

**FACTORS ASSOCIATED WITH MORTALITY OF PATIENTS ON
ANTIRETROVIRAL THERAPY AT THE ANDARA DISTRICT, NAMIBIA**

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Emmy-Else NDEVAETELA

Student Number: 9115730

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Main Supervisor: Dr. A.R.E. Kloppers (UNAM)

Co-supervisors: Dr. S. Kuugongelwa (UNAM)

Associate Prof. Solomon D. Yigeremu (UNAM/ITECH)

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ABSTRACT

Namibia, one of the countries hardest hit by HIV/AIDS, has embarked on a large scale public health sector roll-out of ART. The Catholic Health Services is implementing an HIV/AIDS treatment program in the Andara district since 2004. Even though there is strong evidence to show that antiretroviral therapy (ART) improves the survival and quality of life of people living with HIV/AIDS (PLWHA), an increased trend of mortality in patients on ART in the Andara district was observed, but there was no evidence to establish factors associated with such mortality.

The purpose of this study was to explore, describe and analyse factors associated with mortality of patients on ART in the Andara district. The objectives were to describe baseline socio-demographic and medical characteristics of patients on ART in the Andara district and to determine the independent risk factors associated with mortality of patients on ART on the Andara district. To direct this study, a null hypothesis and alternative hypothesis were formulated. A quantitative, analytical, case-control research design was applied, analysing patients' records retrospectively.

The population consisted of 913 medical records of HIV/AIDS patients aged from 15 years and older, who started ART in the Andara district between the 1st of August, 2004 and the 30th of September, 2009. Case population consisted of 196 adult patients who died and controls population consisted of 697 patients who were alive by the end of July

2011. All records of cases (who died) were taken and for each case, two controls were sampled (alive) to give the ratio of 1:2 using the simple random sampling method.

Data was collected by means of a data abstraction tool (annexure A at page 138) developed by the researcher, based on the information in the standardised patient care booklet or patient file. Standardised patient files, registers and ART database (ePMS) were used to abstract data into a data abstraction tool. Data was entered into the Statistical Package for Social Science (SPSS) database. Data analysis involved both descriptive and analytical statistics. Descriptive statistics focus on the characteristic factors of patients such as socio-demographic factors, baseline information and medicine related factors. Analytical statistics in terms of Odds Ratios (OR), Confidence Intervals (CI), chi-square and P-value are presented to show associations between different variables and treatment outcomes. Strength of association is also indicated.

This study was approved by the Postgraduate Studies Committee of the University of Namibia. Permission was sought from the Ministry of Health and Social Services Research and Ethics Committee, and from Catholic Health Services.

This study concluded that sex, functional status, having a treatment supporter and anaemia are significant risk factors associated with death in the Andara district. The study also revealed that the ART regimen started was a protecting factor.

There is a need for development of a guideline on revision of ART M&E tools in the Ministry of Health and Social Services. There is a need to strengthen health care workers' adherence to ART guidelines, especially regarding the monitoring of patients on ART, as well as improving record keeping in the Andara district. Incomplete records, missing data and missing files limited the study. In addition, there are limited primary sources on the topic of factors associated with mortality of patients on ART.

ACRONYMS

| | |
|--------|--|
| ADL | Activity of Daily Living |
| AIDS | Acquired Immuno Deficiency Syndrome |
| ANC | Antenatal Care |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| BMI | Body Mass Index |
| CAA | Catholic AIDS Action |
| CD4 | Cluster of Differentiation |
| CHS | Catholic Health Services |
| Hb | Haemoglobin |
| HIV | Human Immuno Deficiency Virus |
| IMAI | Integrated Management of Adolescents and Adulthood Illnesses |
| MOHSS | Ministry of Health and Social Services |
| OIs | Opportunistic Infections |
| PEPFAR | President's Emergency Plan For AIDS Relief |
| PLWHA | People Living With HIV and AIDS |
| SPSS | Statistical Package of Social Science |
| SSA | Sub-Saharan Africa |
| UNAIDS | Joint United Nations Program on HIV/AIDS |
| UNGASS | United Nations General Assembly Special Session |
| WHO | World Health Organisation |

ANTIRETROVIRALS (MEDICINES)

| | |
|-------|---------------------|
| TDF | Tenofovir |
| 3TC | Lamivudine |
| NVP | Nevirapine |
| LPVr | Lopinavir/Ritonavir |
| IDV/r | Indinavir/Ritonavir |
| EFV | Efavirenz |
| D4T | Stavudine |
| ddi | Didanosine |
| AZT | Zidovudine |

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CHAPTER 1

INTRODUCTION

1.1 ORIENTATION OF THE STUDY

Namibia, like the rest of Sub-Saharan Africa, is heavily affected by Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS). AIDS is caused by HIV which destroys the immune system of humans by targeting specific white blood cells, known as CD4+ cells, which are crucial in helping the body to fight diseases (CDC, n.d. a). HIV infected individuals whose immunity is compromised are susceptible to different types of infections and diseases which leads to death. In 2008, 2 million people died due to AIDS related diseases universally, of which 1.4 million were from Sub-Saharan Africa (UNAIDS, 2009). In Namibia, 5 400 people died of AIDS related diseases in 2007/2008 (MoHSS, 2008). Because of the high burden of HIV/AIDS, the Government of the Republic of Namibia has implemented more HIV prevention strategies such as male circumcision to add to the existing prevention strategies in an effort to curb the spread of HIV. Namibia follows the World Health Organisation (WHO) guidance to introduce a more efficacious antiretroviral therapy (ART) in order to offer better treatment options for people living with HIV and consequently reduce mortality due to AIDS related diseases. This study refers to the mortality of HIV/AIDS patients on ART.

The Government of Namibia has acknowledged that HIV/AIDS is a serious problem for the development of the country and has invested substantial financial and human resources in fighting the disease. The Ministry of Health and Social Services (MoHSS) started providing ART in 2003. Since 2003, ART has become increasingly available in the country and is now available at all the 34 district hospitals and some health centers.

ART was introduced in the Andara district, one of the Catholic Health Services (CHS) districts in Namibia, in 2004. However, an upward trend in mortality of patients on ART in this district has been noted since 2004 (CHS, 2009). Other Catholic Health Services (CHS) districts experienced the same trends until 2007, and have since reflected a decline or plateau of mortality rates (CHS, 2009). Despite efforts to ensure success of ART, the increase in mortality for patients on ART in Andara continues unabated. A report from the Ministry of Health and Social Services reflected the following factors which might be causing death among patients receiving ART: Failure of HIV/AIDS patients' body systems to respond to ART positively, avoiding starting ART because of stigma, stopping ART or default of ART due to side effects (MoHSS, 2008).

The Oxford English dictionary (2006) defines stigma as “a mark of disgrace associated with a particular circumstance or a person”. Stigma impedes adherence to medication. Fear of stigma has led people to grind drugs into powder, which can results in

inconsistent doses. This is mainly done to avoid taking medicines in front of others (ICRW, 2010).

ART is a life-long commitment which requires strict adherence for effectiveness; thus adherence is the largest determinant of patient survival. ART success is also dependent on the commitment and continuous support of family members, friends and community of the individual receiving the treatment (MoHSS, 2006). In addition to ART, balanced nutrition and adequate food supply is recognised to be critical in enabling treatment uptake and adherence, nutritional recovery and treatment success (MoHSS, 2007a). Physical well-being and hygiene helps contribute to ART success. Equally important is exercise and positive living which refers to taking care of one's own health and emotional well-being, maintaining a sense of optimism and getting support (UNAIDS, 2009).

To support the individual receiving ART, health workers (social workers, community counselors, psychologists, nurses and medical officers) play a critical role in counseling patients, providing them with treatment and educating them to take responsibility for their own health. In addition, health workers closely monitor patients' clinical condition, treatment failure and medication tolerance, providing them with prophylaxis and treatment of opportunistic infections. However the increase in the mortality of patients on ART in the Andara district may be caused by factors not yet known.

1.2 STATEMENT OF THE PROBLEM

A research problem may be defined as an area of concern in which there is a deficiency in the knowledge base required to support practice, and consequently there is a need for improvement (Brink, Van der Walt & Van Rensburg, 2012, Burns & Grove, 2005). Several studies conducted worldwide have reflected a positive impact of ART with respect to prolonging life, improving quality of life, reduction of incidences of opportunistic infections and reducing mortality. The same positive effects also apply to many parts or regions in Namibia, but on the contrary, in the Andara district there is an upward trend in mortality of patients on ART (CHS, 2009).

The researcher, as a Monitoring and Evaluation Officer, for the CHS HIV/AIDS program finds it difficult to understand why the number of patients who die while on ART in the Andara district is high in comparison to other CHS health districts namely Nyangana, Oshikuku and Rehoboth. Amongst the four CHS districts, Andara is well known for having high stigma and discrimination. This is not only among community members; health workers have been known to stigmatise and discriminate against people living with HIV/AIDS (PLWHA) as well. This might have contributed to high negative treatment outcomes.

To date, there is no evidence available to establish factors associated with mortality of patients on ART in the Andara district. Therefore if factors are known, it would be

possible to develop appropriate interventions to reduce the mortality of patients on ART in the Andara district.

1.3 PURPOSE OF THE STUDY

The purpose of the study was to explore, describe and analyse factors associated with mortality of patients on ART in the Andara district.

1.4 OBJECTIVES OF THE STUDY

- To describe baseline socio-demographic, and medical characteristics of patients on ART in the Andara district.
- To determine the independent risk factors associated with mortality of patients on ART in the Andara district.

1.5 HYPOTHESIS

A hypothesis is a “specified testable expectation about empirical reality that follows from a more general proposition; more generally, an expectation about the nature of things derived from a theory. It is a statement of something that ought to be observed in the real world if the theory is correct” (Babbie, 2008:45). Welman, Kruger and Mitchell (2010:12) further define a hypothesis as a “tentative assumption or preliminary statement about the relationship between two or more things that need to be examined”.

To direct this study, an assumption is being made to establish the basis for test of statistical significance of association (Hulley, Cummings, Browner, Grady, Hearst, & Newman, 2001). Therefore a null and alternative hypothesis were formulated.

H₀: The null hypothesis assumes that there is no difference in socio-demographic, baseline and medical related factors between patients who die while on ART and patients who survive while on ART by the end of July 2011.

H₁: The alternative hypothesis assumes that there is a difference in socio-demographic, baseline and medical related factors between patients who die while on ART and patients who survive while on ART by the end of July 2011.

1.6 SIGNIFICANCE OF THE STUDY

The findings of the study could be of benefit to individuals on ART through the improvement of appropriate strategies to improve their quality of care, both self-care and care delivered by nurses in line with MoHSS' Integrated Management of Adolescent and Adulthood Illnesses (IMAI) program and other task shifting strategies. In addition, findings of this study could enhance the body of knowledge of health care practitioners regarding ART to be able to reduce the upward trend in mortality of patients on ART in the Andara district.

Furthermore, findings of this study could help the researcher in the role of monitoring and evaluation to understand what contributes to increased deaths among patients on ART in the Andara district. If factors associated with mortality of patients on ART in the Andara district are known, it will be possible to design specific measures to address the identified factors. This study could help ART programme designers to work with the monitoring and evaluation team to harmonise data collection tools and align them to the existing tools whenever the ART guidelines are updated. This study could, in addition, provide a structured method for the collection of consistent data by means of development of guidelines to revise monitoring and evaluation tools. Recommendations from this study could be applied in other areas in the country and abroad, which could benefit a number of individuals receiving ART.

1.7 OPERATIONAL DEFINITIONS OF KEY CONCEPTS

Factors

Factors are defined as circumstances, facts or influences that contribute to a result (Soanes, 2007). For this study, factors refer to variables that influence the mortality of patients on ART, such as age, sex, marital status, employment status, as well as baseline CD4.

Associated

Associated is defined as follows: “If one thing is associated with another, the two things are connected either because they happen together or because one thing causes the other” (Wehmeier, 2002, p.59). For this study associated refers to the influence the variables have on the death of patients on ART and it was determined using Odds ratio and p-values.

Mortality

Mortality is defined as death. The mortality for a given area is the number of people who die in that area (EBW Health Care, n.d.). For this study mortality refers to death amongst individuals who were receiving ART at the Andara district.

Patient

A patient is a person who undergoes treatment, especially in a hospital or under the care of a doctor, dentist, nurse or pharmacist (Wehmeier, 2002). For this study a patient refers to a person who receives ART at the Andara district.

Antiretroviral therapy

Antiretroviral therapy (ART) refers to the treatment of retroviral infections, such as HIV/AIDS, with antiretroviral medicines. Although these medicines do not kill the virus; they delay its growth. Antiretroviral medicines are referred to as ARV and treatment with antiretroviral medicines is referred to as antiretroviral therapy (ART).

