Addis Ababa University

Faculty of medicine

Department of community health

Predictors of mortality and health related quality of life in patients receiving ART, Adama hospital, Oromia region

BY Reta Angessa

Advisor: Dr. Jemal Haidar (MD., MSc. DRM)

A thesis submitted to the School of graduate studies of Addis Ababa University in partial fulfilment of the requirement for the degree of Master in public health

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Abstract

Background: HIV/AIDS is one of the pandemic diseases affecting many people in the world. In the year 2008 it is estimated that 33.4 million [31.1million-35.8 million] people were living with HIV/AIDS worldwide. The human immune-deficiency virus (HIV) has created an enormous challenge worldwide. Since 1996, the advent of new classes of ARV drugs and their use in combination prolonged many lives, improved quality of life, revitalized communities and transformed perceptions of HIV/AIDS from a plague to a manageable chronic illness. Though there are few researches done in Africa including Ethiopia, a significantly high mortality of patients on ART is registered than mortality of patients on ART in developed countries. In Ethiopia, 179,183 clients have accessed ART till February 2010. The issue of mortality and quality of life in patients on ART is not yet well documented based on previous studies in Africa in general and in Ethiopia in particular except a few study.

OBJECTIVE:

To assess Predictors of mortality and health related quality of in HIV/AIDS patients receiving ART in Adama hospital, Oromia region

Methodology:

Hospital based retrospective analytical study was done in Adama hospital, west shoa zone, Oromia region from October 2009 to June 2010. Quantitative data collection method was employed to collect data from clinical records of patients with special focus on CD4 count, Hg, BMI and WHO staging of the progression of HIV. A total of 255 subjects selected systematically were enrolled for the retrospective assessment. In addition to this, 258 subjects selected randomly who were on ART treatment were also interviewed for Health related quality of life. Data entry, data cleaning was done by EPI INFO2002 version 3.5.1 which was transported to SPSS version 15 and analysed.

Result: In Adama hospital 14,620 patients were ever enrolled for HIV/AIDS care, 8,442 patients ever started ART and 5930 patients are currently on ART. Data of 255 patients on ART (128 male and 127 females) was taken from clinical charts and ART data base. The age ranged from 18-64 with mean age of 34.6 years. All of them started ART from September to August 2005.Of the 255 patients, 167 were from Adama town and 88 were from other places. Mortality rate within five years of retrospective follow up was 41(16.1%). The finding showed WHO stage IV [HR 3.28 95% CI1.65-6.53, p=0.001] and CD4<50/µl [HR 2.07 95% CI 1.05-4.07, p=0.004] were significant predictors of mortality. Similarly drug regimen 1b,

age group greater than 45, bed ridden functional status were also found significant predictors of mortality. Health related quality of life was assessed for 255 patients on ART from Adama hospital. The result showed score of 23.9 for general health and 83.4 for physical function implying that they are with good physical function but with poor health perception.

Conclusion: The overall mortality rate in this finding is similar to most of studies done in Africa as well as in Ethiopia. Low CD4, WHO stage IV are common predictors in most studies. However in this study, in addition, bed ridden functional status, age group greater than 45 and drug regimen 1b were also significant predictors of mortality. Health related quality of life score is from moderate to high in most of health related quality of life (HRQOL) items and it is similar to other studies.

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LIST OF ABBREVIATIONS

AAU... Addis Ababa University

AIDS... Acquired Immune Deficiency Syndrome

ART... Antiretroviral Therapy

ARV... Antiretroviral

BMI... Body mass index

EDHS... Ethiopian Demographic and Health Survey

FHAPCO... Federal HIV/AIDS prevention and control office

HAART... Highly Active Antiretroviral Therapy

Hg... Haemoglobin

HIV... Human Immuno-Deficiency Syndrome

HRQOL... Health related quality of life

IRB... Institutional review board

FMoH.... Federal ministry of Health

NGO... Nongovernmental organization

OIs... Opportunistic Infections

PI... Principal investigator

PLWHA... People Living With HIV /AIDS

PYO... Person year observed

SPH... School of public health

STIs... Sexually Transmitted Infections

TLC... Total leukocyte count

VS... Versus

WHO... World Health Organization

1. INTRODUCTION

1.1 Background

On a global scale, the HIV epidemic has stabilized; however there are still unacceptably high levels of new HIV infections and AIDS deaths. Globally, there was an estimated 33.4 million people living with HIV in 2008 (1).The annual number of new HIV infections declined from 3.0 million in 2001 to 2.7 million in 2008. Overall, 2.0 million people died due to AIDS in 2008, compared with an estimated 1.7 million in 2001. While the percentage of people living with HIV has stabilized since 2000, the overall number of people living with HIV has steadily increased as new infections occur each year. Southern Africa continues to bear a disproportionate share of the global burden of HIV: 35% of HIV infections and 38% of AIDS deaths in 2007 occurred in that sub-region. Altogether, sub-Saharan Africa is a home for 67% of all people living with HIV (1). Since 1996, the advent of new classes of ARV drugs and their use in combination prolonged many lives, improved quality of life, revitalized communities and transformed perceptions of HIV/AIDS from a plague to a manageable chronic illness. Unfortunately, most of the 33.4 million people in the developing world currently living with HIV/AIDS do not share this vastly improved prognosis (2).

Ethiopia is the second populous country in sub Saharan Africa and is one of the most affected by the epidemic. It is now 2 decades since the first AIDS case was reported. At the end of 2009 a total of 1.3million, adults and children were living with HIV/AIDS in Ethiopia. In 2005 alone there were an estimated 128,900 new HIV infections, including 30,300 HIV positive births, and 134,500 AIDS deaths. Life expectancy in Ethiopia is falling as a result of the epidemic and is expected to drop to 50 years by 2010 from a previous estimate of 59 years. There is 5,236,980 life expectance lost till the end of 2009 due to this pandemic disease in Ethiopia. Nine percent of deaths in year 2009 and 13% in the year 2005 is again due to HIV/AIDS. Annual HIV/AIDS is still high in Ethiopia, 89,255 HIV/AIDS patients died in the year 2010 alone. The country also has one of the largest populations of children orphaned by AIDS in sub Saharan Africa. AIDS has become the leading cause of mortality in the 15-49 age groups (4, 5).

According to the calibrated single point estimate the total number of people who have died due to HIV/AIDS in 2006 alone was 88,997; and in 2007, there were 898,350 children who have lost one or both parents due to the epidemic (AIDS orphans). The estimated prevalence rate of adult infection was 2.1 % (urban 7.7 %, rural 0.9 %).The current estimate of people requiring antiretroviral therapy is 258,264 (5).

In Ethiopia initially hospitals in the country were providing fee based ART services to patients at a monthly cost ranging from 300-700 Birr, depending on the regimen used. In a move to make ART more accessible, the government, with partners, launched the free ART initiative on 24 January 2005. The number of sites providing ART has grown from three in June 2005 to 272 in June 2007. At the end of December 2007, a total of 90,212 people living with HIV/AIDS (PLWHA) were receiving ART and in 2009 179,183 people were receiving ART. Likewise the capacity of professionals also improved with escalation of the programme (5, 6). Therefore it is necessary to identify favourable factors which could improve patient management.

1.2 Statement of the problem

AIDS--the chronic HIV infection period—often develops after long time, averaging 10 years, even in the absence of treatment. After variable period of chronic infection, patients eventually progress to AIDS and then to death. The US Centre for Disease Prevention and Control (CDC) defines AIDS by either diagnosis of AIDS-defining events, or by measurement of CD4 levels <200cells/mcL. The median survival time from AIDS to death is about 10 months, though it may vary according to the AIDS-defining event (6). In Africa, the natural course of HIV disease has not been well studied. There is only one study from rural Uganda describing the natural history of HIV disease. Since effective therapy is now available, studying the natural course of untreated HIV disease would be unethical (8, 9).

Highly active anti-retroviral therapy (HAART) has improved the survival of HIV infected patients. However, compared to patients in high-income countries, patients in resource-poor countries have higher mortality rates. Moreover there are few studies done in Africa to show mortality factors in AIDS patients on ART. There are also a few study documented on quality of life in AIDS patients on ART in African settings. In addition this study has more variables which have an association with mortality in patients on ART. Therefore it is worth investigating the risk factors in Ethiopian settings for prognostic and improving patient management.

2. Literature review

2.1 Global HIV/AIDS and ART situation

The number of people receiving ARV drugs in low- and middle-income countries has increased 10-folds in only six years, reaching almost 3 million people by the end of 2008. The rapid expansion of treatment access in resource-limited settings is saving lives, improving quality of life, and contributing to the rejuvenation of households, communities, and entire societies. However children are significantly less likely to receive antiretroviral therapy than adults there is a need for intensified action to ensure timely delivery of treatment to children. On the other hand, coverage of antiretroviral treatment for women is higher than or equal to that of men globally (1, 2).

The impact of antiretroviral drugs on the management of HIV infection has been startling, with improvements in health proving to be far more marked and enduring than anticipated when combination of antiretroviral therapy first emerged in the mid-1990s. Recent studies in Denmark suggest that a young man newly diagnosed with HIV is likely to live an additional 35 years with available medications, a tripling of the life expectancy for people with HIV. In slightly more than a decade, the introduction of combination of antiretroviral therapy has saved an estimated three million years of life in the United States alone. As more is learnt about antiretroviral therapy management through clinical trials and through the accumulation of greater clinical experience, health outcomes as a result of therapy are improving further still. Highly Active Antiretroviral Therapy (HAART) in many countries is likely to be a cost-saving intervention as it enables people living with HIV to remain well, and socially and economically active. In spite of promising signs that improved treatment access is yielding results in low- and middle-income countries, treatment success rates may be somewhat lower in resource-limited settings than in high-income settings. At both 6 and 12 months after initiation of antiretroviral therapy, mortality rates for individuals in low and middle-income countries are at least 28% higher than those for patients in high-income countries. When long-term survival is estimated, although the benefits of ARV(antiretroviral therapy) in low- and middle-income countries are considerable, they are still less than those enjoyed in high-income countries (1, 2, 4).

2.2 Antiretroviral therapy situation in Ethiopia

Since the first evidence of the HIV epidemic was detected in Ethiopia in 1984, AIDS has claimed the lives of millions and left behind an estimated 744,100 orphans. In 2005, an estimated 1.3 million persons were living with HIV. At that time, national HIV prevalence was 2.1%, with urban and rural prevalence of 7.7% and 0.9% respectively. There were an

estimated 128,900 new HIV infections, and some 113,600 adults and 20,900 children had lost their lives to AIDS. Nationally, children comprised almost a quarter (23.5%) of new infections and 18.3% of annual AIDS deaths. In 2003, the Government of Ethiopia introduced its ART programme with the goal of reducing HIV-related morbidity and mortality, improving the quality of life of people living with HIV and mitigating some of the impact of the epidemic. In 2005 an estimated 277,800 including 43,100 children, needed ARV therapy; over 71,000 were initiated on ART by the end of November 2006. Currently 246,347 patients ever enrolled and 179,183 are ART as of February 2010 of which 99.4% are on first line treatment. Similarly 1,572,876 died due to HIV/AIDS up to the end of February 2010 since the advent of the epidemic. Ethiopia is currently decentralizing HIV care and treatment services to selected health centres.. Efforts have been made to demystify HIV care and ART by developing standardized and simplified clinical tools and reference materials. (10).

