaction
WHO clinical stage	1.715	1.378	1.431	1.323	0.08	
Sex	1.310	1.822	*1.693*	1.324	0.047	
Sex	**Males**	**Females**				
Number of symptoms	7.565	5.438	6.234	5.7805	0.632	confounding
Physical symptom distress	2.844	4.177	3.327	3.366	0.3055	
WHO clinical stage	**1/2**	**3/4**				
Number of symptoms	6.966	5.598	5.901	5.781	0.070	
Physical symptom distress	9.601	2.978	3.332	3.366	0.062	

*mOR**(** Mantel Haenszel Odds Ratio), ^COR (crude Odds Ratio), H-test (Homogeneity test)

Table 4.15: Link test results for the final logistic model

Statistic	coefficient	P value	95% CI
-hat	1.129	<0.001*	0.736-1.522
-hatsq	0.238	0.109	-0.054-0.531

*Hosmer-Lemeshow chi2 (8) = 8.40, Prob = 0.4231, *significant p-values*

The significant –hat test result and insignificant –hatsq results provide evidence for good model specification (Table 4.15).

4.13.2 Factors associated with presence of pain

Table 4.16 presents factors that were associated with presence of pain in the final model; the interaction terms were not significant in the final adjusted model and were thus dropped. After controlling for the effect of sex and disease stage, HIV/AIDS patients reporting 9+ symptoms were 3.3 times as likely to have pain as compared to those reporting 4-8 symptoms. Any unit increase in physical symptom distress was associated with a 3.6 fold increase in the likelyhood of presence of pain (OR 3.6, 95% CI 1.86-7.06).

Table 4.16: Logistic regression results of factors associated with presence of pain in 302 ambulatory HIV/AIDS patients

Variable	frequency	OR	95% CI	p-value
Predictors of pain				
Number of symptoms				
4-8	83	1.00		
9+	219	3.30	1.68- 6.52	0.001*
Physical symptom distress		3.63	1.86-7.06	<0.001*
Confounders				
Sex				
Male	108	1.56	0.90-2.70	0.116
Female	194	1.00		
WHO clinical stage				
1	16	1.00		
2	69	0.85	0.27-2.72	0.789
3	164	1.019	0.34-3.03	0.972
4	53	1.520	0.43-5.34	0.514

*significant p values

4.14 Predictors of pain intensity

Physical symptom distress and single marital status were significantly associated with pain intensity in multivariate regression analysis Table 4.17. The model explained 50 % of the variation in pain intensity “on average” (F19.51, P<0.001).

Table 4.17: Multiple regression analysis results for factors associated with pain intensity on average for 143 ambulatory HIV/AIDS patients

Variable	coefficient	t	p-value	95% CI
Physical symptom distress	1.313	7.93	<0.001*	0.985 - 1.641
WHO clinical stage 2	-0.387	-0.73	0.466	-1.435 - 0.661
WHO clinical stage 3	0.241	0.48	0.466	-0.745 - 1.228
WHO clinical stage 4	0.447	0.81	0.422	-0.650 - 1.544
Single marital status	0.958	2.30	0.023*	0.014 - 1.781
Widowed marital status	-0.246	-0.90	0.367	-0.783 - 0.291
Divorced/separated marital status	-0.004	-0.01	0.989	-0.647 - 0.638

*Significant p values

CHAPTER FIVE: DISCUSSION

5.0 Major findings

Pain and discomfort are found to be of great importance in the subjective assessment of quality of life which is the most important outcome in the care for people living with life threatening illnesses like HIV.

Despite lack of awareness of pain as a consequence of HIV infection, the notably high prevalence (47%) of pain experienced by the patients in our sample was comparable to that typically found in patients with cancer.[8, 16, 20]. Similar studies conducted in Europe and America have even reported higher prevalence levels[4, 5, 8] and this could be because they used a wider period prevalence (14 days) as compared to the 7 days reference period. This finding suggested that indeed the need for proper pain assessment and management in HIV is not very different from the need in cancer care as commonly perceived.

In our analysis the HIV/AIDS population who were receiving treatment for pain reported the treatment to be providing only 68% relieve, suggesting some relative degree of under treatment of pain in HIV. Similar findings were reported in an AIDS outpatient population in a study conducted in the UK.[8] This finding may thus provide further evidence to what previous scholars have advanced that pain in HIV is largely under treated despite the existence of the WHO analgesic ladder to support pain treatment efforts.