Standard ART consists of administering at least three antiretroviral (ARV) medicines to maximise the suppression of HIV and stop the progression of the HIV/AIDS disease (WHO, 2010). For this study, 'ART' refers to a combination of at least three different ARV.

Cases

Mann, (2003) defines cases as subjects with a particular attribute. For this study, cases are defined as people who received ART at Andara ART clinic between 01 August 2004 and 31 September 2009, and have died by end of July 2011.

Controls

Mann, (2003), describes controls as subjects without a particular attribute. For this study, controls refer to people who received ART treatment at Andara ART clinic between 01 August 2004 and 31 September 2009 and were still alive by the end of July 2011.

1.8 SUMMARY

Chapter 1 provided an orientation to the study where the background on HIV and AIDS was discussed. A statement to the problem was formulated focusing on the knowledge gap which exists in the Andara district to understand factors associated with mortality of patients receiving ART. The purpose and objectives of the study were highlighted in this

chapter. The hypotheses were formulated, and the significance of the study discussed.

Key concepts used were defined.

The next chapter will provide a detailed literature review pertaining to HIV and AIDS,

Antiretroviral programmes and mortality among patients on ART.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

In line with the purpose of the study, namely to explore, describe and analyse factors associated with mortality of patients on ART in the Andara district as mentioned in Chapter 1, this chapter reviews relevant literature. The scope of this literature therefore is to synthesise evidence from books, published research, scientific reports and other credible sources of scientific work done globally, regionally and nationally mainly on HIV and AIDS, ART programmes and mortality of patients receiving ART. The chapter focuses on the HIV and AIDS treatment program and mortality due to HIV and AIDS related diseases. The review also describes known factors that may have influence on mortality of patients on ART as were reflected by prior studies.

2.2 PURPOSE OF THE LITERATURE REVIEW

A literature review is an organized written presentation of what has been published on a topic by scholars, to convey to the reader what is currently known regarding the topic of interest (Brink, Van der Walt & Van Rensburg, 2012, Burns and Grove, 2005). Literatures were reviewed to generate a picture of what is known about a particular situation and knowledge gaps that exist (Bless, Higson-Smith and Kagee, 2006, Burns and Grove, 2005). This review will focus on research, scripts and discussions related to

effects of ART programmes in general and the treatment outcome with emphasis on mortality in particular.

2.3 HIV AND AIDS

The human immunodeficiency virus (HIV) infects cells of the immune system, destroying or impairing their function. An HIV infection results in the progressive deterioration of the immune system, leading to "immune deficiency." The immune system is considered deficient when it can no longer fulfill its role of fighting infection and disease (MedlinePlus, n.d., WHO, 2013). Acquired immunodeficiency syndrome (AIDS) is a term which applies to the most advanced stages of HIV infection. It is defined by the occurrence of any of more than 20 opportunistic infections (OIs) or HIV-related cancers. Opportunistic infections are those infections associated with severe immunodeficiency, because they take advantage of a weakened immune system (WHO, 2013).

UNAIDS has described three different types of HIV/AIDS epidemics in different countries. These are low epidemic, concentrated epidemic and generalized epidemic. In low level epidemic, HIV has never spread to significant levels in any sub-population. The infection is confined to individuals with high risk behaviours, such as injection drug users and men who have sex with men. With concentrated epidemics, HIV spreads rapidly in a defined sub-population such as sex workers, but not well established in a

general population. While with generalized epidemics, all sectors of the population are affected (UNAIDS, 2009). Namibia is having a generalized epidemic.

AIDS was first identified in the United States of America (USA) in 1981 and has since spread globally (Volberding, Sande, Lange, & Greene, 2008). The number of people around the world living with HIV continued to increase reaching an estimated number of 33.4 million people infected by 2008. It is estimated that 2.7 million people were newly infected in 2008 alone and 2 million people died that year due to AIDS related conditions worldwide (UNAIDS, 2009). These statistics provide a clear indication that the HIV pandemic requires a global strategy if the number of people infected is to be reduced.

Africa is the continent most seriously affected by the HIV/AIDS epidemic. Most countries in Africa have a generalized epidemic (UNAIDS, 2009). Prevalence rates differ substantially with low prevalence figures in North African countries and the highest in Southern Africa (FPD, 2011). In sub-Saharan Africa (SSA), where Namibia is located, 22.4 million people were living with HIV, of which 1.9 million were newly infected in 2008. AIDS claimed 1.4 million lives in Sub-Saharan Africa that year (UNAIDS, 2009).

In Namibia the first case of AIDS was identified in 1986, and since then the disease has spread rapidly (MoHSS, 2007 b). The first HIV sero-sentinel surveillance conducted

among pregnant women attending antenatal care (ANC) in 1992 established an HIV prevalence rate of 4.2% and by 2002 it had risen to 22.0%. Although the HIV prevalence in Namibia has decreased to 17.8% in 2008, and 18.8% in 2010, Namibia remains one of the most seriously affected countries in the world (MoHSS, 2007 b & MoHSS, 2010 b). It is further estimated that, in Namibia 204 000 individuals were living with HIV during the period of 2007-2008 and 69 500 of these (63 600 adults and 5 900 children) were in need of ART as of March 2008 (MoHSS, 2008).

It was further estimated that in some parts of the country, HIV and AIDS related hospital admissions were between 50.0%-70.0% of all admissions in Namibian public health facilities (MoHSS, 2004). The mentioned scenario poses the most serious development challenge for Namibia. The high HIV prevalence rate and mortality due to HIV/AIDS related diseases in Namibia at present may affect the realisation of the National Vision 2030 regarding Namibia becoming “a prosperous and industrialized country, developed by her human resources enjoying peace, harmony and political stability” (GRN, 2004 p.15). If the HIV infection rate and mortality does not decrease, all systems (education, health and agriculture) may be negatively affected. This negative effect will be caused by human capacity decrease (Asemota, 2004).

2.4 ANTIRETROVIRAL THERAPY PROGRAMMES

ART is one of the most successful programmes developed in the world. The goal of antiretroviral therapy is to maximise viral suppression, restore immune function and improve the quality of life. ART is associated with decreased mortality, increased disease-free survival and a decrease in opportunistic infections (Spencer, 2005). In 2001 the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS made recommendations to make ARV medicines available in resource-limited countries, supported by the United States President's Emergency Plan For AIDS Relief (PEPFAR), (MoHSS, 2006). The World Health Organization (WHO) initiative and PEPFAR maintain a strong focus on the availability of treatment for HIV/AIDS people living in developing countries (Volberding, et al., 2008).

A UNAIDS report indicates that by the end of 2009, about 5.2 million people in low and middle-income countries were receiving ART. In Sub-Saharan Africa, close to 37, 0% of people eligible for treatment were able to access life-saving medicines in 2009. A marked increase in the availability of ART in Sub-Saharan Africa was noted by the end of 2008. About 3 million people (44.0%) of those in need of ART were receiving it, while in Asia, only 37.0% received it by 2008 (UNAIDS, 2009). The number of people receiving ART in low- and middle-income countries has increased to more than eight million people at the end of 2011. Until 2003, the high cost of the medicines, weak or inadequate health care infrastructure, and lack of financing prevented wide use of combination antiretroviral treatment in low- and middle-income countries. But in recent

years, increased political and financial commitment has allowed dramatic expansion of access to treatment (WHO, 2013).

The World Health Organisation (WHO) developed the clinical staging and case definition of HIV for resource-constrained settings in 1990 and revised in 2007. Staging is based on clinical findings that guide the diagnosis, evaluation, and management of HIV/AIDS and it does not require a CD4 cell count. WHO clinical staging system is used in many countries, particularly in low-resource settings, where CD4 testing may not be available to determine eligibility for antiretroviral therapy. Clinical stages are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS. These stages are defined by specific clinical conditions or symptoms. For the purpose of the WHO staging system, adolescents and adults are defined as individuals aged ≥ 15 years (WHO, 2005). Stage 1 represents the asymptomatic phase and stage 4 is the phase when the HIV infected patient has life threatening conditions. The first National ART guideline indicated that an HIV infected person in Namibia should start ART when in WHO clinical stage 3 or 4 (MoHSS, 2003).

In Namibia, ART services are being offered successfully at 66 public health facilities, which include all the 34 district hospitals. ART had become necessary because of the high number of HIV positive Namibians and had been described as a success (Avert, 2011). Significant achievements have been noted since the initiation of the programme and, as of March 2009, 64 629 people were on ART (57 087 adults and 7 542 children)

in the public sector (Hamunime, Maisiri & Tjituka, 2009). In 2010, Namibia was among the three countries with the largest number of people living with HIV, which had high coverage of ART. Rwanda achieved 88, 0%, Botswana 83, 0% and Namibia 76, 0%, coverage among adults (UNAIDS, 2010). Thus it was prudent for one to understand why in the Andara district, ART interventions were not successful.

When ART is used appropriately and correctly, there may be a reduction of HIV replication to extremely low levels, restore advanced immunological status to safe levels in majority of treated patients and prevent new HIV infections among partners of HIV infected patients (Volberding, et al., 2008; Spencer, 2005). To achieve good results from ART, a patient's adherence to treatment as prescribed is imperative (MOHSS, 2010 b). Adherence is defined as taking medications or interventions correctly according to prescription, following a prescribed care plan, attending follow-up visits on time and having required laboratory tests done, taking medication on time, adopting a healthy lifestyle and avoiding risky behaviours (Reda and Biadgilign, 2011; Haoses-Gorases, 2007-2008). Adherence to antiretroviral therapy is one of the most important contributing factors to positive clinical outcomes in patients with HIV. Long-term retention of patients on ART in low-income and middle-income countries is emerging as an important issue in rapidly expanding ART programs. Adherence is among the most modifiable variables in treatment. Best estimates demonstrate that adherence in resource-limited settings is equal or superior to that in resource-rich settings, possibly

due to focused efforts on support groups and community acceptance of adherence behaviours (Nachega, Mills, and Schechter, 2010).

There are different methods for assessing adherence and the level of adherence is specific not only to places and patient groups but also to the method of adherence measurement used. Methods of assessing adherence include direct methods such as biologic markers and body fluid assays, or indirect methods such as self-report, interview, pill counts, pharmacy records, computerized medication caps, and viral load monitoring. While a combination of these methods may be employed, patients self-report is the most widely used given its ease of implementation and use of already existing resources. Studies have also indicated that self-reports correlate well with both viral load and clinical monitoring. In developing countries, pharmacy refill reports and self-reports are commonly implemented for adults. Currently, there are no gold standard methods for measuring adherence. In this study, pharmacy records was the tool used to measure adherence whereby self-report and pill count were incorporated.

ART alone is not adequate. ART should be part of a comprehensive care programme that includes a number of interventions such as adequate nutrition, Opportunistic Infections (OIs) prophylaxis, safer sex practices, physical well-being and exercises, good hygiene and psychosocial support. Nutritional interventions should be an integral part of all HIV treatment programmes. Improved attention to diet and nutrition may enhance ART acceptability, adherence and effectiveness. Adequate nutrition which is best

achieved through consumption of a balanced healthy diet is vital for the health and survival of all individuals regardless of HIV status (WHO, 2003).

Although Namibia has achieved tremendous strides against the HIV/AIDS, especially regarding implementing treatment programmes, less effort were made to understand factors leading to deaths of patients receiving ART. Despite high success rates in the treatment of HIV with ARVs, a number of patients still die while receiving ART. Andara is one of the CHS districts which demonstrated high numbers of patients dying while on ART.

2.5 MORTALITY AMONGST PATIENTS ON ART

UNAIDS estimated that about 2 million people died globally due to HIV related causes in 2008, of which 1.4 million were from Sub-Saharan Africa. This number represents an 18, 0% decline in annual HIV-related mortality in Sub-Saharan Africa since 2004 (UNAIDS, 2009). AIDS related diseases have been a leading cause of death in Namibia since 1996. In 1999, AIDS related diseases were responsible for 26.0% of all reported deaths in health facilities of which 46.0% occurred among the 15-49 years age group. Thus indicating that, HIV/AIDS has caused a burden not only to the health sector in particular, but to the whole country at large.

Even though the ART programme has been implemented since 2003 in Namibia, it was estimated that 5 400 people died of AIDS related causes in 2007/08. Statistics of 2002/2003 reflected that 9 200 people died of AIDS related diseases, the estimation indicates that the number of people dying due to AIDS related diseases has decreased to 5 400 in 2007/2008 (MoHSS, 2008).

MoHSS (2008) further reflected that it is expected that even with increased ART coverage, the number of people dying from HIV/AIDS related diseases is likely to increase over the next five years. This increase may be attributed to the increasing population of patients on ART, and with some patients stopping to take their medicines because of negative side effects, or merely defaulting treatment. The other reason for increasing mortality may be that more patients on ART are reaching older ages (MoHSS, 2008).