2.3 HIV/AIDS associated mortality in Ethiopia and some African countries

A prospective cohort study was conducted in Arbaminch hospital in 2003 among 162 adult patients treated with HAART to identify prognostic factors and they followed their patients for about one year. Overall mortality rate was 16.7 per 100 PYO. The highest death rate occurred in the first month of treatment. Weight loss was seen in about a third of patients who survived up to the fourth week, and it was associated with increased death. WHO stage IV and leukocyte count <= 750/mcL were found the independent predictors of mortality (10) in this study.

Similarly a prospective cohort study conducted in rural hospital of Tanzania on 320 adults on ART in 2006 reported overall mortality rate of 29.7% during a follow-up period of around 36 months. The predictors of mortality were reported to be severe (haemoglobin<8gm/dl) and moderate anaemia (haemoglobin 8-9.9gm/dl), thrombocytopenia and severe malnutrition. The hazard of death was significantly reduced in those starting ART in calendar year 2006 compared with the initial period 2003–04 (12).

The five years prospective study conducted in Botswana (2002 to 2007) showed an overall death rate of 20% during the follow up years. Data on cause of death were determined using clinical records and verbal autopsy information. According to this study, 71 (59.2%) patients, causes of death were advanced HIV disease with wasting syndrome and pulmonary tuberculosis as the lead opportunistic illness. Serious medical problems that resulted in a change of ART at six months were anaemia, cutaneous hypersensitivity reaction, and

hepatotoxicity. The major predictors of mortality were Hg<8gm/dl, CD4<50 /µl (12), WHO stage III and IV.

Correspondingly, retrospective study conducted in Durban South Africa using standard data collection tool from medical records from 1999 through 2004 indicated 16% mortality rate. The predictors of mortality were a CD4 count <50 /µl (HR 3.08) and oral candidiasis (HR 2.58) (14).

Despite numerous reports of successful ARV therapy in low-income countries, clinicians and treatment advocates remain concerned by the high death rates being seen in patients who qualify for ARV therapy when compared with higher income countries. In general, clinicians have explained the higher death rate by pointing to the advanced HIV/AIDS disease of patients in their care, but three studies presented in 2006 at the Thirteenth international Conference on Retroviruses and Opportunistic Infections were able to provide much more precise information about the factors that predict an increased risk of death or illness after starting antiretroviral therapy. They found AIDS wasting, haemoglobin <9.5 g/dl as significant predictors of early mortality in Haitian cohort. Similarly in Senegal cohort baseline body mass index below 19, baseline haemoglobin below 10g/dl or a CD4 cell count below 200 were significant predictors of an increased risk of death (15).

In Côte d'Ivoire cohorts, the risk of death was significantly increased among men; older persons; those with lower baseline CD4 cell counts, higher WHO clinical stage, lower haemoglobin levels and lower BMI; and among patients receiving care at the general, not HIV-specific clinics. The risk of being lost to follow-up was greater among men and those with higher clinical stage, lower haemoglobin levels, and who were receiving care at the general clinic. The likelihood of a gain of <50 cells was higher among men with lower baseline CD4 counts and lower haemoglobin levels (16).

2.4 Mortality in developed countries

Studies in the United Kingdom indicate that nearly 11% of patients die within five years of extensive failure of the three primary classes of ARV medications. The prevalence of HIV drug resistance has grown over time in high-income countries for instance in Brazil, where antiretroviral drugs have been in use for longer than anywhere else. In the low- and Lower-middle-income countries where ARV drugs were introduced more recently, much lower rates of resistance prevail, but these may increase as people on therapy live longer. In settings where ARV drugs have been in widespread use since the mid-1990s, treatment has radically altered the natural course of HIV infection, expanding the spectrum of health problems

presented by individuals living with HIV and altering the most common causes of death among HIV-positive people. In particular, chronic illnesses and co-morbidities cause an increasingly large percentage of deaths among people living with HIV in settings where ARV drugs have been used widely for more than a decade. Between 1995 and 2006, the percentage of non- HIV-related deaths among people living with HIV in New York City increased from 8% to 32% with cardiovascular conditions and non- AIDS-defining cancers accounting for nearly half of all deaths. In Norway, while the risk of HIV-related death has declined 80% in the era of ARV combination therapy, the mortality rate for individuals living with HIV is still four times higher than in the general population (1, 4).

2.5 Health related quality of life

In general, health-status-measures describe a person's functioning in one or more domains, physical functioning or mental wellbeing. Currently, one of the most commonly used generic health status instruments is the Medical Outcomes Study 36-Item Short Form (SF-36), a 36-item measure encompassing 8 domains—physical functioning, social functioning, mental health, role limitations due to physical problems, role limitations due to emotional problems, vitality (energy and fatigue), bodily pain, and general health perception. The SF-36 domains can be summarized into physical component summary and mental component summary scores (18).

In a study conducted in Sweden to assess health related quality of life (HRQOL) showed that emotional HRQOL deteriorated during two years of ART, while the physical HRQOL remained stable. Experience of drug adverse effects contributed most to the deterioration of emotional HRQOL. In this sample of patients with relatively advanced state of HIV-infection suggested that a negative development of physical HRQOL had been interrupted by the treatment and the emotional dimension of HRQOL deteriorated during two years after start of ART (19).

A study conducted in west Uganda on patients received ART for at least six months the health quality of life scores were from moderate to high in all measurements. Further they found older age; rural dwelling, alcohol use, CD4 count less than 200, and ART duration of less than one year were significantly associated with lower HRQOL scores (20).

3. Objective of the study

General objective

- To assess predictors of mortality and health related quality of life in HIV/AIDS patients receiving ART in Adama hospital, Oromia region

Specific objectives

- To describe mortality prevalence among HIV/AIDS patients on ART at 6month, one year, three years and five years period
- To assess health related quality of life of patients on ART
- To assess predicting factors of mortality based on socio-demographic and biochemical markers

4. Methods and materials

4.1 Study area and period

This study was conducted in Adama hospital of Oromia regional state which is found in East shoa zone 110 km from Addis Ababa in the south East direction of Addis Ababa and located in Adama town. The population size of Oromia region according to 2007 census is 27,158,471 with male and female population of 50.4 49.6 percent respectively. East Shoa zone has a total population of 1,357,522 of which 340,267 and 1,017,255 live in urban and rural respectively. In Adama woreda there were one private and one governmental hospital. This study was conducted in Adama governmental hospital Adama special Zone was chosen purposively because it has good facility with a 222,035 population. Adama hospital serves for more than1 million populations from west shoa, Arsi, and Bale zones. Adama hospital is selected conveniently because it is easily accessible, has significantly more than ten thousand patients on ART follow up and further more it is one of the first hospitals to start ART in Oromia region five years back which makes Adama hospital convenient for study on mortality analysis. It also has well organized and computerized data management which is an opportunity to get better secondary data. The study was conducted from September 2009 to June 2010.

4.2 Study design

A retrospective cohort study was employed using pre-organized data collection tool to collect secondary data from computerized database and patient charts. The cohorts of this study are treatment cohorts of ART who started treatment in the same year that is 2005 to 2010. In addition cross-sectional study design was used to assess health quality of life of patients on ART.

4.3 Source and study population

The source population are all patients who took or now taking ART in Adama hospital and are aged greater than or equal to 18 years. The study subjects are selected from first cohorts of patients who started ART in Adama hospital in the year 2005 using inclusion exclusion criteria until the calculated sample size was reached.

4.4 Inclusion and exclusion criteria

Patients ever started ART in Adama hospital that are currently on treatment or died and greater than or equal to 18 years old, age, sex, CD4 count, weight, WHO stage, marital status, drug regimen and functional status were completed . Patients less than 18 years, no clinical record, lost to follow up, transferred out; incomplete data on variables of interest were excluded from the study.

4.5 Sample size determination

The formula used for calculating the sample size was

$$n = \frac{(Zá/2)^2 \, P \, (1-p)}{d^2}$$

Where

n=the desired sample size

p=proportion of anticipated death which is 21% based on previous study

Zá/2= critical value at 95% confidence level of certainty (1.96)

d= the margin error between the sample and the population =5%

Using the above formula sample size for the single population proportion the desired total sample size was 510 that is 255 for both primary and secondary data

4.6 Sampling procedure

First Adama hospital is purposively selected from hospitals in Ethiopia. In Adama hospital there are more than eight thousand patients either on pre-ART or ART care. Since the target is to analyse five years mortality of patients on ART, 255 patients who ever started ART in Adama hospital were selected from cohorts of 2005 using systematic random sampling technique and those who fulfil the inclusion criteria were selected until the required sample size was attained. Those patients interviewed for HRQOL were selected also by systematic taking the first comer and then every third patient each day until the required sample size was reached (n=255) (figure 1)

A Structured and standardized questionnaire(WHO Sf-36) was used to collect primary data through interview and data from clinical records was collected using tool with seventeen check lists on independent variables, status (died or alive) and time to death which is the main out come. These tools consist of:

- Socio-demographic (age, sex, income level, marital status, social function)
- Anthropometry (height, weight, BMI)
- Biochemical (CD4 count, viral load, haemoglobin, TLC)
- Other important variables (WHO stage, type of regimen, physical health, mental health) (See Annex 4)

Three data collectors were recruited from Adama hospital from nurses and data clerks who know the local language and have relevant previous experience. All data collectors were trained for one day on data collection techniques for primary and secondary data collection by the PI. All primary and secondary data were collected by the trained nurses and data clerks under close supervision of PI.