The presence of pain was not associated with the several indices of disease progression including WHO clinical stage, time since diagnosis and use of antiretroviral therapy. This lack of association between pain and either CD4count or time since diagnosis is consistent with the clinical observation that the latter factors often appear to be unrelated to severity of HIV disease.[8] Thus although pain appears to be a common consequence of HIV disease and appears to correspond to overall severity of disease, specific markers like CD4+ cell count for the onset of painful symptoms were not found. Pain was prevalent even among HIV/AIDS patients who were relatively a symptomatic demonstrating that even those patients with less advanced disease frequently experience pain.

Further more the proportion of variance explained by our predictive model was modest (r = 0.50, indicating that pain is a complex experience which can only partially be explained by the variables we examined in this study.

Another important finding is that pain in the immediate past has a substantial impact on a person's quality of life, 47% of the sample were in pain in the previous 7 days before completing the brief pain inventory and had notably lower mean scores across all domains of quality of life than those who were not in pain during this period. An implication here is that the quality of life for those in pain is best improved through immediate treatment, without delay. This is supportive evidence for key findings in primary care that demonstrate how damaging treatment delays can be to physical and psychological well-being of pain suffers. [(21)] The casual relationship could not be established from this study but either pain in immediate past creates substantial erosion of quality of life across a wide range of domains or else this decrement enhances the pain patients feel.

Patients with pain reported high levels of pain-related functional interference which increased as pain intensity increased, suggesting that pain greatly impacts on patients' functional capacity and all other aspects of quality of life. This may explain why quality of life pertaining to mobility and activities of daily living have been found to be of great importance in predicting pain and discomfort. [6]) Our findings are consistent with what has been reported in cancer populations , suggesting a relatively similar impact of pain on patient outcomes in malignant and non-malignant conditions.

The relatively high correlation between pain intensity and psychological distress throws more light on the existence and critical importance of the emotional properties of pain which are well documented in the pathophysiology of pain. This finding suggests that pharmacological, surgical and psychological treatments aimed at relieving the suffering described by affective pain could provide most satisfactory therapy if improving quality of life is a major goal.

5.1 Other findings

Although some previous studies found no association between immune status a known predictor of future disease progression and functional deterioration [3, 4], we found an association between number of symptoms reported and immune status. This was in agreement with findings from another large survey of AIDS patients discerned a significant inverse relationship between the frequency of 6 symptoms and CD4+ cell count. (14). The previous study could have minimised differences among patients with varying lymphocyte count by selecting only AIDS outpatients with similar functional status.

5.2 Conclusions and recommendations

Our data supports several conclusions about pain in HIV and AIDS. First the notably high prevalence of pain among patients with HIV/AIDS and lack of specific disease-related markers for pain underscore the need for increased focus on identifying the presence of pain.

The relationship between pain intensity and functional abilities suggests the importance of adequate pain management. In particular, the aspects of functioning that appeared most sensitive to interference from pain were psychological and functional. Pain also greatly affects quality of life of HIV/AIDS patients and the effect cuts across all domains further emphasising the great need for adequate pain management in HIV.

Our findings also suggest a significant physical and psychological burden among HIV/AIDS patients. It is thus essential that quality management of HIV disease addressed these distressing problems. The notably high prevalence of psychological symptom burden also sheds light on the need for treatment strategies that should preferably be implemented through integrated patient management between HIV clinicians, pain and symptom management specialists as well as psychosocial service providers.

Patient rated measures of pain and symptom distress, like the MSAS and the BPI provide invaluable information about a critical aspect of quality of life. This information may be useful in clarifying the need for change in clinical practice and in clinical trails of new therapies.

5.2 LIMITATIONS

Pain related functional impairment relied on self- report measures. Although we attempted to minimise bias by recruiting patients without revealing the emphasis on pain and informing patients that no treatment was offered in conjunction with this study, the possibility of reporting bias cannot be excluded.

Potential biases may have inflated the prevalence of distress associated with some symptoms because the MSAS is a patient rated instrument, reporting bias may have affected prevalence rates or distress scores. Patients were however informed that no treatment was being offered in conjunction with this survey, which could have reduced the level of reporting bias.

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List of appendices

1 socio-demographic questionnaire

PATIENT ID ……..