Age is one of the most important demographic factors that influence the prognosis of AIDS. Increasing age at the time of HIV infection is associated with more rapid progression to AIDS in the absence of ART. Old age is associated with immunologic vulnerability, exposure to infectious diseases as well as psychosocial co-morbidities (Gadpayle, Kumar, Duggal, Rewari & Ravi, 2012). In 2005, persons aged 50 and over accounted for 35% of all deaths of people with AIDS globally (CDC, 2008). The life expectancy at birth in Namibia is estimated at 52.17 in 2013 (Omundi Index, 2013). HIV and AIDS have negatively affected the life expectancy rate of the Namibian population.

The predictors of mortality for HIV patients starting ART in a sample of 320 patients in Tanzania indicated that 30.0% died during a 36-month period of review. However, 60.0% of these patients died within three months of initiating treatment and factors associated with survival were baseline CD4 count, baseline Haemoglobin, Body Mass Index (BMI) and sex (Sieleunou, Souleymanon, Schonenberger, Menten, & Boelaert, 2009; Stringer, Zulu, Levy, Stringer, Mwangi, Chi, Mtonga, Reid, Cantrell, Buiterys, Saag, Marlink, Mwinga, Ellerbrock, & Sinkala, 2006). Furthermore, clinical stage of the disease, Cotrimoxazole Prophylaxis (CTP) at or before ART initiation, functional status and baseline weight; all are associated with survival in patients on ART (Suthar, Granich, Mermin, & Van Rie, 2012; Worku, 2009).

A number of studies conducted in Africa have shown that despite successes achieved by rolling out ART in the public sector, mortality in patients on ART is still significantly high, especially within the first 12 months of initiating treatment (Grant, Komarow, Sereti, Paliwa, Lederman, Powderly, Sattler, Sax, Andersen, & Zolapa, 2009; Sieleunou et al., 2009; Stringer et al., 2006; Zachariah, Fitzgerald, Massaquoi, Pasulani, Arnould, Makombe, & Harries, 2006).

Other studies reveal different aspects that influence mortality rate of patients on ART. Severe malnutrition ($BMI < 17 \text{ kg/m}^2$), low baseline CD4 counts ($<100 \text{ cells/ul}$) and high viral load at initiation of ART contribute significantly to death occurring during the first few months of ART. Other factors associated with early mortality are HIV co-

infection with tuberculosis or hepatitis C, other opportunistic infections (OIs) and severe anaemia (Hb < 8g/dl). A patient with advanced disease at initiation of ART (WHO clinical stage 4) is also a predictor of early mortality (Russell, Charalambous, Pemba, Churchyard, Grant & Fielding, 2010, Zacharia et al, 2006, Zacharia, Harries, Moses, Manzi, Line, Mwangomba & Harries, 2009; Losina, Figueroa, Duncan, Divi, Wolf, Hirschhorn, Robertson, Harvey, Whorms, Freedberg, & Gebre, 2007).

Lower CD4 counts, higher viral loads, low Haemoglobin levels, hepatitis C co-infection and if patient is not physically active at the initiation of ART, were factors associated with higher mortality among patients on ART in the United States Military (Marconi, Grandits, Weintrob, Chun, Landrum, Ganesan, Okulicz, Crum-Cianflone, O'Connell, Lifson, Wartmann & Agan, 2010).

High mortality rates were observed among patients with advanced disease. Most common causes of death noted were tuberculosis and cryptococcal meningitis (Castelnuovo, Manabe, Kiragga, Kanya, Easterbrook & Kambugu, 2009). Other conditions associated with increased mortality as observed in the study in Haiti besides Tuberculosis were persistent wasting syndrome, pneumonia, toxoplasmosis, cancer especially kaposi sarcoma, cryptosporidiosis and sepsis (Severe, Leger, Charles, Noel, Bonhomme, Bois, George, Kenel-Pierre, Wright, Gullick, Johnson, Pape, & Fitzgerald, 2005; Lawn, Harries, Anglaret, Myer, Wood, 2008 & Kumarasamy, Venkatesh, Devaleenol, Poongulali, Zephthomi, Pradeep, Saghayam, Flanigan, Mayer, & Solomon 2010).

Another study done in South Africa indicated that mortality rates in adult HIV positive patients with kaposi sarcoma were high even after initiation of ART especially in the first year of starting treatment (Maskew, Fox, van Custem, Chu, MAcPhail, Boulle & Egger, 2013). Kaposi Sarcoma is defined as a cancer that develops from cells that line lymph or blood vessels. It appears as tumors on the skin or on mucosal surfaces such as inside the mouth but it can also develop in other parts of the body like lymph nodes or the digestive tract (American Cancer Society, 2013).

Even though it was noted that a number of patients died of AIDS related deaths, lifestyle related causes of deaths such as suicide, drug overdose and liver diseases mainly hepatitis occurred frequently (Science Daily, 2010). Nevertheless, it was also found that adherence to treatment is the strongest determinants of survival as mortality rates were higher among non-adherent patients than among adherent patients regardless of the CD4 count at the beginning of ART (Wood, Hogg, Yip, Harrigan, O'Shaughnessy, Montaner, 2003).

In the adjacent district of Nyangana, mortality of patients on ART was more frequent among males and was associated with lower initial CD4 counts (<100 cells/ul) due to late presentation and co-infection with TB. Death occurred most frequently in the first six months after initiation of ART (Kangudie, 2008).

2.6 SUMMARY

Since the discovery of the first case of HIV more than two decades ago, thousands of publications have flooded the literature. It is clear from the literature that HIV/ AIDS is not curable but can however be managed with ART. This qualifies it to be categorised as a chronic condition. Most of the studies have demonstrated the benefits of improved quality of life, prolonged survival, regained dignity and a return to productive life for PLWHA receiving ART. Nevertheless, a number of HIV infected people still die while on ART.

Literature have attributed causes of deaths among patients on ART to late initiation of treatment, where CD4 counts are very low and viral load is very high, co-morbidity with other conditions and diseases like Hepatitis, lack of proper nutrition, anaemia, increased population on ART, side effects, older age, Body Mass Index, sex, advanced disease as reflected by WHO clinical stage 4 at the initiation of ART, cotrimoxazole prophylaxis at or before ART initiation, baseline functional status, baseline weight and lack of physical activity. Opportunistic infections like TB, pneumonia and kaposi sarcoma, worsen the health status of HIV infected individuals and contribute to causes of mortality.

In the next chapter, the research methodology used in this study will be presented.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

Chapter two discussed the literature related to the mortality of patients on ART. This chapter will focus on the research methodology used in this study. Research methodology considers and explains the logic behind research methods and techniques (Welman, Kruger and Mitchell, 2010). The purpose for this study was to explore, describe and analyse factors associated with mortality of patients on ART in the Andara district. To address the purpose of the study, a quantitative, analytical, case-control design which was used is described. Furthermore, the study population, sample and sampling method, research instruments, data extraction form, criteria for measurement quality in terms of reliability and validity are described. Additionally, procedures for data collection and data analysis are also described. Research ethics that were followed during the study are also highlighted in this chapter.

3.2 RESEARCH DESIGN

A research design is a set of procedures that guide the researcher in the process of verifying a particular hypothesis and excluding all other possible hypothesis or explanations (Bless, Higson-Smith and Kagee, 2006). Furthermore, the research design maximizes control over factors that could interfere with the study's desired outcome. In

addition, the research design directs the selection of a population, sampling process and a data collection plan and data analysis (Burns and Grove, 2005). In this study, a quantitative, analytical case-control design was used.

A quantitative study is a “formal, objective, systematic process used to describe and test relationships and to examine cause-and-effect interactions among variables” in which numerical data are used to obtain information about the world (Burns and Grove, 2005, p.747; Carter, 1996). Stommel and Wills (2004) indicate that quantitative researchers study phenomenon that can be measured and described in a standardised numerical scales which allow for statistical analysis. A quantitative method was relevant because the researcher has collected and analysed numerical and measurable information. The quantitative method also produces quantifiable and reliable data that can be generalised to apply to a larger population. Furthermore, a quantitative study does not involve the investigation of processes but only emphasises the measurement and analysis of causal relationships between variables (Welman, Kruger and Mitchell, 2010). A quantitative study is the best method to describe or determine relationships among different variables. For the purpose of this study, a quantitative method was selected to ascertain the relationship between different variables and how these are associated with the deaths of patients receiving ART in the Andara district.

An analytical study is most useful for testing a hypothesised association between human exposure and adverse health effects. Quantitative analytical research designs aim

to determine the relationship between an independent variable and an outcome variable in a population (Wakefield and Fleming, 2009). Analytical study designs are used when investigating the association between an outcome and possible causes or exposure factors. Examples of analytical study designs are case-control and cohort studies (Environmental Health Investigations Branch, n.d.; Stommel and Wills, 2004). For this study, case-control was the appropriate design to use because the researcher wanted to compare the differences among the variables between the patients who died (cases) while on ART and those who survived (control) on ART by end of July 2011.

A case-control study is an analytical study which compares individuals who have a specific disease, referred to as 'cases', with a group of individuals who do not have the disease, referred to as 'controls'. Cases and controls should be drawn from the same population (Environmental Health Investigations Branch, n.d. and US Cancer Institute, n.d.). The aim of case-control studies is to compare exposure factors to outcomes (Thompson and Dowding, 2009). Some of the exposure factors are age, sex, CD4 count, viral load, functional status, Haemoglobin level, opportunistic infections, side effects, employment status and marital status. Case control-studies are useful in generating hypothesis which may need to be tested further by stronger experimental design (Jekel, 2007). For this study, a comparison was made between HIV/AIDS patients who died and patients who did not die by end of July 2011 while on antiretroviral therapy in the the Andara district, to determine possible factors associated with death. It was not possible to take out patients who died of AIDS related diseases because causes of deaths were not

recorded in most files. The study looked at all patients who died irrespective of the cause of death. These patients had similar medical profiles. A case-control allows studying multiple risk factors (exposures) easily (CDC, n.d. b).

3.3 RESEARCH METHOD

Research method is defined by Polit and Hungler (2004) as the steps, procedures and strategies for gathering and analyzing data in a research investigation with the purpose to describe what the researcher did to solve the research problem. LoBiondo-Wood and Harber (1998) further refer to research methods as different ways of conducting research for different reasons, including data collection methods and measurements and techniques of data analysis. Research methods therefore include: study population, sampling method, sample, development of the research instrument, reliability and validity, data collection and data analysis.

3.3.1 Study population

A study population is a full set of individuals who could be included in the study before sampling is performed (Burns and Grove, 2005). For this study, the population consisted of medical records of HIV/AIDS patients aged from 15 years and older, who had started on ART between the 1st of August, 2004 and the 30th of September, 2009 at the Andara district. The target population was 913 people, whereby case population consisted of 196 adult patients who died and controls population consisted of 697 adult patients who were

alive by the end of July 2011. The period July 2011 was used because it is when the data collection started. Figure 3.1 presents the study population selection process.