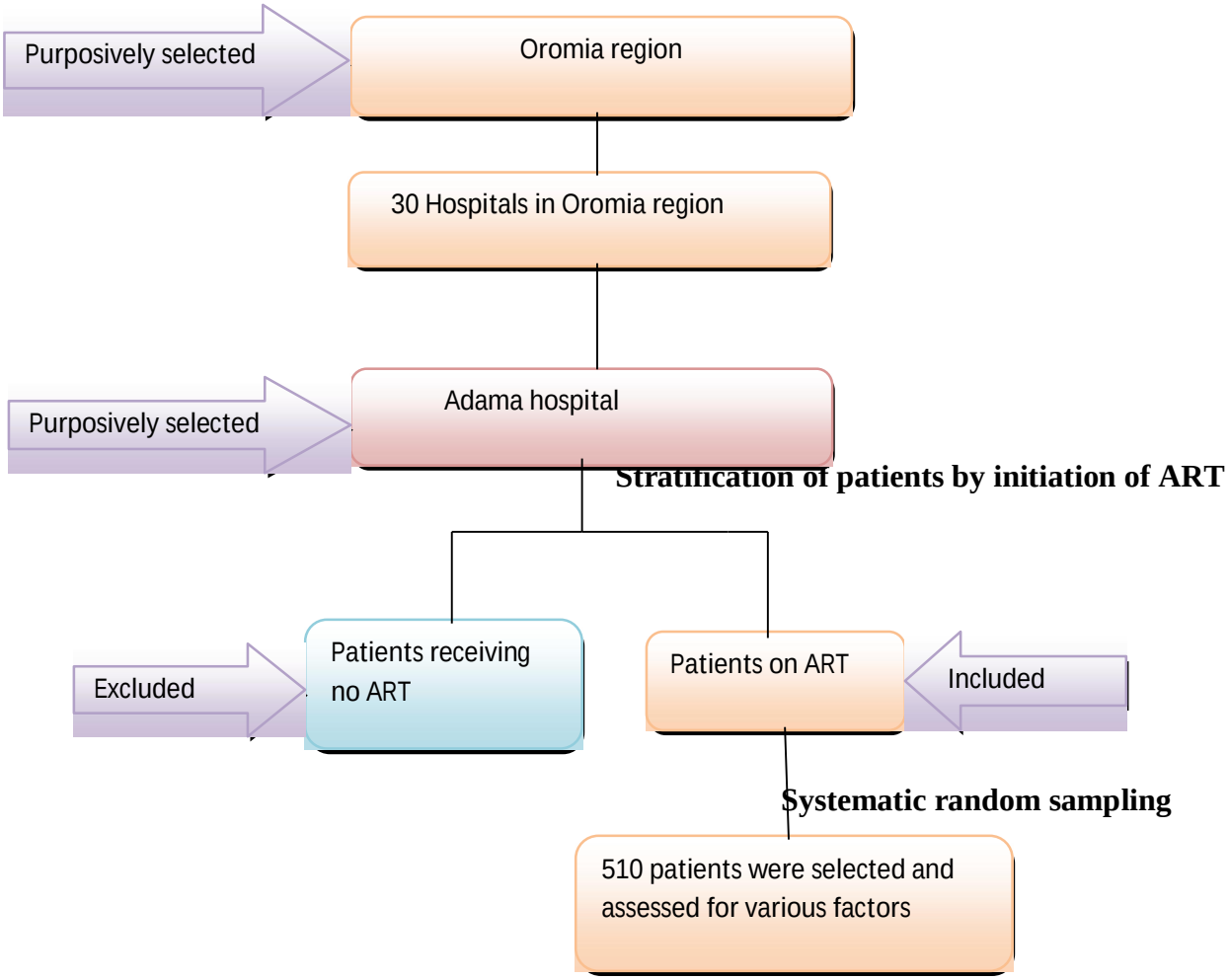

Figure 1: Sampling procedure

4.8 Data processing and analysis procedure

Data entry and analysis is performed using EPI INFO version 3.5.1 and SPSS version 15.0. Data were analysed first by doing frequency for independent variables and cross tabulation of independent variables with status (censored, died). Kaplan-Meier survival function was used to see the difference between factor levels. Then bivariate analysis was first done to see whether there is an association or not for each independent factors. Then multivariate analysis of cox model was used to control for confounding and to see whether variables are predictors of mortality or not. Only those variables with p-value <= 0.1 in bivariate analysis were included in multivariate analysis.

4.9 Study variables

Dependent variables

- **Time to death is main outcome variable**
- **Status (died or censored)**

Independent variables

- **WHO stage**
- **Age of patient**
- **Sex of patient**
- **CD4 count at start of ART**
- **TLC**
- **BMI**
- **Marital status**
- **Haemoglobin**
- **Drug regimen**
- **Patient's income level**
- **Functional status at start of ART**
- **Physical health**
- **Physical role**
- **General health status**
- **Body pain**
- **Mental health**
- **Social function**

4.10 Data quality management

- To ensure external validity of findings appropriate sample size was calculated.
- To ensure internal validity, during data collection random sampling techniques was implemented to select the study subjects.
- Data was collected only by trained and experienced nurses and data clerks working in ART clinic under supervision of PI.
- Furthermore twenty-five records from computerized database were randomly cross checked with available patient charts and the same database by the PI.
- Data were checked for completeness, cleaned before analysis and entered by the PI for better quality.

4.11 Ethical considerations

§ Ethical clearance was obtained from the school of public health, REC and IRB of the AAUMF.
§ A formal letter was submitted to all the concerned bodies to obtain their co-operation during data collection
§ All data collectors were nurses and data clerks working in the same ART clinic
§ When we collect computerized secondary data confidentiality was assured and no personal details recorded or produced on any documentation related to this study
§ Informed written consent was obtained from all study subjects who underwent interview
§ Subjects were assured to withdraw at any time if they are not comfortable with the study
§ All interview were conducted in private
§ For those Subjects who were interviewed, adequate information and clarification was given to them about their illness whenever they ask or come across any problem related to their health

4.12 Dissemination of results

The findings of this study will be submitted to School of Public Health, college of health sciences, Addis Ababa University and other relevant bodies (Adama hospitals, MOH, other NGOs) to use the as baseline information, reference documents for researchers, experts or

policy makers for intervention. In addition, the findings will also be presented in different seminars and workshops.

Results

Five hundred ten patients were included in the study. Reasons for exclusion during secondary data collection were missing charts or chart where substantial clinical data was missing (29 patients), lost to follow up (102 patients), transferred out(87 patients), less than 18 years(9 patients). A total of 227(47%) were excluded and there were 102(21%) lost to follow up. The response rate for the interview was 98.8%.

Table-1 displays the various characteristics of the study subjects. The mean age at initial presentation was 34.60 years and ranging from 18 to 64 years. One hundred and twenty-eight patients (50.2%) were male and 127(49.8%) were female. Hundred-sixty seven (65.5 percent) were from Adama town the rest 88(34.5 %) were out of Adama. Hundred sixty two (63.5 %) were Orthodox followed by Protestant 40 (20.4 %) and Muslims 40(15.7 %) . Many of them were jobless 91 (35.7 %) and farmers 28(11 %). Fifty-four (21.2 %) have no education, 75 (29.4 %) had primary, 108 (42.4 %) were secondary and 18 (7.1 %) were tertiary education. The median CD4 cell count was 106/µl and the mean CD4 cell count 120.7/µl (significant deviation (SD) 94.25/µl). Twenty patients (7.8%) had an initial CD4 cell count of <20/µl, 52(20.4%) a count of less than or equal to 50/µl, 55 (21.6%) a count of 50 99/µl and 148 (58%) a count of 100/µl. Seventy per cent of patients were in WHO stage III and nineteen per cent WHO stage IV at presentation. Forty-one patients (16%) had died by the conclusion of the study.

Table 1: **Socio-demographic characteristics of the study participants (n=255) pre-HAART, Adama hospital, 2010**

Characteristics	Frequency	%
Sex		
Male	**128**	**50.2**
Female	**127**	**49.8**
Age(years)		
18–24	**18**	**7.1**
25–34	**127**	**49.8**
35–44	**66**	**25.9**
>=45	**44**	**17.3**
Mean age(SD)	**34(8.4)**	
Permanent address		
Adama	**167**	**65.5**
Out of Adama	**88**	**34.5**
Marital Status		
Never married	**48**	**18.8**
Married	**109**	**42.7**
Divorced	**33**	**12.9**
Widowed	**58**	**22.7**
Separated	**7**	**2.7**
Religion		
Orthodox	**162**	**63.5**
Muslim	**40**	**15.7**
Protestant	**52**	**20.4**
Catholic	**1**	**0.4**
Educational status		
No education	**54**	**21.2**
Primary	**75**	**29.4**
Secondary	**108**	**42.4**
Tertiary	**18**	**7.1**
Occupation		
No work	**91**	**35.7**
Farmer	**28**	**11**
House wife	**28**	**11**
Private work	**26**	**10.2**
Gov't Employee	**19**	**7.5**
Merchant	**17**	**6.7**
Daily labourer	**14**	**5.5**
Others	**32**	**12.5**

Table-2 shows mortality rate according to treatment duration .Among those who died twelve (29.3 %) of them died within six months, 24 (58.5 %) within one year after start of treatment and the rest 17 (41 %) died between year one and year five. Thirty-two (78 %)) of them died within three years after start of ART. The majority (58.5%) of patients died before year one after start of ART.

Table 2: Mortality rates and rate ratios by treatment duration of patients on ART, Adama hospital, 2010

Treatment duration	Deaths	Rate	Rate ratio (95%CI)
0–6 months	**12**	**4.70**	**0.29(0.14,0.59)**
6-12 months	**12**	**4.70**	**0.29(0.14,0.59)**
0–12 months	**24**	**9.4**	**0.61(0.35,1.06)**
12-36 months	**8**	**3.14**	**0.2(.08,0.44)**
0–36 months	**32**	**12.55**	**0.78(0.46,1.31)**
36-60 months	**9**	**3.53**	**0.22(0.1,0.48)**
0_60 months	**41**	**16.08**	**1(0.61,1.49)**

95%CI = 95% Confidence Interval

Table 3 shows mortality associated with baseline characteristics. The mortality rate for males was 21(16.4%) while for females 20 (15.7%). Out of forty-one patients died during five years of treatment 3(7.3 %) were among 18-24 years old, fourteen (34.1 %) among 25-34 years old, 13(31.7 5%) among 35-44 years and 11(26.8 %) among those greater or equal to forty-five

years. Similarly of those forty-one died 6(14.6 %) working, 5 (12.2 %) ambulatory, 30 (73.2 %) bed ridden. The same way, out of 41 died one (2.4 %) with WHO stage I-II, nineteen (46.3 %) WHO stage III, and the rest 21(51.2 %) WHO stage IV at the start of ART. Similarly 17 (41.4 %) were with CD4 count <50, 23 (56.1 %) were with CD4 count 50-199 and 1 (2.4 %) with CD4 count 200-499.

Table 3: Baseline characteristics and associated five years mortality of patients receiving ART, Adama hospital, 2010

Characteristic	Number of patients	Number of Deaths	Percent
Age (years)			
18–24	**18**	**3**	**16.7**
25–34	**127**	**14**	**11**
35–44	**66**	**13**	**19.7**
45	**44**	**11**	**25**
Sex			
Male	**128**	**21**	**16.4**
Female	**127**	**20**	**15.7**
Clinical stage			
WHO stage I–II	**27**	**1**	**3.7**
WHO stage III	**179**	**19**	**10.6**
WHO stage IV	**49**	**21**	**42.8**
Functional status			
Working	**123**	**6**	**4.9**
Ambulatory	**82**	**5**	**6.1**
Bed ridden	**50**	**30**	**60**
CD4 at start of ART			
<50	**52**	**17**	**32.7**
50_199	**171**	**23**	**13.5**
200_500	**30**	**1**	**3.3**
>500	**2**	**0**	**0**

ART, antiretroviral therapy; WHO, World Health Organization

Table 4 shows overall hazard ratio according to baseline variables. Patients who died had a mean pre-ART CD4 cell count of 72/µl compared with 130/µl for those who were alive. In the bivariate analysis, a baseline CD4 cell count <50/µl (HR 3.41 95% CI 1.83-6.35, p<0.0001) compared to CD4 count >50/µl, WHO stage IV (HR 5.26 95% CI 2.85-9.72,p<0.0001) compared to WHO stage I-III, functional status bed ridden (HR 16.88 95% CI 8.4-34.0, p<0.0001) compared to working and ambulatory, drug regimen 1b(HR 4.33 95% CI 2.32-8.08, p<0.0001), occupation being farmer(HR 2.66 95% CI 1.27-5.57, p=0.01) were found to significant predictors of mortality. Hence these variables were therefore included in the multivariate cox model. However age group, marital status, gender, religion, educational status were not significant predictors of mortality in the univariate analysis. These variables were not included in multivariate cox model except age group which was included in multivariate analysis because p value is 0.068 which is less than 0.1.