Date: ☐☐☐☐☐☐

P1. Please indicate the patient's Gender ☐

1 Male

2 Female

P2. How old are you? (years) ☐☐

P3. What is your highest level of education? ☐

None=1

Attended primary=2

Attended secondary=3

Diploma=4

Degree or higher=5

P5. Religion

1 Anglican

2 Catholic

3 Muslim

4 Pentecostal

5 other (specify)

P7. Do you currently drink alcohol?

1 Yes

2 No

P8. Which type do you normally drink?

1 Beer
2 Waragi
3 Local brew
4 . Whisky
5 Other (specify)
6 7(N/A)

P9. How often do you drink a week?

1 1-3 times

2 4-5 times

3 > 5times

7 Not applicable

P10. How many bottles do you drink a week?

1 1-5 bottles

2 6-12 bottles

3 > 12 bottles

7 Not applicable

P11. For how long have you been drinking? ☐

1 1-5 years

2 6-12 years

3 > 12 years

7 Not applicable

P12.Do you smoke? ☐

1 yes

2 No

P13. How many cigarettes do you smoke a day? ☐

1 1-5 cigarettes

2 6-12 cigarettes

3 > 12 cigarettes

7 (N/A)

P14. For long have you been smoking? ☐

1 1-5 years

2 6-12 years

3. > 12 years

7 Not applicable

P15. Do you use any drugs like cocaine or marijuana? ☐

1 yes

2 No

P16. For how long have you been using the drugs? ☐

1 1-5 years

2 6-12 years

3 12 years

7 (N/A)

HIV Diagnosis History

P17. Are you ART/HAART? ☐

1 yes

2 No

P18.Date diagnosed HIV + dd/mm/yy

unknown day= 15, unknown month= 06, unknown year enter 08/08/8888

P19.What date started on ARV treatment **dd/mm/yy**

unknown day= 15, unknown month= 06, unknown year enter 08/08/8888

777777=not on ARV

P20. Current WHO clinical stage (1-4) **8=don't know** ☐

P21. Most recent CD4 count **don't know=8888** ☐☐☐☐

22. date of most recent CD4 count **dd/mm/yy**

unknown day= 15, unknown month= 06, unknown year enter 888888

P21. Most recent viral load **don't know=8888** ☐☐☐☐

P22. date of most recent viral load **dd/mm/yy**

☐☐☐☐☐☐

unknown day= 15, unknown month= 06, unknown year enter 08/08/8888

2 B1. Brief Pain Inventory (Short Form)

Study ID#_____ Hospital#_____

Do not write above this line

Date:____/____/____

Time:_____

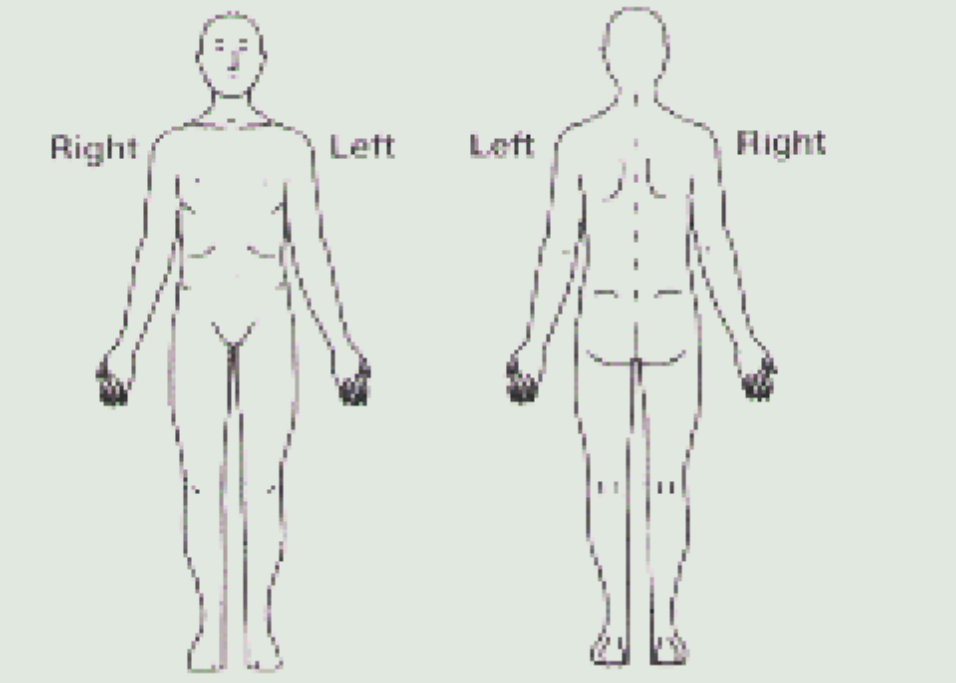
Name:_____

Last First Middle Initial11

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain Over the past 2 weeks+ ?