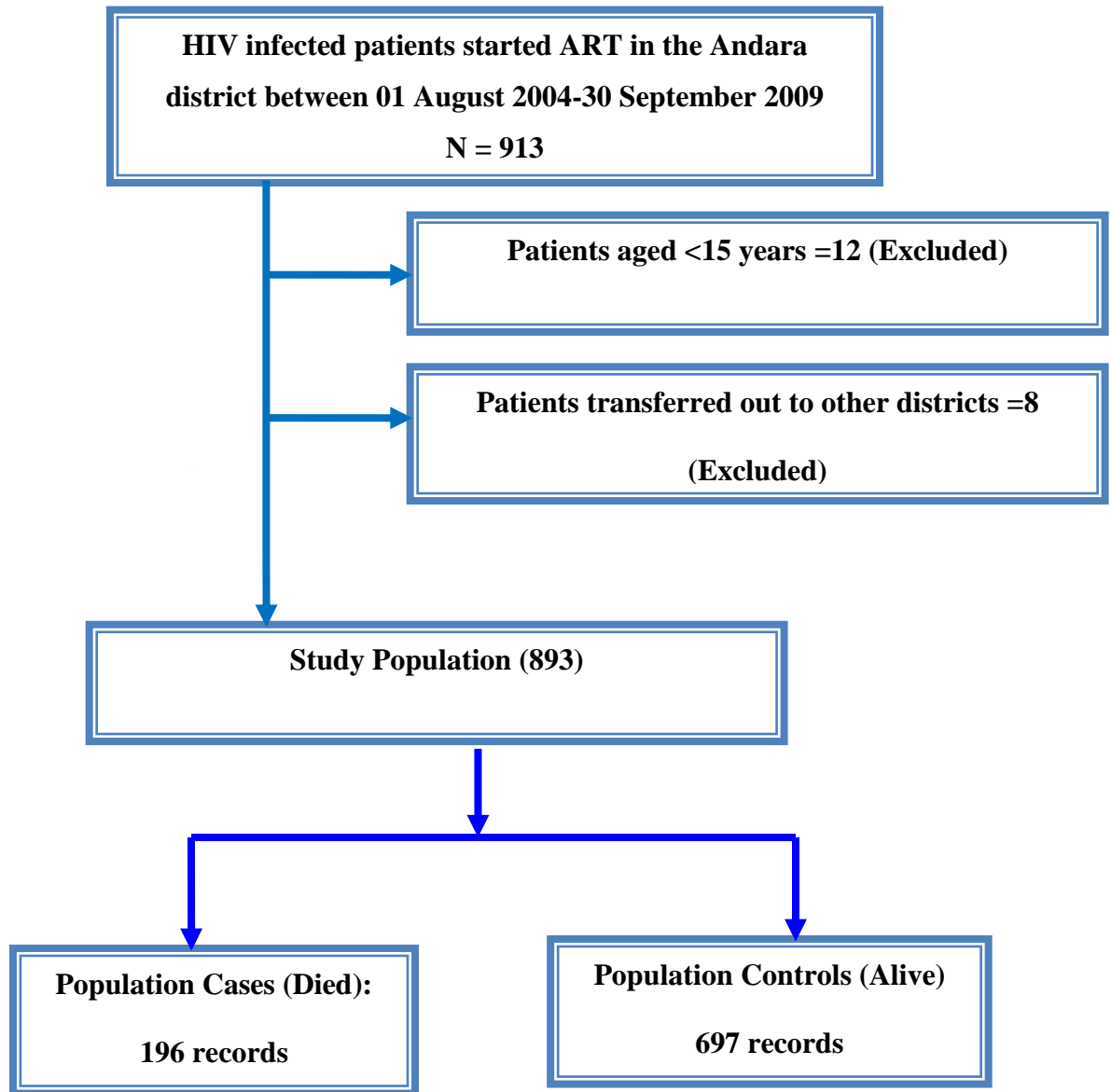


Figure 3.1: Schematic diagram of the study population selection process

3.3.2 Sampling method

Sampling is a process of selecting subjects, events, behaviour or elements for participation in a study to be representative of the entire population and that reflects the characteristics of the group which the researcher wishes to make a statement (Uys and Puttergill in Kloppers, 2002, Burns and Groove, 2005, De Vos, Strydom, Fouche and Delport, 2007). Trochim 2000, further defines sampling as a process of selecting units, such as people, records (as in this study), or organizations, from a population of interest so that by studying the sample, the results may fairly be generalized to the population from which they were chosen. This is done to obtain information regarding a phenomenon in a way that represents the whole population (Brink, Van der Walt & Van Rensburg, 2012).

In this study sampling was only done for the controls (alive), for cases, retrieved records matched the estimated sample size. All 196 records for patients who died (cases) were included and a sample of 1:2 (2 controls per 1 case), 697 records were drawn from patients who were alive at the end of July 2011, when data collection started. A simple random sampling method was used with Statistical Package for Social Sciences (SPSS) by entering the unique number of all files of patients who were alive and run the sample query. In simple random sampling, elements are selected at random from the sampling frame for inclusion in the study (Burns and Groove, 2005). This sampling method is relevant because a list of participants was available and records are kept at the health

facility. This accessibility gave the researcher ample opportunity to review the study elements in a short period of time.

A sampling frame “is a full set of members of a population from which the study participants will be selected” (De Vos, et al, 2007:194). For this study, the sampling frame includes all eligible patients that started ART in the Andara district between August 2004, and end of September 2009 according to the inclusion criteria. This allowed for an intention to treat analysis.

3.3.3 Sample

A sample is a part or fraction of a whole, a subset of the whole population that is selected for a particular study or which is actually investigated and the member of a sample are subjects (Bless, Higson-Smith & Kagee, 2006; Brink, Van der Walt & Van Rensburg, 2012, Burns and Grove, 2005). The sample size for this study was calculated using EPI info version 6.1 statistical package size calculators applying 95% confidence interval, 80% power a ratio of 1:2 (cases: controls). An estimated sample size according to EPI info sample calculator was 215 cases and 430 controls. The retrieved records were 194 cases and 392 controls. For cases, all records were taken because they were less than the estimated sample size but 2 files could not be traced, so they were not included. For controls 430 records were sampled, using the simple random sampling method. However 38 files were missing, so 392 records of controls were reviewed. Table 3.1 depicts the population and the sample for this study.

Table 3.1: The population and sample for this study

| | Population | Sample | Missing records | Records reviewed |
|-----------------|-------------------|---------------|------------------------|-------------------------|
| Cases | 196 | 196 (100%) | 2 (1%) | 194 (99%) |
| Controls | 697 | 430 (48%) | 38 (9%) | 392 (91%) |
| Total | 893 | 626 (70%) | 40 (6%) | 586 (94%) |

The above table indicates the 1:2 ratio for the cases and controls sampled.

Inclusion criteria for cases

- HIV and AIDS patients aged 15 years and above who were initiated on ART in the Andara district between 01 August 2004 and 30 September 2009
- The record should indicate that the patient is dead

Inclusion criteria for controls

- HIV and AIDS patients aged 15 years and above who were initiated on ART in the Andara district between 01 August 2004 and 30 September 2009

3.3.4 Development of the research instrument

A data abstraction tool was developed in which variables of interest were entered (Annexure A). These variables were guided by the ART patient booklet. Data elements

also referred to as variables in this study were categorized in the following groups: socio-demographic information, baseline information, follow up /longitudinal data, co-morbidities and opportunistic infections, medicine related information, treatment interruptions, therapy changes, adherence information and treatment outcome.

Socio-demographic information included age, sex, marital status and employment status; hence this information is only collected once at the initiation of ART, besides sex which does not change over time. It is being acknowledged that other variables may change over time. This study concentrated on the information recorded in the patient booklet, meaning the status the patient was in at the initiation of ART.

It was necessary to study sex as a variable because, generally women account for high population infected with HIV globally, regionally and in Namibia (MoHSS, 2008). Potentially sex-specific influences, such as endogenous or exogenous hormones could impact antiretroviral tolerance. Women also have different pharmacokinetic profiles for selected antiretrovirals compared with men. These factors could influence how women respond and react to antiretrovirals. Several observational studies have described a higher frequency of antiretroviral-related adverse effects among women compared with men. Women appear to be at an especially high risk for lactic acidosis, nevirapine-associated rashes and hepatotoxicity, and fat redistribution after highly active antiretroviral therapy exposure. Although a statistical association between antiretroviral toxicity and pregnancy has not been described, pregnancy may provide an additional influence on the toxicity of several antiretrovirals or antiretroviral combinations.

Potential tolerability should be an important component in discussions of antiretroviral options among women (Hawkins, Chalamilla, Okuma, Spiegelman, Hertzmark, Aris, Ewald, Mugusi, Mtasiwa, & Fawzi, 2011).

Baseline information included treatment supporters, weight, functional status, WHO clinical stage, CD4 and haemoglobin.

A **treatment supporter** is a committed and trustworthy adult helping someone living with HIV/AIDS to make their treatment a success (MoHSS, n.d.). According to WHO (2002), the role of a treatment supporter, is to make sure that the patient takes the medicines regularly, on schedule, for the full duration of treatment. A treatment supporter will also need to listen and encourage the patient as part of the support. The first national ART guideline spelled out having a treatment supporter as one of the social criteria for an HIV infected person to be initiated on ART (MoHSS, 2003).

Functional status refers to the individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being. Decline in functional status is measured by an individual's loss of independence in performing activities of daily living (ADLs) over a period of time. According to grades of disability, functional status for HIV patients is categorized into three categories by WHO as follows:

Working – patient is able to perform usual work inside and or outside home;

Ambulatory – patient is able to perform Activity of Daily Living (ADL) like eating, bathing, dressing, toileting, transferring (moving out of bed or chair) and continence but not able to work;

Bedridden – patient is not able to perform ADL (Shelkey and Wallace, 2012; Bierman, 2001; Thejus, Jeeja & Jayakrishnana, 2009).

The CD4 T-cell count serves as the major laboratory indicator of immune function in patients who have HIV infection. It is one of the key factors in determining both the urgency of antiretroviral therapy (ART) initiation and the need for prophylaxis for opportunistic infections. A number of clinical trials and cohort studies revealed that CD4 count is the strongest predictor of subsequent disease progression and survival (AIDS Info, 2013). Although the first national ART guideline indicated among clinical criteria that for an HIV infected person to be started on ART, one must have a CD4 count of less than 200 cells/mm³, the revised (third edition) National guideline recommended that HIV/AIDS patients should be initiated on ART with a CD4 count of 350 cell/mm³ in line with WHO 2009 ART guideline (MoHSS, 2003; MoHSS, 2010a).

When the number of red blood cells or concentrations of **haemoglobin** are low a person is said to have anaemia. Haemoglobin is a protein inside the red blood cells that contains iron and transports oxygen (Medical News Today, 2009). National Institutes of Health Division of AIDS (2004), defined anaemia as a haemoglobin level of <10g/dL. The

major cause of anaemia is impaired erythropoiesis resulting from the release of inflammatory cytokines and decreased production of hematopoietic growth factors, coupled with malabsorption and impaired recycling of iron (Camacho, Poveda, Zamorano, Valencia, Vazquez, & Arnalich, 1992).

Follow up or longitudinal data included the same information at six months' interval. This was meant to determine the change in the patients' conditions over time. Most of the longitudinal data were missing in the patients' booklets as well as in the data base, which made it difficult to analyse.

Co-morbidity and opportunistic infections partly covered TB co-infection before and after ART and opportunistic infections suffered by patients on ART.

Medicine related information included ART regimen started and side effects experienced after initiation of ART. The recommended ART regimen consists of three or more antiretrovirals from at least two different classes. This combination is effective in controlling HIV (AIDS info, n.d).

The first Namibian ART guideline (2003) indicated the first line regimen for HIV treatment as Stavudine (d4T)/Lamivudine (3TC)/Nevirapine (NVP). However, when a patient is on TB treatment or have side effects due to NVP, NVP should be substituted with Efavirenz (EFV) because one of the drugs in standard treatment of TB, Rifampicin

decreases the serum level of NVP, and NVP causes toxicity to the liver (hepatotoxicity). Furthermore, the guideline indicates that patients with Hepatitis B should not receive NVP; the recommended regimen for patients with Hepatitis B is Lamivudine (3TC)/ Tenofovir (TDF)/ Efavirenz (EFV).

On the other hand, pregnant women should not receive EFV due to the negative side-effect it might have on the unborn fetus (teratogenic effects). The recommended second line ART regimen in Namibia per 2003 national ART guideline was Zidovudine (AZT)/Didanosine (ddi)/ Indinavir/Ritonavir (IDV/r and Zidovudine (AZT)/Didanosine (ddi)/ Lopinavir/Ritonavir (LPV/r (MoHSS, 2003).

The Namibian ART guideline for 2010 shifted from D4T to Zidovudine (AZT) containing regimen as a preferred first line regimen due to side effects of d4T especially fat maldistribution. However, AZT reduces the Hb and it was recommended that when the patient is having low Hb, AZT should not be used. Tenofovir (TDF) is the best alternative in anaemic patients (MoHSS, 2010).

Treatment interruption covered reasons for interruptions. Treatment interruption is defined as discontinuation of all ART for any period of time after the ART was started. The period of interruption is defined differently, varying between 24-48 hours to one month. Treatment interruption is categorized in two groups: Unstructured and structured interruption. Unstructured interruption is the discontinuation of ART by the patient self,

while structured interruption is the discontinuation initiated by the clinician (Kranzer and Ford, 2011; Mocroft, Phillips, Soriano, Rockstroh, Blaxhult, Katlama, Boron-Kaczmarska, Viksna, Kirk, & Lundgren, 2005; Mussini Pinti, Bugarini, Borghi, Nasi, Nemes, Troiano, Guaraldi, Bedini, Sabin, Esposito & Cossarizza 2005). In this study, treatment interruption is defined as discontinuation of ART for more than one month.

Therapy change includes treatment substitution and treatment switching. Treatment substitution refers to changing one or more ARVs within the first line regimen while switching refers to changing ART regimen from first ART regimen to second line regimen (WHO, 2010). Two reasons for ART change could be either therapy failure or toxicity. Treatment failure can be evaluated clinically, immunologically (using CD4 count test) or virologically (using viral load test). Toxicity refers to inability to tolerate the side effects to medications significant organ failure that may occur (MoHSS, 2003).

Adherence information was determined at six months' interval. As with other longitudinal information, adherence levels at 12, 18 and 24 months were not analysed as most records missed longitudinal adherence level information.

Adherence to antiretroviral therapy is one of the most important contributing factors to positive clinical outcomes in patients with HIV. Low adherence to treatment has been associated with higher hospitalization rates, productivity loss, disease progression, and

death in both high-income and resource-limited settings (Bajunirwe, Arts, Tisch, King, Debanne & Sethi, 2009).