Table 4: Overall Hazard ratios of mortality according to baseline variables in HIV/AIDS patients receiving ART, Adama hospital, 2010

	Unadjusted		Adjusted	
Baseline variables	**HR (95% CI)**	***P***	**HR (95% CI)**	***P***
WHO stage IV vs. I-III	**5.26(2.85, 9.72)**	**0.000**	**3.28(1.65, 6.53)**	**0.001**
CD4<50 vs.>50	**3.41(1.83, 6.35)**	**0.000**	**2.07(1,05, 4.07)**	**0.004**
Functional status B vs. A,W	**16.88(8.4, 34.0)**	**0.000**	**12.71(5.79,27.87)**	**0.000**
Drug regimen 1b vs. 1a,1c,1d	**4.33(2.32, 8.08)**	**0.000**	**2.88(1.44, 5.79)**	**0.003**
Age group >45 vs. <45 years	**1.90(0.95, 3.79)**	**0.068**	**2.71(1.25, 5.87)**	**0.01**
Occupation farmer vs. all other	**2.66(1.27, 5.57)**	**0.01**	**1.20(0.42, 3.43)**	**0.71**
Marital status married vs. all	**1.57(0.85, 2.91)**	**0.15**	**-**	**-**
Gender female vs. male	**0.94(0.51, 1.74)**	**0.85**	**-**	**-**
Religion Orthodox vs. all other	**1.11(0.58, 2.12)**	**0.75**	**-**	**-**
Educational status no education vs.	**1.68(0.85, 3.29)**	**0.13**	**-**	**-**

HR, hazard ratio; CI, confidence interval; ART, antiretroviral therapy; WHO, World Health Organization; A, ambulatory; B, bed ridden; W, working.

Table 5 shows significant predictors of mortality after controlling for confounding effect. In multivariate analysis, patients with a CD4 cell count <50/µl had a 2-fold higher risk of mortality (HR 2.07, 95% CI 1.05 – 4.07, *p*=0.004), WHO stage IV had a 3-fold increased risk of mortality (HR 3.28, 95% CI 1.65 – 6.53, *p*=0.001), those bed ridden at start of ART had 12-fold higher risk of mortality(HR 12.71 95% CI 5.79-27.87, p=0.000), drug regimen 1b had 3-fold higher risk of death(HR 2.88, 95% CI 1.44, 5.79,p=0.003), age group greater than forty-five had 3-fold increased risk of mortality(HR 2.71, 95% CI 1.25-5.87, p=0.01). Therefore CD4 count less than 50/µ, WHO stage IV disease, functional status bed ridden, drug regimen 1b, age group greater than forty-five at start of ART were statistically significant predictors of mortality. Occupation, gender, marital, status, religion and educational status were not predictors of mortality.

Table 5: predictors of overall mortality according to cox regression analysis of patients on ART, Adama hospital,2010

Factor	Crude HR (95%CI)	P-value	Adjusted HR (95%CI)	P-value
WHO stage IV vs. I-III	**5.26(2.85, 9.72)**	**0.000**	**3.28(1.65, 6.53)**	**0.001**
Functional status B vs. A,W	**16.88(8.4, 34.0)**	**0.000**	**12.71(5.79,27.87)**	**0.000**
CD4 <50 vs.>50	**3.41(1.83, 6.35)**	**0.000**	**2.07(1,05, 4.07)**	**0.004**
Drug regimen 1b vs. 1a,1c,1d	**4.33(2.32, 8.08)**	**0.000**	**2.88(1.44, 5.79)**	**0.003**
Age group >45 vs. <45 years	**1.90(0.95, 3.79)**	**0.068**	**2.71(1.25, 5.87)**	**0.01**

A=ambulatory, B= bed ridden, W=working WHO=World Health Organization HR=Hazard Ratio 95%CI = 95% Confidence Interval

The mean duration of retrospective follow-up after ART initiation was 229.5 weeks, ranging from 4.2 to 328.3 weeks. Patient follow-up time was censored due to patient still on follow-up in the hospital or if he/she is alive during telephone contact or study time was completed. If a patient not returns to the clinic beyond appointment and within 6 months of the conclusion of the study, they were designated lost to follow-up and excluded from study. In total, 102 patients (21%) were designated as such. No difference in age, gender, occupation, CD4 count, functional status, marital status, educational status was noted between patients

who were lost to follow-up and those who were not and hence they don't have significant difference on the result.

Table 6: Hazard ratios (HR) of death in the first one year of ART treatment according to baseline variables, Adama hospital, 2010

Factor	Crude HR(95%CI)	P-value	Adjusted HR (95%CI)	P-value
WHO stage IV vs. I-III	**3.88(1.74, 8.66)**	**0.001**	**3.91(1.75, 8.72)**	**0.001**
CD4<50 vs.>50	**4.49(2.02, 10.00)**	**0.000**	**2.64(1.06, 6.61)**	**0.04**
Functional status B vs A,W	**9.91(4.24, 23.18)**	**0.000**	**6.94(2.69, 17.9)**	**0.000**
Drug regimen 1b vs. 1a,1c,1d	**4.22(1.90, 9.40)**	**0.000**	**2.55(1.05, 6.19)**	**0.04**
Age group >45 vs. <45 years	**2.52(1.08, 5.88)**	**0.03**	**3.04(1.18, 7.78)**	**0.02**
Occupation farmer vs. all other	**2.33(0.87, 6.24)**	**0.09**	**1.06(0.35, 3.24)**	**0.92**
Marital status married vs. all others	**1.62(0.72, 3.62)**	**0.24**	**-**	**-**
Gender female vs. male	**0.840.38, 1.87)**	**0.66**	**-**	**-**
Religion Orthodox vs. all other	**1.14(0.49, 2.67)**	**0.76**	**-**	**-**
Educational status no education vs. All other	**1.59(0.66, 3.84)**	**0.3**	**-**	**-**

A=ambulatory, B= bed ridden, W=working WHO=World Health Organization HR=Hazard Ratio 95%CI = 95% Confidence Interval

Figure 2 shows overall survival according to baseline CD4 count. Kaplan-Meier curves comparing patients within four different initial CD4 cell count strata (<50/µl, 50-199/µl, 200-499/µl and 500/µl).No significant difference was noted in survival among patients with an initial CD4 cell count of 50 199/µl, 200-499/ µl, >=500/ µl. Patients with a CD4 cell count <50/µl had significantly higher mortality than those with CD4 cell count >=50/µl (p<0.004). One-year mortality for patients with a CD4 cell count <50/µl was high (2.07, 95% CI 1.05 –

4.07 p=0.004) and with significantly different when compared to patients with a CD4 cell count >=50/µl. The lowest 1-year mortality was noted for patients with a baseline CD4 cell count 500/µl (figure-2).

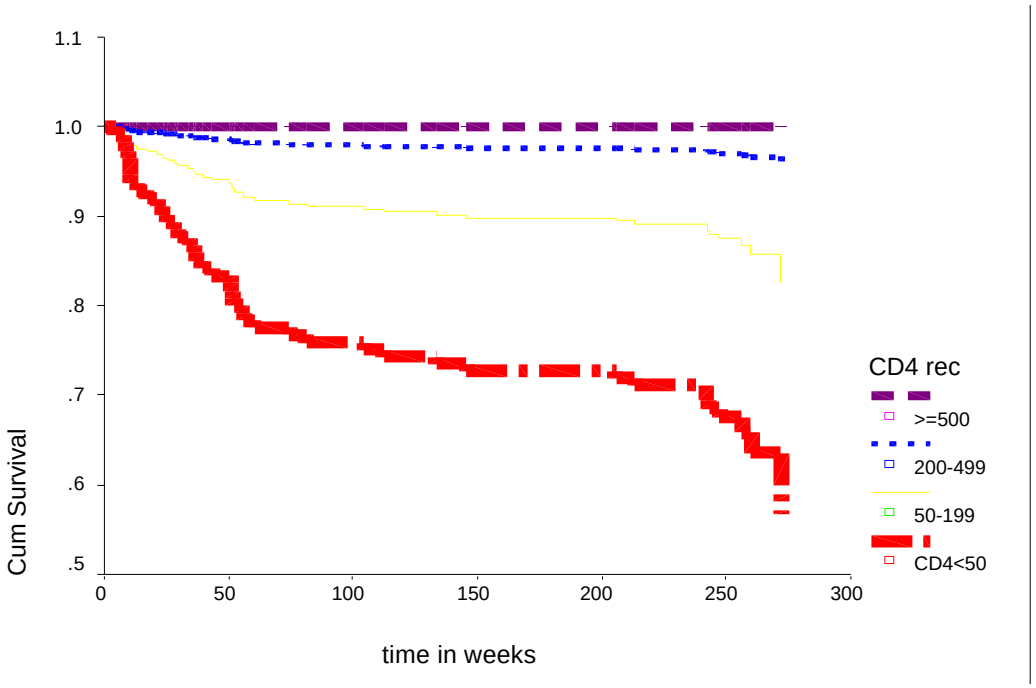

Figure 2: Five years survival function of patients on ART according to baseline CD4 count, Adama hospital, 2010

Figure 3 shows overall survival according to baseline functional status. In general there is difference in survival among different functional status. There are six deaths (4.9%) from 123 patients with functional status working, five deaths (6.1%) death from 82 ambulatory patients and thirty (60%) death among 50 patients who were bed ridden at time of ART initiation. For three strata of functional status there is no statically significant difference in survival between working and ambulatory. However there is significant difference in survival between bed ridden and working or ambulatory (HR 12.71 95% CI 5.79-27.87, p=0.000). Similarly mortality in the first one year there is significant difference between bed ridden and working or ambulatory (HR 6.94 95 CI 2.69-17.9, p=0.000).