1. yes 2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its WORST in the past 24 hours.

---

0 1 2 3 4 5 6 7 8 9 10

No pain **Pain as bad as you can imagine**

---

4) Please rate your pain by circling the one number that best describes your pain at its LEAST in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the AVERAGE.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.

0 1 2 3 4 5 6 7 8 9 10
No Pain as bad as
pain you can imagine

7) What treatments or medications are you receiving for your pain?

8) In the past 24 hours, how much RELIEF have pain treatments or medications provided? Please circle the one percentage that most shows how much.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Complete
relief relief

9) Circle the one number that describes how, during the past 24 hours, PAIN HAS INTERFERED with your:

A. General Activity:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not interfere **Completely interferes**

Source: Pain Research Group, Department of Neurology, University of Wisconsin-Madison.

3 The MOS-HIV

Question number	QUESTION	POSSIBLE RESPONSES	ANSWER
I would like to ask you a few questions about your health.			
Q1	In general would you say your health is:	Excellent=1 Very good=2 good=3 fair=4 poor=5	
Q2	How much *bodily* pain have you generally had during the past thirty days?	None=1 Very mild=2 Mild=3 Moderate=4 Severe=5 Very severe=6	
Q3	During the past thirty days, how much did pain interfere with your normal work, including both work outside the home and housework?	Not at all=1 A little bit=2 Moderately=3 Quite a bit=4 Extremely=5	
The following questions are about activities that a person might do during a typical day. Does your health now limit you in the following activities? And if so, how much?			
		Yes, limited a lot=1 Yes, limited a little=2 No, not limited at all=3	
Q4.1	The kinds or amounts of vigorous activities you can do like digging, fetching water from a well, carrying a load, splitting firewood, running , lifting heavy objects or engaging in strenuous sports		

Q4.2	The kinds of moderate activities you can do like washing clothes, moving a jerrican of water or cleaning the house .		
Q4.3	Walking up hill, climbing stairs		
Q4.4	Bending, lifting light objects or kneeling		
Q4.5	Walking a moderate distance, like the length of a football pitch, about 100 meters or taking a village walk		
Q4.6	feeding, dressing , bathing yourself, or ability to use the latrine		

The following questions are about work. Does your health now restrict you in doing the following kinds of work?			
Q5	Does your health keep you from working at a job, doing work around the house or attending school?	Yes=1 No=2	
Q6	Have you been unable to do certain kinds or amounts of work, housework, schoolwork, because of your health?	Yes=1 No=2	
For each of the following questions, please tell me the answer that comes closest to the way you have been feeling.			
	(Interviewer must begin by reading this introductory question to the patient) ***How much of the time during the past 30 days:***	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	
Q7	Has your health limited your social activities, like visiting with friends or family?		
Q8.1	Have you been a very nervous person?		
Q8.2	Have you felt calm and peaceful?		
Q8.3	Have you felt depressed?		
Q8.4	Have you been a happy person?		
Q8.5	Have you felt so depressed that nothing could cheer you up?		
Q9.1	Did you feel full of life and energy?		

Q9.2	Did you feel totally without energy?		
Q9.3	Did you feel tired?		
Q9.4	Did you have enough energy to do the things you wanted to do?		
Q9.5	Did you feel weighed down by your health problems?		
Q9.6	Were you discouraged by your health problems?		
	(Interviewer must begin by reading this introductory question to the patient) ***How much of the time during the past 30 days:***	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	
Q9.8	Were you afraid because of your health?		
Q10.1	Did you have difficulty reasoning and making decisions, for example, making plans or learning new things?		
Q10.3	Did you have trouble keeping your attention on any activity for long?		
Q10.4	Did you have difficulty doing activities involving concentration and thinking?		
	Please tell me the answer that comes closest to describing whether the following statement is true or false for you.	Definitely true=1 Mostly true=2 Don't know=3 Mostly false=4 Definitely false=5	
Q11.1	You are somewhat ill		