For this study pharmacy records were used to measure adherence whereby self-report and pill count were incorporated. Due to incomplete information on follow-up adherence levels at six month intervals, the analysis was only done for adherence levels at six months not at 12, 18 and 24 months respectively.

Treatment outcome is whether the patient was alive or dead by end of July 2011 when data collection started; the duration of treatment at the time of death was looked at, causes and places of deaths were covered as well. Obtaining specific information on causes and places of deaths in most records proved challenging for this study. This could be attributed to the fact that when the patient is admitted, another inpatient record is used and not the patient's usual booklet. Therefore, if the patient dies, the patient booklet is usually not updated with the inpatient information. Thus, information on places and causes of deaths were missing in most of the records.

3.3.5 Pilot of the data abstraction tool

Data abstraction tool was not pilot tested because the researcher felt that hence the sample size was small, conducting the pilot testing and excluding those records in the study will cause the sample to be even smaller. Conducting pilot study in another ART clinic could be the best option, but the researcher had observed that record keeping

varies significantly among ART clinics due to constant changing of the ART M&E tools countrywide.

3.3.6 Reliability and validity of the research instrument

Reliability and validity of a measuring instrument are very crucial characteristics of the research instrument (Treece and Treece, 1986; Polit and Hungler, 2004; De Vos et al, 2007).

Reliability

Reliability arises from the stability and consistency of the measurement techniques used; how reproducible the measures are on a retest and it provides an indication of the random error in the measurement (Burns and Grove, 2005). A data collecting tool is considered reliable if it produces consistent results over repeated testing. Reliability also refers to how well a researcher measures whatever it is that is being measured regardless of whether or not it is the right quantity to measure (Rindskopf, 2001). Babbie (2008) further defines reliability as a matter of whether a particular technique, applied repeatedly to the same object, yields the same result each time.

This concurred with Presley (1996) who added that similar results should be achieved even if different people at different settings and different times do the measuring. To

obtain reliable data from the measuring instrument, it is important to ensure that it can be replicated and provide accurate information before administering the instrument, for the researcher to make acceptable conclusions (Stommel and Wills, 2007). To ensure reliability for this study, the data abstraction tool was constructed in such a way that it contained information extracted from the ART patient care booklet and piloted. Thus, if the same information is collected by different reviewers at different times, chances are high that one would get the same or similar findings. This helps to reduce bias. To ensure reliability, the data extraction tool was piloted at Katutura Hospital and Rehoboth hospital ART clinics. This necessitated the adjustment of the tool.

Validity

Validity is a “measure of the truth or accuracy of a claim” (Burns and Groove 2005: 214). According to Babbie (2004), validity refers to how far a data collection instrument actually measures what it is supposed to measure. It is further referred to as the appropriateness, correctness, meaningfulness and usefulness of the inferences researchers make based on the data collected (Fraenkel and Wallen, 2006). Validity determines the precision of the research instrument in providing results that can be generalized to a population (Hopkins, 2000).

Once validity is improved, errors in research can be reduced. Hassan, (2006) highlights those errors that can occur in case-control studies, as random and systematic errors.

Random errors result in low precision of epidemiological measure. This can be reduced by ensuring that the sample size is adequately large.

Furthermore, uses of confidence interval quantify the degree of random errors. Systematic error causes low validity of epidemiological measure due to selection and information bias or confounding factors. In this study, selection bias was addressed by applying the simple random sampling. Another effort applied in this study to reduce systematic errors was by clearly defining the terms used and consistently using them as defined. It is further noted that systematic errors can be reduced by good measuring methods, restrictions of the study, matching and using multivariate regression to account for confounders during analysis (Pearce, 2005).

From these definitions, it can be concluded that validity has two aspects: firstly the instrument does in fact measure the concept it is intended to measure and secondly, it measures accurately. Content validity is the extent to which the method of measurement includes all major and important elements (De Vos, et al, 2007). In this study, content validity was ensured by sharing the data abstraction tools with ART experts, a medical officer and a public health practitioner who had been working in the ART clinic and a registered nurse working in the Katutura Hospital ART clinic. These experts provided guidance in the content of the data abstraction tool based on data routinely collected in ART clinics. Using the ART patient care booklet, to guide in the development of data abstraction, also ensured content validity, as all variables collected were derived from the patient care booklet.

3.3.7 Data Collection

Data collection is “the process of selecting subjects and gathering data from these subjects” (Burns and Grove, 2005: p.430). The use of existing records is an acceptable research source and it is an important source for researchers in health (Polit and Beck, 2004). For this study, data collection was accomplished through a review of files (medical records) of patients who received ART in the Andara district and died by the end of July 2011(cases) and patients who received ART in the Andara district but were alive by the end of July 2011 (controls) in the Andara district. These records included pre-ART registers, ART registers, in-patient files and death notification registers during the study period. Both hard copies and electronic records were referenced. Data were collected and captured on the data abstraction tool developed by the researcher. The approach used was relevant for this study as the required data elements were directly extracted from the patient care booklet complimented by the electronic database. Names of patients were not captured to ensure confidentiality, but unique numbers were used in case it was necessary to go back to the record and verify information. Data were entered in the coded SPSS 17.0.data entry form.

3.3.8 Data Analysis

Data analysis is “conducted to reduce, organize and give meaning to the data” (Burns and Grove, 2005: p.43). Ardagna and Zhang, 2010 define data analysis as a process of inspecting, cleaning, transforming and modeling data with the intention to highlight

useful information, suggest conclusion and support decision-making. Data were entered and analysed in SPSS 17.0. SPSS was preferred as a statistical package of choice because its functions support analysis of a wide range including descriptive analysis, comparing means, general linear model, correlation, regression and classifications. Using SPSS also allows for coding of values which makes data entry simple and fast. Descriptive statistics allow researchers to describe, summarise and make sense of a particular set of data (Johnson and Christensen, 2004).

Descriptive research analyses techniques, specifically the frequency procedure and graphical techniques were used to describe and characterize the sample studied. The distributions of variables that describe the characteristic factors of patients receiving ART in the Andara district are presented in numerical data, tables and graphs. The mean for the age of both cases and controls were calculated and the standard deviation thereof. The mean weight at the initiation of ART was also calculated. Data were analyzed following the data abstraction tool and they were classified in the following sections: socio-demographic information, baseline information, co-morbidities and opportunistic infections, medicine related factors, treatment interruptions, therapy changes, adherence information and treatment outcomes. The section for longitudinal/follow up information could not be analysed because most of the data were missing from the patient booklet.

This was followed by a bivariate analysis which investigated the existence of association between sample characteristics (factors) and mortality. This was achieved by performing

the Chi-Square test for association at the 5% significance level. This process was also initially performed to identify variables for the logistic regression models. Variables which were significant at 0.25 significance level were candidates for the models. However, due to an epidemiological concern that this approach may fail to identify some variables which may turn to be significant in the regression model, all variables were considered for the modeling process.

In order to determine the predictors of mortality among the study participants, logistic regression models were fitted. The univariate logistic regression analysis was particularly performed to quantify mortality risks associated with various factors before controlling for confounders and other covariates. The multivariate logistic regression analysis was then performed to quantify mortality risks associated with various factors after controlling for other explanatory variables. In research, statistical analysis can be used to determine the association between multiple factors and the outcome factors through multiple logistic regression analysis (Guido, Winters and Rains, 2006). The purpose of multiple logistic regression analysis is to isolate the relationship between the exposure variable and the outcome variable from the effects of one or more other variable or confounders (Allison, 1999). For the purpose of this study only the point estimates of the odds ratios and the corresponding 95% confidence interval for the adjusted estimates (multivariate results) were reported. Odds ratio is a relative measure of risk, that indicates how much more likely it is for someone under study who is exposed or having a certain factor will develop the outcome as compared to someone

who is not having the same exposure (Westergren, Karlsson, Anderson, Ohlsson & Hallberg, 2001). For this study, death is the outcome, the exposure factors are socio-demographic, baseline and medical factors.

In an effort to build the multivariate logistic model, the backward stepwise regression method was used. This process involved adding all important variables into the model, followed by removing one variable at a time to assess the improvement in fit due to the removal of that variable. To select the best model for the data, deviances from competing nested models were compared to assess the improvement in fit due to the removal of each model term. To do this the likelihood ratio statistic (deviance) was used to compare the larger (L) model with k parameters with the smaller (S) model with $k-1$ parameters. The deviance statistic (D) was calculated as follows:

$$D = -2\log(\hat{L}_L / \hat{L}_S) = -2[\log \hat{L}_L - \log \hat{L}_S]$$

3.4 RESEARCH ETHICS

Christensen, Johnson & Turner (2011) define research ethics as a set of guidelines to assist the experimenter in conducting ethical research. Fundamentally, the study was based on a review of medical records and does not involve human participants or experimentation with patients. Therefore, no personal risk to or exposure of human subjects was foreseen and consequently patients' consent was not necessary. Patient confidentiality and privacy were guaranteed because no patient names were recorded

during data collection. The data set for this study was protected by use of unique numbers and password restricted computers.

This study was conducted only after it has been approved by the Postgraduate Studies Committee of the University of Namibia (Annexure B). Permission was sought from the Ministry of Health and Social Services Research and Ethics Committee (Annexure C) and from the CHS Director (Annexure D). The researcher declares that no conflict of interest exists in any aspects of the study. Results of this study will be made available to the Ministry of Health and Social Services as indicated in annexure C, and also to Catholic Health Services.

3.5 SUMMARY

This chapter explicitly discussed and presented the research design and method used to achieve the purpose of this study. The study population selection, sample and sampling method used were described. The development of the research instruments, the reliability and validity for the study were ensured. Data collection and analysis methods were described. The ethical principle that guided the study was also outlined.

In the next chapter, findings of the study will be presented.

CHAPTER 4

DATA ANALYSIS

4.1 INTRODUCTION

Chapter 3 focused on the research design and research method followed in this study. In this chapter, data analysis and findings of the study will be presented. Both descriptive and inferential statistics are used to present the findings. Descriptive statistics are used to present the characteristic factors of patients who started ART in the Andara district between 01 August 2004 and 30 September 2009. This focuses on socio-demographic factors, baseline information and medicine related factors. Analytical statistics in terms of Odds Ratios (OR), confidence intervals (CI), chi-square and P-value are presented to show the association between different variables and the treatment outcome. Strength of identified factors and the treatment outcome is also indicated. Results of multiple logistic regression analysis are presented in the model.

The data abstraction tool was divided in nine (9) sections, which guided the data analysis:

Section A: Socio-demographic Information

Section B: Baseline information

Section C: Follow up/longitudinal data

Section D: Co-morbidities and opportunistic infections

Section E: Medicine related information

Section F: Treatment interruptions

Section G: Therapy changes

Section H: Adherence information

Section I: Treatment outcomes

The data will be presented in two areas, namely: Area A contains descriptive analysis of socio-demographic data, baseline, follow up data, co-morbidities and opportunistic infections, medicine related information, treatment interruptions, therapy changes, adherence information and treatment outcomes. Area B contains analytical analysis.

4.2 DESCRIPTIVE ANALYSIS OF THE DATA

Descriptive statistics are used to present the results of socio-demographic factors, baseline information and medicine related factors of patients who were receiving ART in the Andara district between 01 August 2004 and 30 September 2009. Tabulation results are used to present the frequencies and percentages while the graphic presentation is mainly used to show both occurrences and distribution of treatment outcomes by different variables. The socio-demographic factors included age, sex,

marital status and employment status. Data was analysed from 586 records, representing 194 cases and 392 controls.

4.2.1 Section A: Socio-demographic information

Socio-demographic is a term used to describe an element or variables of a group within a society. It comes from two words: sociology and demography (Thomson, 2007). Thomson (2007) further defines demography as the study of human populations, size, composition and distribution. Age, sex and population economic status are basic demographic features of the population while marital status is one of the social characteristics. Thomson (2007) indicates that demography is especially useful for understanding social and economic problems. For this study, the socio-demographic section includes age, sex, marital status and employment status.

4.2.1.1 Age distribution among cases and controls

Age at the time of initiating ART ranged from 18 to 70 years in cases and 16 to 73 years in controls. The mean age at initiation of ART for the study sample was 37 years with a standard deviation of 10 years. The mean age for cases and controls were 36.7 and 37.0 respectively. Age was grouped in the interval of five from 15 years as indicated in Table 4.1.