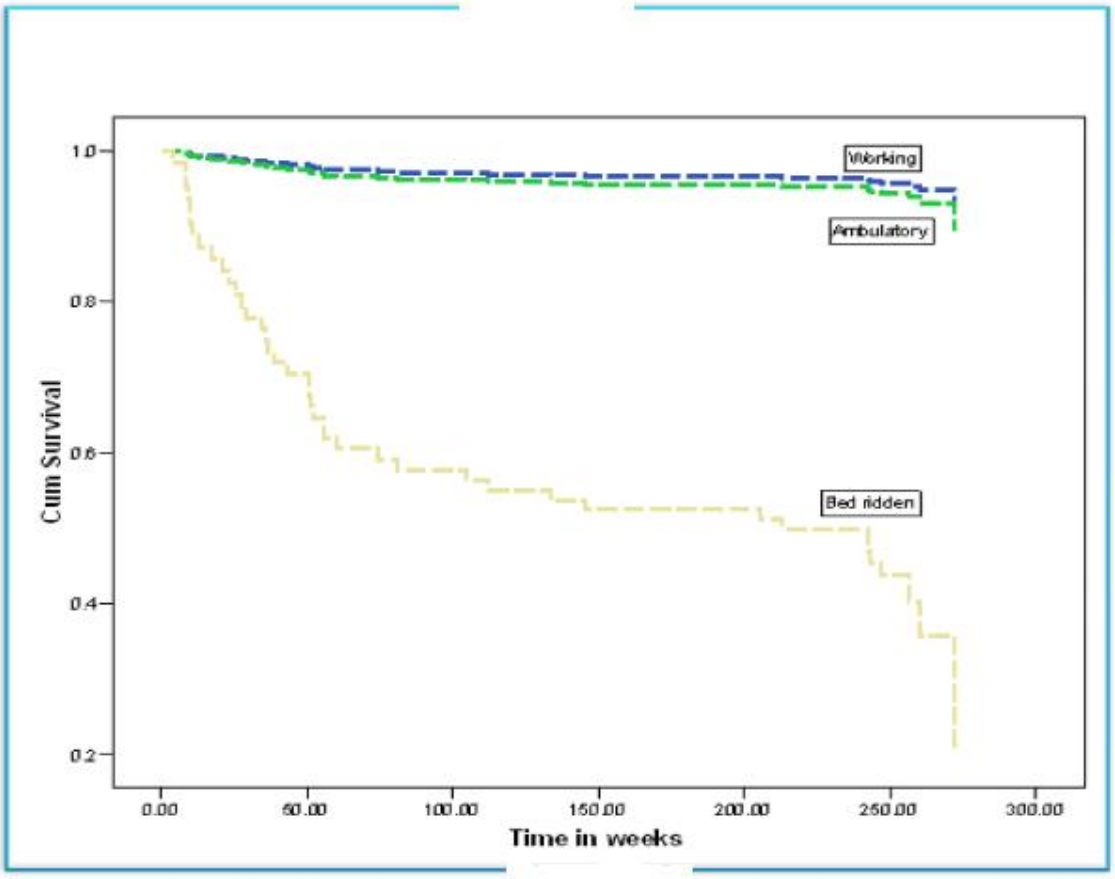

Figure 3: Five years survival function according to baseline functional status among patients on ART, Adama hospital, 2010

Figure 4 shows survival function according to baseline WHO stage. Among twenty-seven patients with WHO stage I-II only one (3.7 %) of them died and among hundred seventy-nine patients with WHO stage III, only 19(10.6 %) died but out of 49 patients with WHO stage IV twenty-one (42.9%) of them died.

For four strata of WHO (stage I to IV), there is no significant difference in survival between WHO stage I and II, stage I and III, stage II and III. However there is significant difference between WHO stage IV and WHO stage I-III (HR 3.28 95% CI 1.65-6.53, p=0.001). The same way in the first one year there is significant difference in survival between WHO IV and WHO stage I-II(HR 3.91 95% CI1.75-8.72, p=0.001) (figure-4).

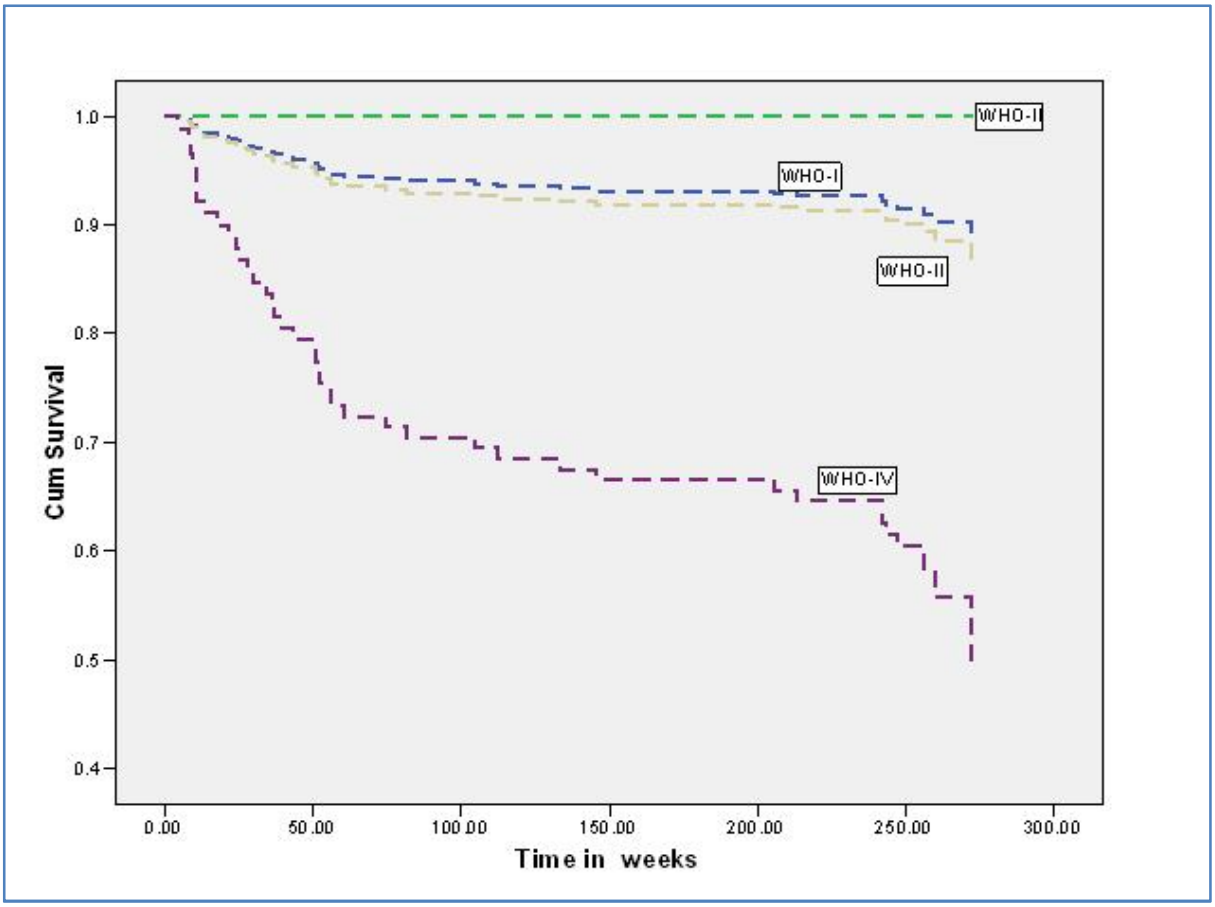

Figure 4: Five years survival function according to baseline WHO stage among patients on ART, Adama hospital, 2010

Figure 5 shows survival function according to drug regimen among patients on ART. All patients included in this study were under first line treatment regimens, namely 1a (d4T+3TC+NVP), 1b (d4T+3TC+EFV), 1c (ZDV+3TC+NVP), 1d (ZDV+3TC+EFV). 109 (42.7 %) are on drug regimen 1a, 54 (21.2 %) are on drug regimen 1b, 72 (28.2 %) are on drug regimen 1c and the rest 20 (7.8 %) are on drug regimen 1d. This study shows statistical significant difference in survival among patients on different first line treatment regimens. There is no significant difference between 1a, 1c and 1d but there is significant difference between drug regimen 1b and 1a, 1c, 1d (HR 2.88, 95% CI 1.44-5.79, p=0.003)

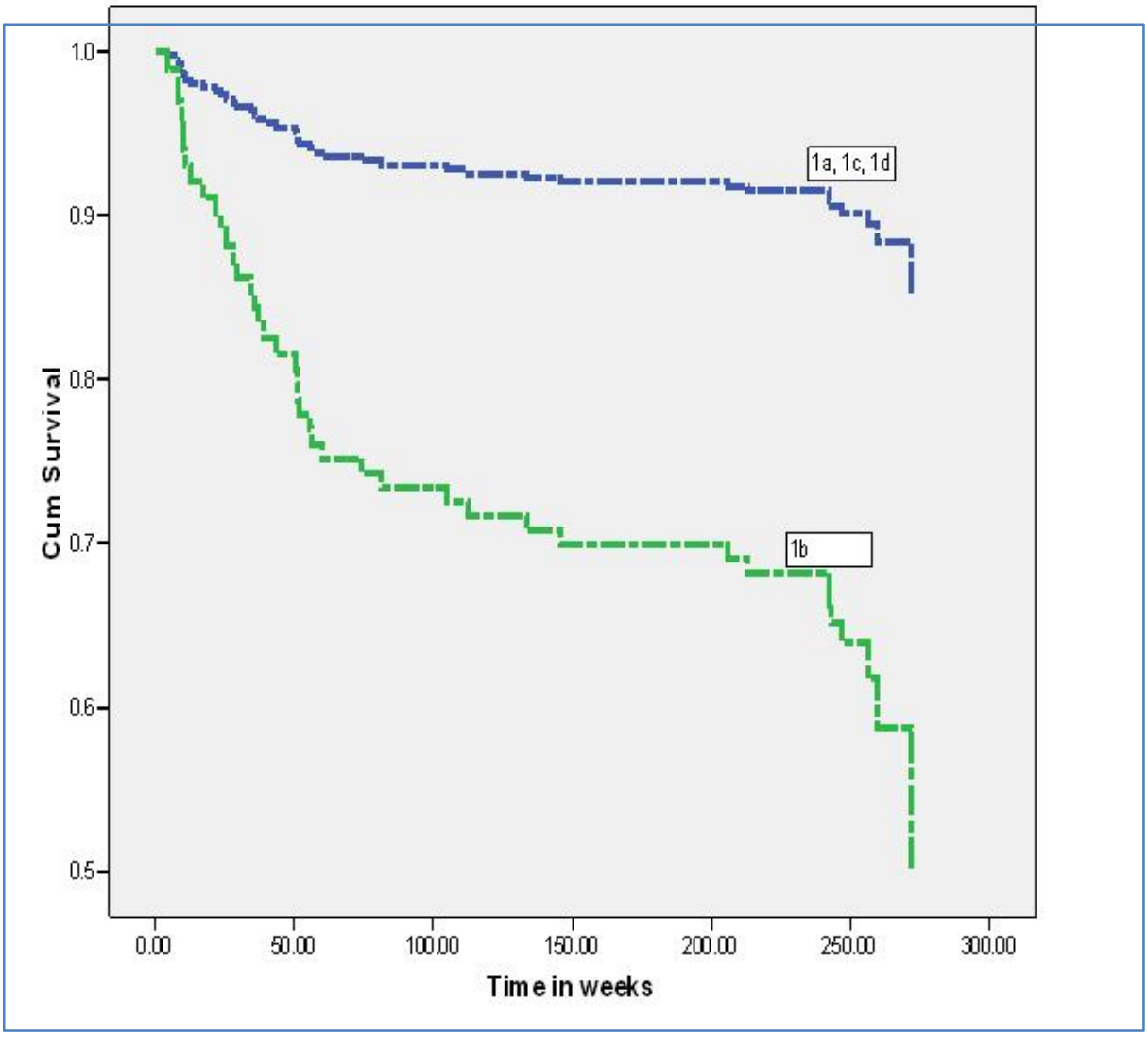

Figure 5: Five years survival function according to type of drug regimen among patients on ART, Adama hospital, 2010

Result for health related quality of life

Table 7: Age of patients receiving ART interviewed for health related quality of life, Adama hospital, 2010

		sex		Total
		MALE	FEMALE	
Age of participant	18-24	1	11	12
	25-34	33	93	126
	35-44	40	44	84
	>=45	19	14	33
	Total	93(36.5%)	162(63.5%)	255s

Health related quality of life was assessed for 255 patients who are currently on ART and follow up. Out of 258 patients on ART asked for their consent for the interview three of them refused to participate making a response rate of 98.8 percent for the health related quality life assessment. Ninety-three (36.5 percent) and 162(63.5 percent) of the participants were males and females respectively. The majority of participants (54.0%) were in the age range between 25 and 44 years.