Q11.2	You are as healthy as any other person you know		
Q11.3	Your health is excellent		
Q11.4	You have been feeling bad recently		
Q12	How has the quality of your life been during the past thirty days? That is, how have things been going for you?	Very well, could hardly be better=1 Pretty good=2 Good and bad parts about equal=3 Pretty bad=4 Very bad, could hardly be worse=5	
Q13	How would you rate your physical health and emotional condition now compared to thirty days ago?	Much better=1 A little better=2 About the same=3 A little worse=4 Much worse=5	

4 The Memorial Symptom Assessment Schedule (Short Form expanded)

(MSAS-SF)

Below is a list of symptoms. Ask the patient 'Have you had this symptom DURING THE LAST WEEK?' If the patient says 'Yes', please tick YES for that symptom. If 'No', go on to the next item.

If the patient answered 'Yes', ask him/ her 'How much has the symptom DISTRESSED or BOTHERED you?', providing the 5 options listed. Tick the answer the patient gives.

N.B. For each symptom row, there should either be 0 ticks (if no symptom in past week) or 2 ticks (if symptom)

Tick ALL the symptoms the patient had during the PAST WEEK.	**Yes** ✓	→ **If YES: How much did it DISTRESS or BOTHER the patient?**				
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Difficulty concentrating						
Pain						
Lack of energy						
Cough						
Changes in skin						
Dry mouth						
Nausea						
Feeling drowsy/ tired						
Numbness/tingling in hands or feet						

Difficulty sleeping						
Feeling bloated						
Problems urinating						
Vomiting						
Shortness of breath						
Diarrhoea						
Sweats						
Mouth sores						
Problems with sexual interest/ activity						
	Yes ✓	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
Itching						
Lack of appetite						
Dizziness						
Difficulty swallowing						
Changes in way food tastes						
Weight loss						
Hair loss						
Constipation						
Swelling of arms or legs						
"I don't look like myself"						
Sores or lumps on private parts						
Discharge from						

private parts						
Bad smell/ odour						
Difficulty moving						
Difficulty walking						
Muscle aches						
Difficulty seeing well – poor vision						
Difficulty hearing well – poor hearing						
Hunger						
Please ask the patient and write in any other symptoms the patient has had during the past week:	**Yes** ✓	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
1.						
2.						

Below are other common symptoms. Ask the patient 'Have you had this symptom DURING THE LAST WEEK?' If the patient says 'Yes', please tick YES for that symptom. If 'No', go on to next item.

If the patient answered 'Yes', ask him/ her 'HOW OFTEN did you have the symptom in the past week?', providing the 4 options listed. Tick the answer the patient gives.

Tick ALL the symptoms the patient had during the PAST WEEK.	**Yes** ✓	→ **If yes, how OFTEN did it occur?**			
		Rarely	**Occasionally**	**Frequently**	**Almost constantly**
Feeling sad					
Worrying					
Feeling irritable					
Feeling nervous					

Please tell me about me about any other symptoms that have been bothering over the past 7 days

……

…….

…….

How many minutes did it take you to conduct this questionnaire with the patient?

_____

5 The modified *Karnofsky* scale

Adapted from Downing MG, 1998

%	AMBULATION	AMBULATION AND EVIDENCE OF DISEASE	SELF CARE	IN TAKE	CONSCIOUS LEVEL
100	Full	Normal activity no evidence Of disease	Full	Normal	Full
90	Full	Normal activity some evidence of disease	Full	Normal	Full
80	Full	Normal activity with some evidence of disease	Full	Normal or reduced	Full
70	Reduced	Unable normal job/ Work, some evidence of disease	Full	Normal Or reduced	Full
60	Reduced	Unable hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full
50	Mainly sit or lie	Unable to do any work, extensive disease	considerable assistance required	normal or reduced	Full + /- Confusion
40	Mainly in bed	As above	Mainly assistance	Normal or reduced	Full or drowsy +/_ Confusion
30	Total bed bound	As above	Total care	Reduced	As above
20	As above	As above	Total care	Minimal Sips	As above
10	As above	----------	----------	Mouth care only	Drowsy Or comma
0	Death	----------	----------		