Table 4.1: Age distribution among cases and controls (n=586)

| Age category | Number and percentages of cases (Died) | Number and percentage of controls (Survived) | Total |
|--------------|--|--|-------|
| 15-19 | 1 (33.3%) | 2 (66.7%) | 3 |
| 20-24 | 14 (30.4%) | 32 (69.6%) | 46 |
| 25-29 | 31 (32.0%) | 66 (68.0%) | 97 |
| 30-34 | 46 (37.1%) | 78 (62.9%) | 124 |
| 35-39 | 38 (31.9%) | 81 (68.1%) | 119 |
| 40-44 | 25 (32.1%) | 53 (67.9%) | 78 |
| 45-49 | 17 (34.0%) | 33 (66.0%) | 50 |
| 50-54 | 10 (35.7%) | 18 (68.1%) | 28 |
| 55-59 | 6 (28.6%) | 15 (71.4%) | 21 |
| 60-64 | 3 (27.3%) | 8 (72.7%) | 11 |
| 65-69 | 1 (16.7%) | 5 (83.3%) | 6 |
| 70-74 | 1 (50.0%) | 1 (50.0%) | 2 |
| Missing age | 1 (100.0%) | 0 (0.0%) | 1 |
| Total | 194 (33.0%) | 392 (67.0%) | 586 |

Table 4.1 shows the distribution of treatment outcomes by age in years among people on ART in the Andara district. For those in the age group 15-19, one (33.3%) died whilst two (66.7%) were still alive at the end of July 2011. For the 20-24 age group 14 (30.4%) died whilst 32 (69.6%) were still alive at the end of the study. The highest percentages

of people dying from HIV/AIDS whilst on ART in the Andara district was observed in the following age groups: 15-19 (33.3%), 30-34 (37.1%), 44-49 (34.0%) and 70-74 (50.0%) These results indicate that more patients survived in all age groups by end July 2011.

4.2.1.2 Other socio-demographic characteristic factors of the sample

Besides age, frequencies and percentage distribution of other socio-demographic factors in the study sample are presented in Table 4.2. These factors are sex, marital status and employment status.

Table 4.2: Other socio-demographic characteristic factors of the sample (N=586)

| Socio-demographic characteristic factor | Categories | Number and percentages of Cases (Died) by end of July 2011 N=194 | Number and percentages of Controls (Alive) by July 2011 N= 392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|--|-------------------|---|---|---------------------------------------|-----------------------------|
| Sex | Males | 87 (44.2%) | 110 (55.2%) | 197 | 33.6 |
| | Females | 107 (27.5%) | 282 (72.5%) | 389 | 66.4 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

| | | | | | |
|--------------------------|-----------------|--------------------|--------------------|------------|-------------|
| Marital Status | Single | 39 (29.8%) | 92 (70.2%) | 131 | 22.4. |
| | Married | 83 (29.7%) | 196 (70.3%) | 279 | 47.6 |
| | Cohabiting | 0 | 1 (100%) | 1 | 0.2 |
| | Widow | 21 (35.5%) | 38 (64.4%) | 59 | 10.1 |
| | Divorcee | 26 (44.8%) | 32 (55.2%) | 58 | 9.9 |
| | Not indicated | 25 (43.1%) | 33 (56.9%) | 58 | 9.9 |
| | Total | 194(33.1%) | 392 (66.9%) | 586 | 100 |
| Employment Status | Employed | 23 (35.9%) | 41 (24.7%) | 64 | 10.9 |
| | Self-employed | 2 (20.0%) | 8 (80.0%) | 10 | 1.7 |
| | Unemployed | 109 (30.5%) | 248 (69.5%) | 357 | 60.9 |
| | Seasonal worker | 1 (4.5%) | 21 (95.5%) | 22 | 3.2 |
| | Not indicated | 59 (44.4%) | 74 (55.6%) | 133 | 22.7 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

4.2.1.2.1 Sex

This study yielded that from the Andara district, 389 (66.4%) of the people who receive ART treatment are females whilst only 197 (33.6%) are males. Of 197 males in the study, 87 (44.16%) died by the end of July 2011 and 110 (55.84%) were alive. Among the females, only 107 (27.51%) died by the end of July 2011 and 282 (72.49%) were

alive at the end of July 2011. This shows that mortality of males on ART due to HIV and AIDS is higher than that of females.

4.2.1.2.2 Marital status

A total number of 528 records had marital status indicated while marital status was not indicated on 58 records. A large proportion of patients who received ART treatment in the Andara district were married. Only one record indicated cohabitation as a marital status. A total number of 131 (24.8%) were single, 279 (52.8%) were married, only one (0.2%) patient was in a cohabitating relationship, 59 (11.1%) were widowed and 58 (11.0%) were divorced.

Of 131 who were single, 39 (29.8%) died and 92 (70.2%) were still alive by the end of July 2011. For 279 patients who were married at the start of ART, 83 (29.7%) died while 196 (70.3%) were alive by the end of July 2011. The percentage for the single and married patients was almost the same. The only patient who was recorded to be in a cohabitating relationship was alive by the end of July 2011. Patients who were widowed by the time they were starting ART were 59 of which 21 (35.5%) have died while 38 (64.4%) were alive by the end of July 2011. Patients who were divorced by the time they started ART were 58 of which 26 (44.8%) died and 32 (55.2%) were alive by the end of July 2011. Despite the fact that a big proportion of patients were married at the time of

ART initiation, the percentages of those who have died was high among the divorced (44.8%) followed by the widowed (35.6%).

4.2.1.2.3 Employment status

Overall, a bigger proportion of patients were unemployed 357 (78.8%) at the initiation of ART. Only 96 (21.2%) were employed of which 64 (14.1%) were employed by others, institutions and/or government whilst 10 (2.2%) were self-employed. Seasonal workers represented 22 (4.9%). Seasonal workers are employed on a seasonal basis mainly in grape farms in the Hardap region. They usually spend about six months at work especially during harvesting time, which is when more workers are required at the grape farms. In 133 (22.7%) records, employment status was not indicated.

Findings for this study indicate that from the total of 96 people who were employed, 23 (35.9 %) of employed people who were on ART in the Andara district died by the end of July 2011. This represents the highest percentage of (employed) people who died in comparison to other employment status (seasonal, self-employed and unemployed). For those who were self-employed at the initiation of ART, two (20.0%) have died while eight (80.0%) were alive by the end of July 2011. For the unemployed group at the initiation of ART, 109 (30.5%) died while 248 (69.5%) were still alive by the end of July 2011. It was interesting to learn that of 22 patients who were seasonal workers only one (4.5%) had died whilst 21 (95.5%) were still alive by the end of July 2011.

4.2.2 Section B: Baseline information

This section presents the information that was collected at the time of ART initiation. This information is compared to the follow-up/longitudinal information and used to determine the patients' response to ART. Baseline information presented for this study is: availability of a treatment supporter, weight, functional status, WHO clinical stage, Cluster of Differentiation 4 (CD4) and Haemoglobin (Hb). Table 4.3 presents the baseline information for both cases and controls.

Table 4.3: Baseline information (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---|-----------------------------|
| Treatment supporter | Available | 156 (40.2%) | 232 (59.8%) | 388 | 66.2 |
| | Not available | 28 (14.9%) | 160 (85.1%) | 188 | 32.1 |
| | Not indicated | 10 (100%) | 0 | 10 | 1.7 |
| | Total | 194 (31.4%) | 392 (68.6%) | 586 | 100 |
| Weight in Kg | <40 | 40 (50.0%) | 40 (50%) | 80 | 13.7 |
| | 40-49 | 59 (31.7%) | 127 (68.3%) | 186 | 31.7 |
| | 50-59 | 60 (29.3%) | 145 (70.7%) | 205 | 35.0 |
| | 60 and above | 35 (30.4%) | 80 (69.6%) | 115 | 19.6 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| Functional status | Working | 20 (12.3%) | 143(87.7%) | 163 | 27.8 |
| | Ambulatory | 83 (28.0%) | 214(72.0%) | 297 | 50.7 |
| | Bedridden | 91 (72.2%) | 35 (27.8%) | 126 | 21.5 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| WHO Clinical Stage | Stage 1 | 5 (14.3%) | 30 (85.7%) | 35 | 6.0 |
| | Stage 2 | 27 (17.9%) | 124 (82.1%) | 151 | 25.8 |
| | Stage 3 | 97 (33.3%) | 194 (66.7%) | 291 | 49.7 |
| | Stage 4 | 46 (56.1%) | 36 (43.9%) | 82 | 14.0 |

| | | | | | |
|---------------------------------|---------------|--------------------|--------------------|------------|------------|
| | Not indicated | 19 (70.4%) | 8 (29.6%) | 27 | 4.6 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| CD4 cells/mm³ | 0-49 | 33(60.0%) | 22 (40.0%) | 55 | 9.4 |
| | 50-99 | 56 (33.3%) | 112 (66.7%) | 168 | 28.7 |
| | 100-199 | 80 (30.5%) | 182 (69.5%) | 262 | 44.7 |
| | 200+ | 25 (24.8%) | 76 (75.2%) | 101 | 17.2 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| Hb level g/dL | < 8 | 51 (84.3%) | 8 (15.7%) | 59 | 16.6 |
| | 8 – 9.9 | 63 (65.1%) | 38 (34.9%) | 109 | 35.4 |
| | 10-11.9 | 47 (47.5%) | 52 (52.5%) | 99 | 32.1 |
| | 12+ | 33 (28.6%) | 294 (71.4%) | 327 | 15.9 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

4.2.2.1. Availability of a treatment supporter

Table4.4: Availability of a treatment supporter (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| Treatment supporter | Available | 156 (40.2%) | 232 (59.8%) | 388 | 66.2 |
| | Not available | 28 (14.9%) | 160 (85.1%) | 188 | 32.1 |

| | | | | | |
|--|---------------|--------------------|--------------------|------------|------------|
| | Not indicated | 10 (100%) | 0 | 10 | 1.7 |
| | Total | 194 (31.4%) | 392 (68.6%) | 586 | 100 |

Table 4.4 indicates that most patients 388 (66.2%) had treatment supporters whilst 188 (32.1%) of the patients in the study sample had no treatment supporters. For ten records (1.7%) there was no indication whether patients had treatment supporters or not. Although 388 patients had treatment supporters, 156 (40.2%) died by the end of July 2011, and only 28 (14.9%) of those who were without treatment supporters died by the end of July 2011.

4.2.2.2 Weight

Table 4.5: Weight (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| Weight in Kg | <40 | 40 (50.0%) | 40 (50%) | 80 | 13.7 |
| | 40-49 | 59 (31.7%) | 127 (68.3%) | 186 | 31.7 |
| | 50-59 | 60 (29.3%) | 145 (70.7%) | 205 | 35.0 |
| | 60 and above | 35 (30.4%) | 80 (69.6%) | 115 | 19.6 |

| | | | | | |
|--|--------------|--------------------|--------------------|------------|------------|
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
|--|--------------|--------------------|--------------------|------------|------------|

Weight was grouped in four categories; less than 40kg, 40-49 kg, 50-59 kg and 60 kg and above. The mean weight at initiation was 50.4 kg with a standard deviation of 9.6 kg. Of the 586 patients, 80 (13.7%) weighed less than 40 kg at the initiation of ART, half of which have died by the end of July 2011. A number of 186 (31.7%) patients initiated ART with weight measurements ranging from 40-49 kg of which 59 (31.7%) have died and 127 (68.3%) survived by the end of July 2011. A total of 205 (35%) patients initiated ART weighing between 50-59 kg, of which 60 (29.3%) have died while 145 (70.7%) survived. A number of 115 (19.6%) initiated ART with a weight measurement of 60 kg and above, whereby 35 (30.4%) died and 80 (69.6%) survived by the end of July 2011.

4.2.2.3 Baseline functional status

Table 4.6: Baseline functional status (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| | Working | 20 (12.3%) | 143(87.7%) | 163 | 27.8 |

| | | | | | |
|--------------------------|--------------|--------------------|--------------------|------------|------------|
| Functional status | Ambulatory | 83 (28.0%) | 214(72.0%) | 297 | 50.7 |
| | Bedridden | 91 (72.2%) | 35 (27.8%) | 126 | 21.5 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

As reflected in the table above, patients who started ART with a working functional status were 163 (28.0%); whilst most patients 297 (51.0%) started ART when they were in the ambulatory functional status. Furthermore, a number of 126 (21.0%) patients were in ambulatory status at the time of ART initiation. Of the 163 patients who were started on ART with a working functional status, 20 (12.3%) died by the end of July 2011, while out of 297 patients who started ART with ambulatory functional status 83 (27.9) have died as compared to 213 (71.7%) who were still alive by the end of July 2011. As the functional status decreased; the likelihood of dying increases. This is indicated by the number of patients who started ART in bedridden functional status and have died. Out of 126 patients who started ART in bedridden functional status, 91 (72.2%) have died by the end of July 2011, while 35 (27.8%) were still alive during the same period.