The health related quality of life is summarized using eight items. This summary includes physical function (PF), role limitation due to physical health (RP), role limitation due to emotional health (RE), energy/fatigue (VT), emotional well being (MH), social function (SF), and body pain (BP) and general health (GH). According to this score, as the score increases it means the individual is in good functional status on item being scored and the lowest score implies the individual is in poor condition on that component of functionality. In this regard, score of 100 is the best and 0 is the least or worst score. According to this study, physical function has, role physical and role emotional have got score of 83.4, 61.4 and 61.7 respectively. Whereas vitality, emotional well being, social function and body pain components has got scores of 67.6, 67.3, 71.6 and 81.7 respectively. The lowest score found was for general health and health perception which is 23.9 and it is very low score. For a question I am as healthy as anybody, 89 percent of respondents mentioned the answer definitely true which made the score 11 out of 100.This implies general health perception is

poor in this study. All emotional components of health are lower score when compared with physical function. Health related quality of life is here measured at single point in time.

Table 8: Summery Quality of life score for patients receiving ART, Adama hospital, 2010

SN	Scale	score
1	Physical function(PF)	83.4
2	Role limitation due to physical health(RP)	61.4
3	Role limitation due to emotional health(RE)	61.7
4	Energy/fatigue(VT)	67.6
5	Emotional well-being(MH)	67.3
6	Social function(SF)	71.6
7	Body Pain(BP)	81.7
8	General health(GH)	23.9

Discussion

According to the present study, the burden of death in this cohort is among the productive age group of 25 to34 years. Moreover 49.8 percent of study subjects, and 34.1 percent of those died are in this age group. The burden of death is yet again on those married (20.2%) and less educated (22.5%). The proportion of death rate was higher among those with no education or primary education 70 percent indicating the disease burden is among younger age groups and less educated deserves more attention during targeting.

In this study, the sex ratio observed is in conformity with the 2007 Ethiopian census data suggesting the strength of the present study. The mortality rate of 16.1 percent during the five years observed in this study is similar to South African cohort which was 16 percent. However, when compared with the Ethiopian general population, the rate is 5 times higher (17). On the other hand, the study conducted in Arbaminch hospital in 2003 by Degu, a mortality rate of 16.7% within one year of follow up was reported which is higher than one year mortality in the present study which observed 9.4% in the first one year. The observed higher difference in the Arbaminch study could be explained partly as follows: a) the enrolled

or studied patients were those patients with advanced stages of the disease b) free ART was not initiated in Ethiopia c) other ART care quality was poor compared to the present situation in which the care issue has improved dramatically(11). The present mortality findings are also better when compared with the five years mortality rate of 20.0% reported in Botswana prospective cohort. Some of the explanations forwarded for the higher prevalence in Botswana are not different from what has been stated in the Arbaminch in that at that time of the study, ART was newly started in most of African countries and hence patients were with advanced disease secondly professionals were new for the ART including the care required for such patients. Similarly a very high mortality rate of 29.7% was reported in Tanzanian cohort study conducted in the year 2006. The Tanzanian report is probably the highest mortality rate registered in Africa; this may question ART quality of care in Tanzanian rural hospital (12). All the cohorts of Arbaminch, Tanzania, Botswana and Uganda were on first line regimen. The five years mortality rate reported in developed country, where the health facility and care is better, is much lower than mortality rate in Africa for instance mortality in UK was 11 percent (4).

In this study WHO stage IV, CD4<50/mcl, bed ridden functional status, age group greater than 45 and drug regimen 1b are found significant predictors of mortality. Patients with WHO stage IV are found to have three fold risk of death compared to WHO stage I-III patients. This is again similar to other studies in Africa in general and in Ethiopia in specific. For example in the Arbaminch 2003 study, WHO stage IV and leukocyte count <750/mcl were found to be significant predictors of mortality. Similarly a study done in Botswana in 2007, WHO stage III and IV were also reported as the major significant predictors of mortality. However, in this study there is no significant difference in mortality between WHO stage I, II and III, this is also true in most of the previous studies with the exception of Botswana study where WHO stage III was documented as a significant predictor of mortality. Another important finding is that there is no death registered in patients with WHO stage II suggesting that WHO stage is an independent marker of mortality in patients treated with HAART. Compared to the CD4, the WHO stage is a stronger predictor of death While the ultimate goal should be to treat patients before they progress to such advanced WHO stage. It is usually easy, cheap and in line with bio-chemical markers like CD4 in resource limited settings that is why WHO staging is used to initiate ART in Ethiopian patients as well as in resource poor settings. Therefore, it is praiseworthy for clinicians and programme managers to prioritize and decide on patient's clinical and supportive cares (11, 13) based on their WHO disease staging.

In the same way CD4 count less than 50/mcl is significant predictor of mortality in this study. This finding is consistent with earlier studies done in Africa. Study done in Arbaminch hospital, Ethiopia found leukocyte count <750/mcl as predicting factor of mortality. Here CD4 and Leukocyte counts are markers of one another that is to say low leukocyte count implies low CD4 count and vice versa. But for Asian and some African countries including Ethiopia the normal CD4 range is lower than other population so Leukocyte count alone should not be a surrogate marker of CD4 though it gives some clue as an indicator. Studies conducted in Botswana in 2007 and Durban, South Africa showed CD4 count less than 50/mcl as a significant predictor of mortality.

The high early mortality in patients with advanced disease (WHO stage IV) implies the need for starting treatment earlier. This however, requires early diagnosis of HIV infection through improved HIV counselling and testing practices (HCT). For patients who present at advanced stage and low CD4 count more frequent contact with the patient may help prevent potentially treatable conditions such as mycobacterial infections. The other striking finding in this study is the very low CD4 count which predicted mortality. Although the recommended CD4 for initiating treatment is below 200/mcL, this failed to identify patients at immediate risk of dying. This highlights the need for paying closer attention to patients with very low levels of CD4 count.

Another important finding in this study is, which is not been registered in other studies is patient functional status such as being bed ridden is the strongest predictor of mortality. Similarly age greater than 45 years and drug regimen 1b are found to be significant predictors of mortality in this study. This finding is in line with study conducted in Côte d'Ivoire which showed old age as significant predictor of mortality. However the study found no association between drug regimen and death. Bed ridden functional status may imply advanced disease as that of WHO stage four where patients usually have very low CD4 and advanced stages of the disease Age group greater than 45 and drug regimen 1b were not registered as predictor of mortality in other study. This is another important new finding observed which requires further attentions during programme implementation.

Body mass index (BMI) less than 19, leukocyte count less than 750/mcl, haemoglobin less than 8g/dl, old age and severe malnutrition were found significant predictors of mortality in many studies done in Africa. However in this study it was difficult to analyse for these factors because height, haemoglobin, and leukocyte count were not available almost for all patients. In Adama hospital height was measured only for paediatric age groups and hemoglobin was measured only for those with complaint signifying anemia (12, 13, and 16).

In order to have an effective ART management and follow up of patients, these are the gray areas which require further the attention of program mangers and other allied ministries.

Although occupation such as being a farmer was a significant predictor of mortality in bivariate analysis, this association was lost when other confounding factors were controlled in the multivariate analysis. Some other independent factors like marital status, gender, religion, educational status are found not predicting factors of mortality in patients on ART.

Health related quality of life (HRQL) was measured using Sf-36 HRQL questionnaire which is standardized. Sf-36 was analysed in many study and it shows high reliability almost in all of them. The HRQL questionnaire is a said to be reliable both if self administered or interview administered. In this study it was interview administered by trained attending health workers. The result of HRQL score was high for physical function, moderate for emotional and mental health but is low for general health perception. This result is consistent with study conducted in west Uganda. The result obtained in the present study is again similar to health related quality of life score reported in Sweden except for general health score which is lower in this study than that of Sweden probably because of the low health perception observed in this study and possibly because of low literacy rate and response bias(18).

The HRQL study attempted in the present study is one of a few studies in our setting and revealed the situation in a candid manner. The study could serve as a benchmarking for other studies as well in African region including Ethiopia for those dealing with such kind of study patients on ART. The five-year follow-up is longer than follow-up in other studies of clinical outcomes with ART in this region. Clinical and biochemical measures were appropriate variables to predict mortality. The loss to follow-up and transfer-out rates is high and, as such, the outcome from these patients is not known. It may be those patients who were lost to follow-up may had higher death rate, in which case the survival benefit would have been over-estimated. For patients who transferred out to another treatment site, it could be argued that their outcomes would be similar to those who remained at Adama hospital.

Strength and limitations of the study

Limitations:

- There are some weaknesses of this study. First, mortality might be underestimated, since patients lost to follow-up probably includes more of individuals dying at home without being reported. The proportion of patients lost to follow-up and transferred out in the present study is around half so data quality would be improved with better cohort retention.
- Second, the results might be affected by selection bias towards patients with more severe disease, since the study is conducted in a hospital setting.
- Third because of retrospective study design baseline variables like haemoglobin, leukocyte count, BMI were not included in analysis since they are not routinely measured this may introduced confounding bias.
- Fourth selection bias is possibly introduced during secondary data collection because charts with incomplete records were jumped. It is known that the generalizability of a prognostic factors can be impaired if important independent predictors are left out. However, our results strongly suggest that simple and available measurements can be useful alternative prognostic markers.

Strength:

- The main strength of this study is that it is carried out in Typical African hospital which serves both urban and rural community with use of trained ART staff and with long retrospective follow-up of five years unlike other studies which used data of one to three years.
- Health related quality of life is done in Ethiopia on patients receiving ART for the first time this will be a good baseline data for researchers in the area as well as in the country.