4.2.2.4 Baseline WHO clinical staging

Table 4.7: Baseline WHO clinical staging (N=856)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| WHO Clinical Stage | Stage 1 | 5 (14.3%) | 30 (85.7%) | 35 | 6.0 |
| | Stage 2 | 27 (17.9%) | 124 (82.1%) | 151 | 25.8 |
| | Stage 3 | 97 (33.3%) | 194 (66.7%) | 291 | 49.7 |
| | Stage 4 | 46 (56.1%) | 36 (43.9%) | 82 | 14.0 |
| | Not indicated | 19 (70.4%) | 8 (29.6%) | 27 | 4.6 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

Patients who started ART with WHO stage 1 were 35 (6.3%), 151 (27.0%) were in WHO stage 2 at the time of starting ART. Most patients 291 (52.0%) were in WHO stage 3 when they were initiated on treatment while 82 (14.7%) of the patients initiated ART when they were already in WHO stage 4.

For patients who started ART in clinical stage 1, 30 (85.7%) were still alive by the end of July 2011 and five (14.3%) have died. Of 151 patients who started ART in WHO clinical stage 2, 124 (82.1%) were still alive by the end of July 2011, while 27 (17.9%) have died. Out of 291 patients who started ART in WHO clinical stage 3, 194 (66.7%)

were still alive by the end of July 2011 but 97 (33.3%) have died. Those who started treatment while in clinical stage 4, more than half 46 (56.1%) died before or by the end of July 2011 and 36 (43.9%) were still alive by that time. The percentage of patients who died increased with the clinical stage at which the patient started ART treatment.

4.2.2.3 Baseline cluster of differential (CD4) count

Table 4.8: Baseline cluster of differential (CD4) count (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| CD4 cells/mm³ | 0-49 | 33(60.0%) | 22 (40.0%) | 55 | 9.4 |
| | 50-99 | 56 (33.3%) | 112 (66.7%) | 168 | 28.7 |
| | 100-199 | 80 (30.5%) | 182 (69.5%) | 262 | 44.7 |
| | 200+ | 25 (24.8%) | 76 (75.2%) | 101 | 17.2 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

For this study, CD4 counts were grouped as less than 50 cells/mm³, 50-99 cells/mm³, 100-199 cells/mm³ and 200 and above cells/mm³. The minimum CD4 count was 1 cell/mm³ and the maximum was 841 cells/mm³. The table above indicates that 55 (9.4%)

patients started ART with a CD4 count of less than 50 cells/mm³, 168 (28.7%) had a CD4 count ranging between 50-99 cells/mm³. The majority 262 (44.7%) had a CD4 count ranging between 100-199 cells/mm³ while 101 (17.2%) had a CD4 count of 200 cell/mm³.

Out of 55 patients who started ART in Andara with a CD4 count below 50 cell/mm³, 33 (60.0%) died whilst only 22 (40.0%) were still alive by the end of July 2011. Out of 168 patients who started ART with their CD4 count between 50-99 cells/mm³, 56 (33.3%) have died by the end of July 2011, while 80 (30.5%) out of 262 patients who started ART with a CD4 count ranging between 100-199 cells/mm³ have died. Of those who started ART with a CD4 count above 200 cells/mm³, only 24.8% were dead by the end of July 2011 whilst the majority, 75.2% were still alive.

4.2.2.5 Baseline haemoglobin levels

Table 4.9: Baseline Haemoglobin levels (N=586)

| Baseline information characteristic factor | Category | Number and percentages of Cases (Died) N=194 | Number and percentages of Controls (Survived) N=392 | Total Frequency (Number) N=586 | Total Percentage (%) |
|---|-----------------|---|--|---------------------------------------|-----------------------------|
| | < 8 | 51 (84.3%) | 8 (15.7%) | 59 | 10.1 |

| | | | | | |
|----------------------|--------------|--------------------|--------------------|------------|------------|
| Hb level g/dL | 8 – 9.9 | 63 (65.1%) | 38 (34.9%) | 109 | 18.6 |
| | 10-11.9 | 47 (47.5%) | 52 (52.5%) | 99 | 16.9 |
| | 12+ | 33 (28.6%) | 294 (71.4%) | 327 | 55.8 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

For this study Hb level was categorized as follows: Hb less than 8g/dL, 8-9.9g/dL, 10-11.9g/dL and 12 and above. As indicated in the table above, 59 (10.1%) had baseline Hb less than 8g/dL, most patients 109 (18.6%) were having hemoglobin levels ranging between 8 and 9.9g/dL, 99 (16.9%) started ART with Hb between 10-11.9g/dL and a big number of people 327 (55.8%) started ART with an Hb of more than 12g/dL.

For those who had haemoglobin levels of less than 8g/dL at initiation of ART, 51 (84.3%) died by July 2011, whilst only 8 (15.7%) were still alive. It came out that patients who started ART with their Hb between 8 and 9.9g/dL, 63 (65.1%) have died by the end of July 2011. During the same period, patients who started ART with an Hb ranging between 10 and 11.9g/dL, 47 (47.7%) have died. Of those who had haemoglobin levels higher than 12g/dL, 294 (71.4%) were still alive by the end of July 2011, and only 33 (28.6%) had died.

4.2.3 Section D: Co-morbidities and opportunistic infections

Co-morbidity is either the presence of one or more disorders in addition to a primary disease or disorder, or the effect of such additional disorders or diseases. In this study,

co-morbidity is defined as a presence of one or more diseases in addition to HIV infection.

Opportunistic infections are defined as viruses, bacteria, parasites that affect HIV infected people because these infections take advantage of a weakened immune system, and they can cause devastating illnesses (AIDS.gov n.d.). This section will include information related to whether patients suffered from TB before and while on ART, existence of other co-morbidities and side opportunistic infections patients on ART suffered from.

4.2.3.1 TB before and while on ART and other co-morbidities

Table 4.10: TB before and while on ART and other co-morbidities (N=586)

| TB-co infection | Status | Cases (Died) Number and % | Controls (Alive) (Number and %) | Total frequency (Number) | Total percentage (%) |
|----------------------------------|---------------|--------------------------------------|--|---|-------------------------------------|
| TB before ART | Yes | 82 (67.8%) | 39 (32.2%) | 121 | 20.6 |
| | No | 103 (77.6%) | 353 (22.4 %) | 456 | 77.8 |
| | Not indicated | 9 (100%) | 0 | 9 | 1.5 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| TB while on ART | Yes | 78 (76.5%) | 24 (23.5%) | 102 | 17.4% |
| | No | 106 (77.6%) | 368 (22.4%) | 474 | 80.9% |
| | Not indicated | 10 (100%) | 0 | 10 | 1.7 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |
| Other co- morbidities | Yes | 44 (53.6%) | 38 (46.3%) | 82 | 14.0 |
| | No | 142 (28.6%) | 354 (71.3%) | 496 | 84.6 |
| | Not indicated | 8 (100%) | 0 | 8 | 1.4 |
| | Total | 194 (33.1%) | 392 (66.9%) | 586 | 100 |

Of 121 patients who started ART treatment and had a history of suffering from TB before starting ART, 82 (67.8%) were dead by the end of July 2011 whilst out of 456 who did not suffer from TB prior to initiating ART, only 103 (22.6%) had died within the same period. Nine (9) records had no indication of the TB history before starting

ART. Of 586 records reviewed, 102 (17.0%) patients suffered from TB while on ART, 474 (80.9%) did not suffer from TB while receiving ART. On ten records, this variable was not indicated.

Patients who experienced TB before ART were 121 (21.0%) whilst those who experienced TB while on ART treatment were 102 (17.4%). Eighty two (1.4%) patients suffered from other co-morbidities other than TB. Table 4.10 indicates that out of 102 patients who suffered from TB while on ART, 78 (76.5%) have died while patients who did not suffer from TB while receiving ART only 106 (22.4%) died by July 2011. Out of 82 patients who suffered from other co-morbidities other than TB; 44 (53.6%) have died by the end of July 2011. This is a reflection of higher mortality among HIV/TB co-infected patients.

A total number of 82 (14.0%) patients suffered from other co-morbidities rather than TB Table 4.11 indicates the distribution of the co-morbidities suffered.

Table 4.11: Frequencies and percentages of co-morbidities among cases and controls (N=82)

| Co-morbidity | Cases (Died) (number and %) | Controls (Alive) (number and %) | Total frequency (number) | Total percentage (%) |
|-------------------------------------|--|--|---|-------------------------------------|
| Hepatitis B | 35 (48.6%) | 36 (51.4%) | 72 | 87.8% |
| Diabetes | 0 | 1 (100%) | 1 | 1.2% |
| Asthma | 2 (100%) | 0 | 2 | 2.4% |
| Cardiovascular disease | 1 (100%) | 0 | 1 | 1.2% |
| Sexual Transmitted Infections | 2 (66.7%) | 1 (33.3%) | 3 | 3.7% |
| Other | 2 (66.7%) | 1 (33.3%) | 3 | 3.7% |
| Total | 44 | 38 | 82 | (100%) |

Most patients 72 (87.8%) were co-infected with Hepatitis B whilst other co-morbidities were also registered with few cases. Of the 72 patients who had co-infections with Hepatitis B, 35 (48.6%) died by the end of July 2011. Other co-morbidities had very few cases, like cardiovascular diseases, asthma, diabetes mellitus and STI.

4.2.4 Section E: Medicine related information

Table 4.12: Frequencies and percentages of medicine related information (N=586)

| Medicine related information | ART Regimen Initiated | Cases (Died) Number and % | Controls (Alive) Number and % | Total frequency (Number) | Total Percentage (%) |
|-------------------------------------|------------------------------|----------------------------------|--------------------------------------|---------------------------------|-----------------------------|
| ART regimen initiated | D4T/3TC/EFV | 46 (54.1%) | 39 (45.9%) | 85 | 14.5 |
| | D4T/3TC/NVP | 85 (38.5%) | 136 (61.5%) | 221 | 37.7 |
| | AZT/3TC/EFV | 14 (46.7%) | 16 (53.3%) | 30 | 5.1 |
| | AZT/3TC/NVP | 32 (16.2%) | 165 (83.8%) | 197 | 37.8 |
| | AZT/3TC/LPV _r | 1 (33.3%) | 2 (66.7%) | 3 | 0.5 |
| | TDF/3TC/EFV | 13 (32.5%) | 27 (67.5%) | 40 | 6.8 |
| | TDF/3TC/NVP | 1 (16.7%) | 5 (83.3%) | 6 | 1.0 |
| | Others | 2 (50.0%) | 2 (50.0%) | 4 | 0.7 |
| | Total | 194 | 392 | 586 | 100 |
| Side Effects suffered | Yes | 24 (66.7%) | 12 (33.3%) | 3 | 6.1 |
| | No | 163 (30.0%) | 380 (70.0%) | 543 (94.0%) | 92.7 |
| | Not indicated | 7 (100%) | 0 | 7 | 1.2 |
| | Total | 194 | 392 | 586 | 100 |

4.2.4.1 ART regimen initiated

A number of 85 (14.5%) patients were started on D4T/3TC/EFV regimen, most patients 221 (37.7%) were started on D4T/3TC/NVP, 30 (5.1%) were started on AZT/3TC/EFV, 197 (37.84%) were started on AZT/3TC/NVP. Patients started on AZT/3TC/LPVr, TDF/3TC/EFV, TDF/3TC/NVP and other regimens were 3 (0.5%), 40 (6.8%), 6 (1.0%) and 4 (0.6%) respectively. This is not in line with the national ART guidelines because the ART guideline indicates D4T/3TC/NVP and D4T/3TC/EFV as the recommended first line regimen.

This study shows that out of 85 patients who were started on D4T/3TC/EFV, 46 (54.1%) have died by the end of July 2011, patients who were started on D4T/3TC/NVP 85 (38.5%) have died during the same period. Out of 30 patients who were started on AZT/3TC/EFV, 14 (46.7%) have died, while of 197 patients who were started on AZT/3TC/NVP, only 32 (16.2%) have died. One (33.3%) out of 3 patients who were started on AZT/3TC/LPVr, have died by the end of July 2011, while 13 (32.5%) out of 40 and 1 out of 6 (16.7%) of patients who were started on TDF/3TC/EFV and TDF/3TC/NVP regimen respectively have also died during the same period. These results show that patients who started on TDF/3TC/NVP and AZT/3TC/NVP had higher survival prospects with 83.3% and 83.8% survival rates respectively. On the contrary, those who were started on D4T/3TC/EFV and AZT/3TC/EFV had limited prospects of survival with 54.1% and 46.7% on these drugs being dead by end of July 2011 respectively.

Although most of the patients were alive as compared to the one who have died, there is a clear reflection that patients initiated on EFV based regimens are more likely to die. It is possible that patients who were started on EFV based regimens are the same patients who had TB co-infection.

4.2.4.2 Side effects in the study sample

Results in table 4.12 indicate that only 36 (6.1%) of the patients in the study suffered some side effects from taking ARV drugs within the first two months after initiating ART. Side effects are symptoms or problems that one may have when taking medication. Almost all medicines used to treat illnesses can cause side effects. HIV medications are not different. Most side effects can be felt or seen but one may not be aware of some side effects such as liver or kidney damage. Side effects are one of the main reason some people may stop taking ARVs (Pataki, n.d.; Calmy, Hirschel, Cooper & Carr, 2007)).