Conclusion

This study demonstrates that simple laboratory and clinical data, available to health care providers prior to ART initiation, can predict which patients are at increased risk of death when they start therapy. The findings from this study again demonstrate that ART has clear clinical and survival benefits in patients not treated with HAART death is demonstrated as high as fifty- eight percent in Ethiopia (10). The mortality rate in this cohort is 16.1 percent which is similar to mortality rate in other African countries. Given that the disease severity in this cohort was high, one could expect better outcomes in patients who initiate therapy earlier. Additional co-morbid conditions such as poor nutrition and tuberculosis are likely to contribute to the deaths observed. Interventions enabling more patients to be identified before they develop these clinical markers and earlier initiation of ART will help ensure maximum

benefits of therapy. The health quality of life score is from moderate to high in most of the eight items which is similar to study done in Uganda.

Recommendations

Based on the present study findings, the following recommendations are forwarded:

1. A Different type of follow up schedule should be developed for those ART patients with advanced disease (WHO stage IV) and those with very low CD4 count
2. There should be good data management and mechanism to trace defaulters and those transferred out to get more reliable national mortality figure
3. There is a need for improved patient retention in the same service, the retention rate is very low
4. The ART care in Ethiopia should be further improved to decrease the current death rate
5. CD4 count level to start ART is better revised in Ethiopian Situation because CD4 count below 200/mcl failed to show significant association with increased risk of death in many African studies
6. There is a need for further study to verify the findings or to see changes over time

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Annex 1: Conceptual framework of analysis

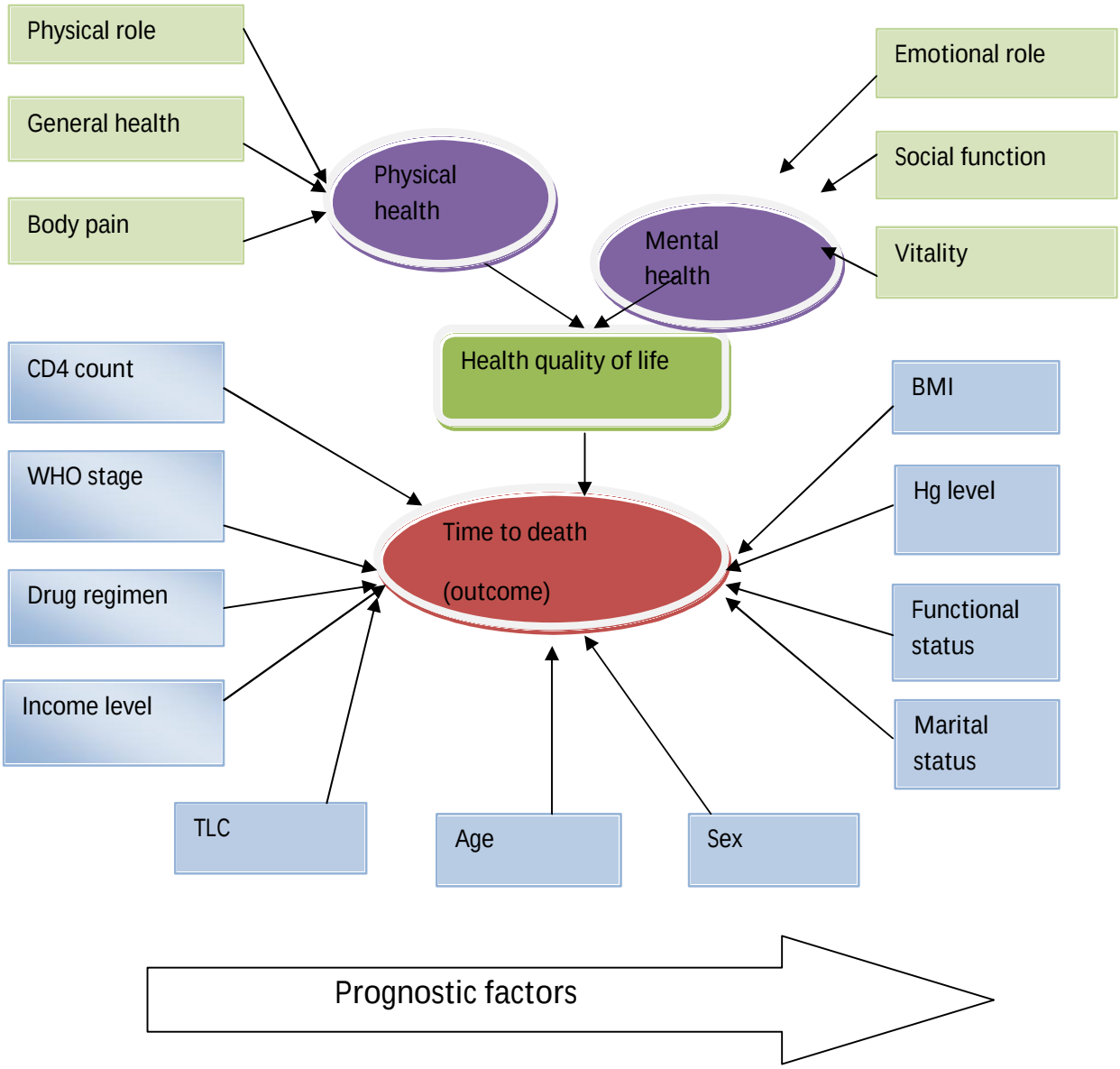

Figure 6: Conceptual framework of analysis for the proposed study

Annex 2: Consent Form

INFORMED CONSENT FORM

My name is _____. I am working with the research team of Addis Ababa University. Here in Adama hospital we are interviewing people with HIV/AIDS to measure their health quality of life. We believe that this study would help to bring about practical changes on the problems related to health quality of life of HIV/AIDS patients on ART and will improve the understanding of factors for death. We assure you that the study has no any harm for you. Moreover we would like to assure you that your name will not be mentioned in this form and will never be used in connection with any of the information you tell me and the information that you give us will be kept confidential. You have full right to; to take part, not to take part or to interrupt the interview at any time and your participation or non participation will not affect your treatment. However your honest answer to these questions will help us to identify quality of life of patients on ART and will enable to design better treatment or intervention. The interview will roughly take ten minutes.

Address:

Principal investigator -0911086484

IRB-0115538734

According to information above, are you willing to participate in the interview of this study?

1. Yes

2. No

Signature of the respondent which shows that the respondent has consented to participate_____

Guca hubatanii waliif galuu ibsu

Maqaan koo_____.Ani garee qorannaa University Finfinnee waliinan hojjachaa jira. As hospitaala Adaamatti namoota viyirasii HIV/AIDS tiin qabamanii dawaa farra HIV fudhachaa jiran sadarkaa qulqullinaFayyaan isaanii irra jiru

baruuf gafiif deebii adeemsifna.Qorannoon kunis sadarkaa fayyinsa namoota dawaa fara HIV fudhataa jiran irratti jijiirama qabatamaa ni fida jennet amanna. Akasumas sababa namoonni dawaa fudhachaa jiran du'aniif hubannoo haaraa ni fida. Qorannaan kun namoota gaaficha deebisan irratti rakkoo tokko hin qabu.Maqaan keesan gonkumaa guca kana irratti kan hin bareefamne yoo ta'u karaa fedheenuu odeefannoon isin nuuf kennitan maqaa keessan waliin walhinqabatu. Odeefannoon isin nuuf kenitanis icitiidhan qabama.Qorannoo kana irratti hirmaachuf, hirmaachuu issuuf, yeroo barbaadan adda kutuuf mirga guutuu qabdu.Hirmaachuu yookin iisun keesan tajaajila Fayyaa isiniif kennamu irratti jijiirama tokko hin qabu.Haata'u malee odeefannoon isin nuuf kennitan haalli sadarkaa qulqullinni Fayyaa namoota dawaa farra HIV fudhatan sadarkaa irra jiru baruuf akkasumas fooya'insa barbaachisaa ta'e fiduuf fayyidaa guddaa qaba.Gafiin kun tilmaaman daqiiqaa 10 ni fudhata.

Bilbila:

Kan ogeessa Qorannicha adeemsisuu-0911086484

Universitii finfinneetti kooree calallii-0115538734

Akaataa hubannoo asii olitti argataniin, hirmaachuf fedhii keessanii?

Fedhii isaanii ibsanii 1.Eeyee

2.Lakki

Mallattoo fedhiidhan hirmaachuu isaanii ibsu_____

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2.: Ã

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Questionnaire to assess health related quality of life

Instructions for completing the questionnaire: Please answer every question. Some questions may look like others, but each one is different. Please take the time and answer the one that best represents your response.

SSN#: _____ Date: _____

Person helping to complete this form: _____

1. In general, would you say your health is:

- q Excellent
- q Very good
- q Good
- q Fair
- q Poor

2. Compared to one year ago, how would you rate your health in general now?

- q Much better now than a year ago
- q Somewhat better now than a year ago
- q About the same as one year ago
- q Somewhat worse now than one year ago
- q Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- q Yes limited a lot.
- q Yes limited a little.
- q No not limited at all.

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?

- q Yes limited a lot.
- q Yes limited a little.
- q No not limited at all.

c. Lifting or carrying groceries.

- q Yes limited a lot.
- q Yes limited a little.
- q No not limited at all.

d. Climbing several flights of stairs.

- q Yes limited a lot.
- q Yes limited a little.
- q No not limited at all.

e. Climbing one flight of stairs.

- q Yes limited a lot.
- q Yes limited a little.
- q No not limited at all.

f. Bending, kneeling or stooping.

- q Yes limited a lot.
- q Yes limited a little.

q No not limited at all.

g. Walking more than one mile.

q Yes limited a lot.

q Yes limited a little.

q No not limited at all.

h. Walking several blocks.

q Yes limited a lot.

q Yes limited a little.

q No not limited at all.

i. Walking one block.

q Yes limited a lot.

q Yes, limited a little.

q No not limited at all.

j. Bathing or dressing yourself.

q Yes limited a lot.

q Yes limited a little.

q No not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down the amount of time you spent on work or other activities?

c Yes c No

b. Accomplished less than you would like?

c Yes c No

c. Were limited in the kind of work or other activities

c Yes c No

d. Had difficulty performing the work or other activities (for example, it took extra time)

c Yes c No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down the amount of time you spent on work or other activities?

c Yes c No

b. Accomplished less than you would like

c Yes c No

c. Didn't do work or other activities as carefully as usual

c Yes c No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

q Not at all

q Slightly

q Moderately

q Quite a bit

q Extremely

7. How much bodily pain have you had during the past 4 weeks?

q Not at all

q Slightly

q Moderately

q Quite a bit

q Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

q Not at all

q Slightly

q Moderately

q Quite a bit

q Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. did you feel full of pep?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

b. have you been a very nervous person?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

c. have you felt so down in the dumps nothing could cheer you up?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

d. have you felt calm and peaceful?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

e. did you have a lot of energy?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

f. have you felt downhearted and blue?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

g. did you feel worn out?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

h. have you been a happy person?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

i. did you feel tired?

q All of the time

q Most of the time

q A good bit of the time

q Some of the time

q A little of the time

q None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

q All of the time

q Most of the time

q Some of the time

q A little of the time

q None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

b. I am as healthy as anybody I know

q Definitely true

q Mostly true

q Don't know

q Mostly false

q Definitely false

c. I expect my health to get worse

- q Definitely true
- q Mostly true
- q Don't know
- q Mostly false
- q Definitely false

d. My health is excellent

- q Definitely true
- q Mostly true
- q Don't know
- q Mostly false
- q Definitely false

Questionnaire to assess quality of life

Afaan Oromoo version

Qajeelfama deebii kennuuf barbaachisu: Gaafii hundaa osoo deebiftanii gariidha.Gaafileen tokko tokko waan walfakaatan fakaatu garuu hundi adda.

Lakk: _____

Guyyaa: _____

Nama kana guutuuf gargaare:

_____

1. Walligala haalli Fayyaa keetii akkami:

- q Garmalee bayee gaariidha
- q Bayee gaariidha
- q Gariidha
- q Hamaa hin jedhu
- q Garii miti

2. Wagaa tokko dura kan jirura amma haalli Fayyaa kee akkami?

- q Wagaa har'aa irra guddaa amma naaf wayya
- q Xiqqoo amma naaf wayya
- q Akkuma wagaa hari'aati
- q Wagaa hari'aatii xiqqoo gadi
- q Waggaa hari'aatii bayee gadi

3. Kanaa gaditti kan jiran hojii ati guyyaa keessatti hojachuu malan. Hojii dura hojjattu amma da'abdeetaa? Yoo ta'e hagam?

a. Hojiiwan akka, fiiguu, mi'a guddaa kaasuu, sochii qaamaa cimmaa taasisuu.

- q Eeyee bayeen dadhaba

- q Xiquman dadhaba
- q Homaa hin dadhabne

b. Hojiiwan akka, jabala bakkaa waraaksuu?

- q YEeyee bayeen dadhaba
- q Eeyee xiqqoo dadhabeera
- q Homaa hin dadhabne

c. Waan nyaataa ol-kaasuu fi baachuu

- q Eeyee bayeen dadhaba
- q Eyee xiqqoo dadhabeera
- q Homaa hin dadhabne

d. Tabba yookin sadarkaa manaa bahuu.

- q Eeyee bayeen dadhaba
- q Eyee xiqqoo dadhabeera
- q Homaa hin dadhabne

e. Sadarkaa manaa tokko yookiin yaa’ xiqqoo.

- q Eeyee bayeen dadhaba
- q Eyee xiqqoo dadhabeera
- q Homaa hin dadhabne

f. Gadi jechuu jilbiifachuu yookiin dhaabachuu.

- q Eeyee bayeen dadhaba
- q Eyee xiqqoo dadhabeera
- q Homaa hin dadhabne

g. Kollo-meetira tokko deemuu.

- q Eeyee bayeen dadhaba

q Eyee xiqqoo dadhabeera

q Homaa hin dadhabne

h. Mandara bayee deemuu.

q Eeyee bayeen dadhaba

q Eyee xiqqoo dadhabeera

q Homaa hin dadhabne

i. Mandara tokko deemuu.

q Eeyee bayeen dadhaba

q Eyee xiqqoo dadhabeera

q Homaa hin dadhabne

j. Ofiin dhiqachuu fii ufachuu.

q Eeyee bayeen dadhaba

q Eyee xiqqoo dadhabeera

q Homaa hin dadhabne

4. Torbee arfan darban keessatti, da'abinsa qaamaairraa kan ka'e hojiin yookin sochiin gochuu dadhabde ni jiraa?

a. Eerina yeroo dur hojjattu yookiin sochootu gabaabsuu?

c Eeyee c Lakki

b. Haga hojjachuu yookiin socho'uu barbaadduu gaddi raawachuu?

c Eeyee c Lakki

c. Sochiiwaan, hojii duraan hojjattu iisuu

c Eeyee c Lakki

d. Hojiin, sochiin dur raawattu yeroo dabalataa sijalaalfudhachuu

c Eeyee c Lakki

5. Torbee arfan darbe keessatti, ofitti aaruu yokiin of jibbuu irraa kan ka'e hojiin yookin sochiin raawachuu dadhabde ni jiraa?

a. . Eerina yeroo dur hojjattu yookiin sochootu gabaabsuu?

c Eeyee c Lakki

b. Haga hojjachuu yookiin socho'uu barbaadduu gaddi raawachuu?

c Eeyee c Lakki

c. Akka duraan xiyeefannaadhaan raawadhutti raawachuu iisuu

c Eeyee c Lakki

6. Torbee arfan darbe keessatti, rakkoon qamaa fi sammuu of jibbuu walitti ufeenya maatii, hiriyaa, olla, garee biraa waliin qabdu jeeqee?

q Homaa hin jeeqne

q Bayee xiqaa

q Xiqaa

q Bayee

q Garmalee bayee

7. Torbee arfan darbe keessatti ukkuba qamaa hagam qabda?

q Homaa hin qabu

q Bayee xiqaa

q Xiquma

q Bayee

q Garmalee baayee

8. Torbee arfan darbe keessatti, dhukubni qamaa hojii manaa yokiin alatti hojjattu hagam si oowwe?

- Homaa hin qabu
- Bayee xiqaa
- Xiquma
- Bayee
- Garmalee baayee

9. Gaafiwan kanaa gadii torbee arfan darbe maaltu akka sitti agahamaa tire gaafatu. Gafiwan kanaaf deebii haala keetti iyaatu fi hagamii akka ta'e ibsu deebisi.

a. Chiki jechaa kan turte?

- Yeroo hundaa
- Yeroo irra caala
- Yeroo bayee
- Yeroo muraasaaf
- Darbee darbee
- Gonkumaa hin jiru

b. Bayee ofitti araa kan turte?

- Yeroo hundaa
- Yeroo irra caala
- Yeroo bayee
- Yeroo muraasaaf
- Darbee darbee
- Gonkumaa hin jiru

c. Kan homtuu si hin gamachiifne fii gaddaa kan turte?

- Yeroo hundaa
- Yeroo irra caala
- Yeroo bayee
- Yeroo muraasaaf
- Darbee darbee
- Gonkumaa hin jiru

d. Nagaa fii tasgabiin sitti dhagahamaa kan turte?

- Yeroo hundaa
- Yeroo irra caala
- Yeroo bayee
- Yeroo muraasaaf
- Darbee darbee
- Gonkumaa hin jiru

e. Jabina gahaan kan sitti agahame?

- Yeroo hundaa
- Yeroo irra caala
- Yeroo bayee
- Yeroo muraasaaf
- Darbee darbee
- Gonkumaa hin jiru

f.Onneen kee cabee kan of jibite?

- Yeroo hundaa

- q Yeroo irra caala
- q Yeroo bayee
- q Yeroo muraasaaf
- q Darbee darbee
- q Gonkumaa hin jiru

g. Bayee miidhamuun kee kan sitti agahame?

- q Yeroo hundaa
- q Yeroo irra caala
- q Yeroo bayee
- q Yeroo muraasaaf
- q Darbee darbee
- q Gonkumaa hin jiru

h. Gamadaa kan turte?

- q Yeroo hundaa
- q Yeroo irra caala
- q Yeroo bayee
- q Yeroo muraasaaf
- q Darbee darbee
- q Gonkumaa hin jiru

i. Bayee da'abinsi kan sitti agahame?

- q Yeroo hundaa
- q Yeroo irra caala
- q Yeroo bayee
- q Yeroo muraasaaf

- q Darbee darbee
- q Gonkumaa hin jiru

10. Torbee arfan darbe keessatti rakkoon, fayyaa qaama keetii, hiphina sammuu fira yookin hiriyaa gaafachuu irratti rakkoon sitti uume?

- q Yeroo hundaa
- q Yeroo irra caala
- q Yeroo bayee
- q Yeroo muraasaaf
- q Darbee darbee
- q Gonkumaa hin jiru

11. Hagam dhugaa yookiin soba akka ta'e deebisi?

a. Nama biraa irra salphaatan dhukubsadha

- q Siriidha
- q Yeroo bayee siriidha
- q Hin beeku
- q Yeroo bayee soba
- q Soba

b. Ani akkuma nama fedhee fayaadha

- q Siriidha
- q Yeroo bayee siriidha
- q Hin beeku
- q Yeroo bayee soba
- q Soba

c. Haalli Fayyaa kootii hir'ataa akka deemun tilmaama

- q Siriidha

- q Yeroo bayee siriidha
- q Hin beeku
- q Yeroo bayee soba
- q Soba

d. Haalli Fayyaa kiyyaa bayyee gaaridha

- q Siriidha
- q Yeroo bayee siriidha
- q Hin beeku
- q Yeroo bayee soba
- q Soba

¾Ö? ¾Ø ^ ' Å [Í K T ¨ p ¾ } ² Ò Ì ØÁo - 9

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ð u:w³ ¬ ^¬ ’ ¬

ð :K¬pU

ð U:w³ ¬ ¬g’ ¬

ð u^ÓÖ Ü’ ¬g’ ¬

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ð u^ `ÓØ ^¬ ’ ¬

ð u:w³ ¬ ^¬ ’ ¬

ð :K¬pU

ð U:w³ ¬ ¬g’ ¬

ð u^ÓÖ Ü’ ¬g’ ¬

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Annex 4: steps in scoring Sf-36

STEP 1 SCORING QUESTIONS

QUESTION NUMBER	ORIGINAL RESPONSE	RECORDED VALUE
1, 2, 20, 22,34, 36	**1**	**100**
	2	**75**
	3	**50**
	4	**25**
	5	**0**
3, 4, 5, 6, 7, 8, 9, 10,11, 12	**1**	**0**
	2	**50**
	3	**100**
21, 23, 26, 27, 30	**1**	**100**
	2	**80**
	3	**60**
	4	**40**
	5	**20**
	6	**0**
24, 25, 28, 29, 31	**1**	**0**
	2	**20**
	3	**40**
	4	**60**
	5	**80**
	6	**100**
32, 33, 35	**1**	**0**
	2	**25**
	3	**50**
	4	**75**
	5	**100**
13, 14, 15, 16, 17, 18, 19	**1**	**0**
	2	**100**

STEP 2 AVRAGING ITEMS TO FORM 8 SCALES

SCALE	NUMBER OF ITEMS	AFTER RECORDING AS PER STEP 1 AVRAGE THE FOLLOWING ITEMS
Physical functioning(PF)	**10**	**3, 4, 5, 6, 7, 8, 9, 10, 11, 12**
Role limitation due to physical health(RP)	**4**	**13, 14, 15, 16**
Role limitation due to emotional problem(RE)	**3**	**17, 18, 19**
Energy/fatigue(VT)	**4**	**23, 27, 29, 31**
Emotional well being(MH)	**5**	**24, 25, 26, 28, 30**
Social function(SF)	**2**	**20, 32**
Pain(BP)	**2**	**21, 22**
General health(GH)	**5**	**1, 33, 34, 35, 36**