The types of side-effects suffered by some patients in the first two months are shown in Table 4.13.

Table 4.13: Frequencies and percentages of side effects suffered in the first two months (N=36)

| Side effect | Frequency | Percentage |
|---|-----------|------------|
| Nausea | 1 | 2.8 |
| Diarhoea | 4 | 11.1 |
| Vomiting | 4 | 11.1 |
| Fatigue | 2 | 5.6 |
| Numb/burning | 2 | 5.6 |
| Rashes | 13 | 36.1 |
| Anaemia | 3 | 8.3 |
| Abdominal pain | 1 | 2.8 |
| Jaundice | 1 | 2.8 |
| Central Nervous System (dizzy, nightmare, depression) | 4 | 11.1 |
| Gynaeconastia | 1 | 2.8 |
| Total | 36 | 100 |

As reflected in table 4.13, side effects suffered in the first two months after starting ART included vomiting, numb/burning/tingling of limbs, rashes and anaemia. Rashes were the side effects frequently occurring amongst patients. This could be a side effect of Nevirapine, as this is one of the recommended ARV in the first line combination (MoHSS, 2010a).

In addition, 28 patients suffered side effects two months after started ARV treatment and this represent 4.8%.

4.2.5 Section F: Treatment interruption

Table 4.14: Treatment interruption among cases and controls (N=586)

| | Cases (Died) | Controls (Alive) | Total (Number) | Percentage (%) |
|---------------------|---------------------|-------------------------|---------------------------|---------------------------|
| ART interrupted | 83 (80.6%) | 20 (19.4%) | 103 | 17.6 |
| ART not interrupted | 111 (23.0%) | 372 (77.0%) | 483 | 82.4 |
| Total | 194 | 392 | 586 | 100 |

Out of 103 patients with records of treatment interruption only 2 (0.3%) were stopped by a clinician (structured interruption) and both have died. Common toxicity such as lipodystrophy and metabolic side effects related to prolonged use of ART may improve when ART is stopped.

However, 101 (17.2%) patients had interrupted ART by themselves (unstructured interruption). Of patients who had unstructured treatment interruption, 89 (15.2%) were either lost to follow up or have ran out of pills. Few have indicated that they were too ill, had travel problems, alcohol problems and other factors as reasons for interrupting treatment and were 1, 5, 2 and 2 respectively. These findings are in agreement with the

study conducted in Ethiopia which shows forgetting, transport problems and fear of stigma as some of the reasons for patients interrupting their treatment (Assefa and Wencheke, 2012).

4.2.6 Section G: Therapy changes

Therapy change covers two areas: therapy substitution and therapy switch. As it was defined in Chapter 3, treatment substitution refers to changing one or more ARVs within the first line regimen while switching refers to changing ART regimen from first ART regimen to second line regimen.

4.2.6.1 Therapy substitution within first line regimen in the study sample

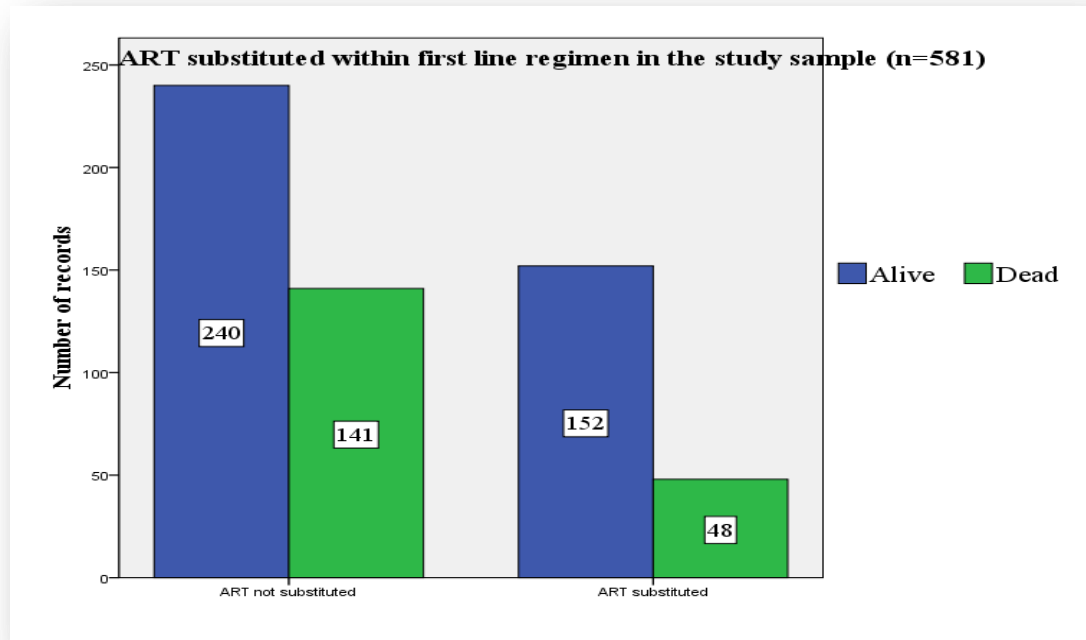


Figure 4.1 ART substitution within first line regimen in the study sample (n=581)

Figure 4.1 shows that 381 patients had no therapy substituted within first line regimen. Of these, 141 (37.0%) died by the end of July 2013 while out of 200 patients who had treatment substitution, 48 (24.0%) have died during the same period. Table 4.14 indicates reasons for therapy substitution.

Table 4.15: Reasons for therapy substitution within first line regimen (N=200)

| Reason for substitution | Frequency | Percentage |
|-------------------------|-----------|------------|
| Toxicity | 34 | 17.0% |
| Pregnancy | 4 | 2.0% |
| New TB infection | 49 | 24.5% |

| | | |
|--------------------|-----|--------|
| New drug available | 79 | 39.5% |
| Drug out of stock | 0 | 0 |
| Guideline change | 5 | 2.5% |
| Other | 21 | 10.5.0 |
| Not recorded | 8 | 4.0% |
| Total | 200 | 100% |

4.2.6.2 Therapy switched to second line regimen in the study sample

Out of 586 records reviewed, only nine reflected therapy switch from first line to second line regimen. A total number of 571 patients were not switched to second line regimen while six records were not indicated if regimen was switched or not. Out of the nine records which indicated therapy switch to second line regimen, reasons indicated were toxicity, virological failure and immunological failure for one, five and one records respectively.

4.2.7 Section H: Adherence information

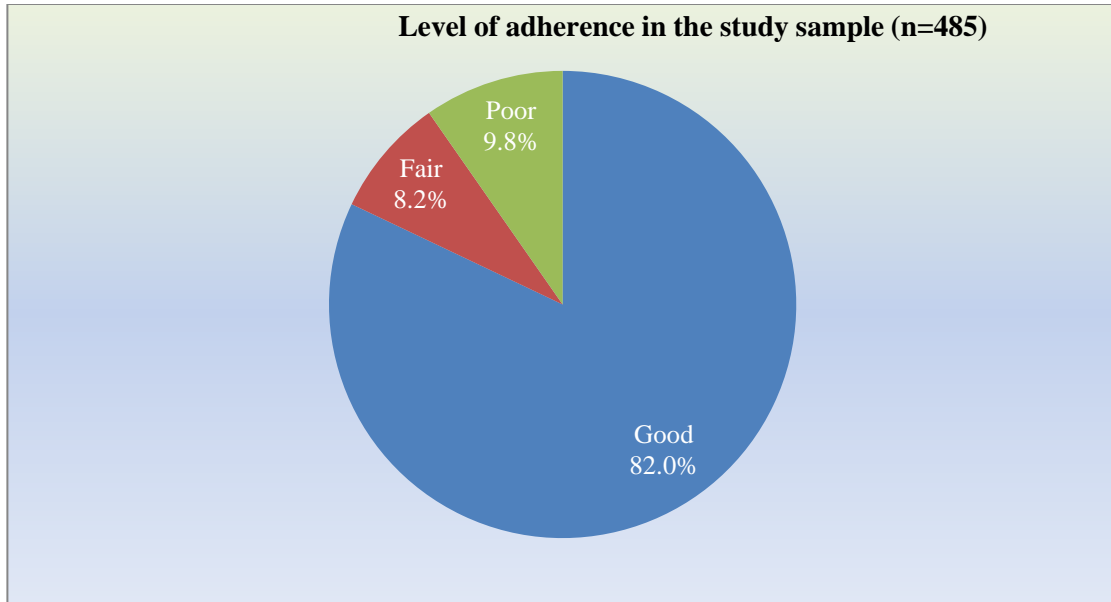


Figure 4.2: Level of adherence in the sample (n=485)

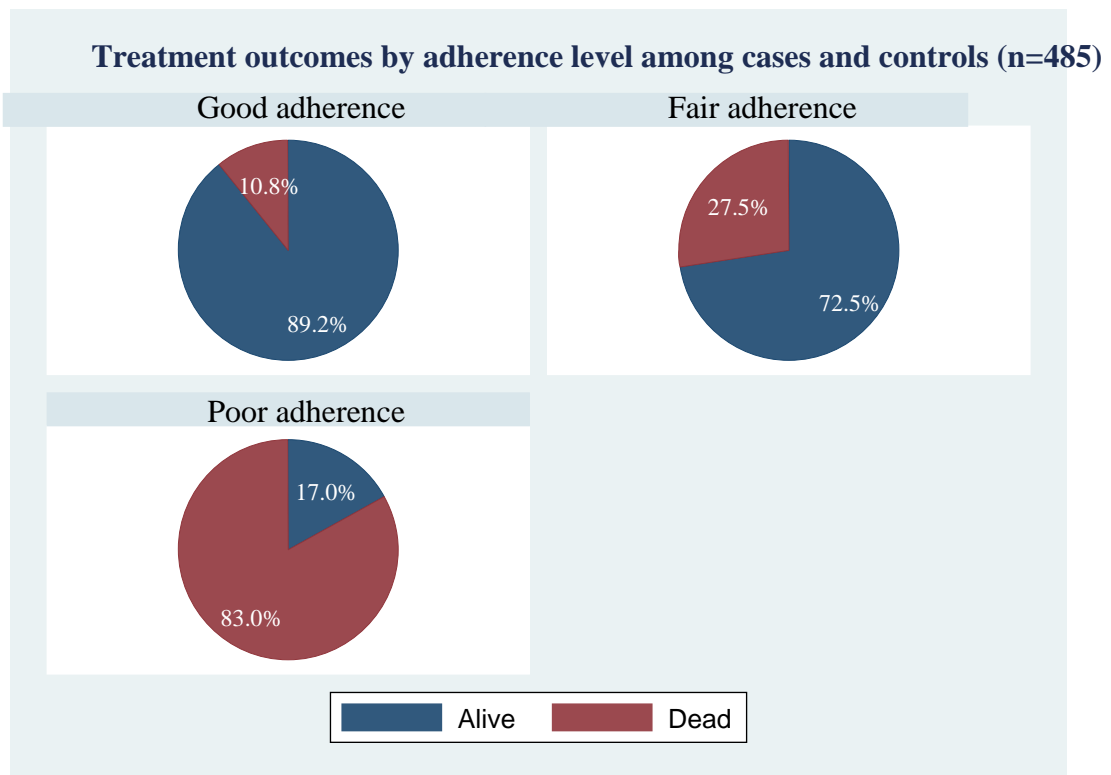


Figure 4.3: Treatment outcomes by adherence level among cases and controls (n=485)

As shown in Figure 4.2, most patients 398 (82.0%) in the study had good adherence to treatment, 40 (8.2%) had fair adherence and 47 (9.8%) were poorly adhering to treatment. Figure 4.3 indicates that out of 398 patients who had good adherence, only 43 (10.8%) died by the end of July 2011 as compared to 11 (27.5%) who died from 40 patients who had fair adherence and 39 (83.0%) out of 47 who were poorly adhering to ART. These results indicate that poor adherence increases the chance of dying. It is further reflected that out of 398 patients who were good in adhering to treatment at six months, 355 (89.2%) were still alive by the end of July 2011. Out of 40 patients who had fair adherence levels, 11 (27.5%) have died by the end of July 2011, whilst 39 (83.0%) of 47 patients who poorly adhered to treatment died by the end of July 2013.

4.2.8 Section I: Treatment outcome

Table 4.16 Treatment outcome

| Treatment outcome | Frequency (Number) | Percentage (%) |
|--------------------------|---------------------------|-----------------------|
| Alive | 392 | 66.9% |
| Dead | 194 | 33.1% |
| Total | 586 | 100% |

As indicated earlier in Chapter 3, treatment outcome in this study refers to whether patients were alive or dead by end of July 2011. Figure 3.1 depicted the number of cases and controls used in this study. As shown in table 4.16, a total number of 194 cases (dead) and 392 controls (alive) records were reviewed.

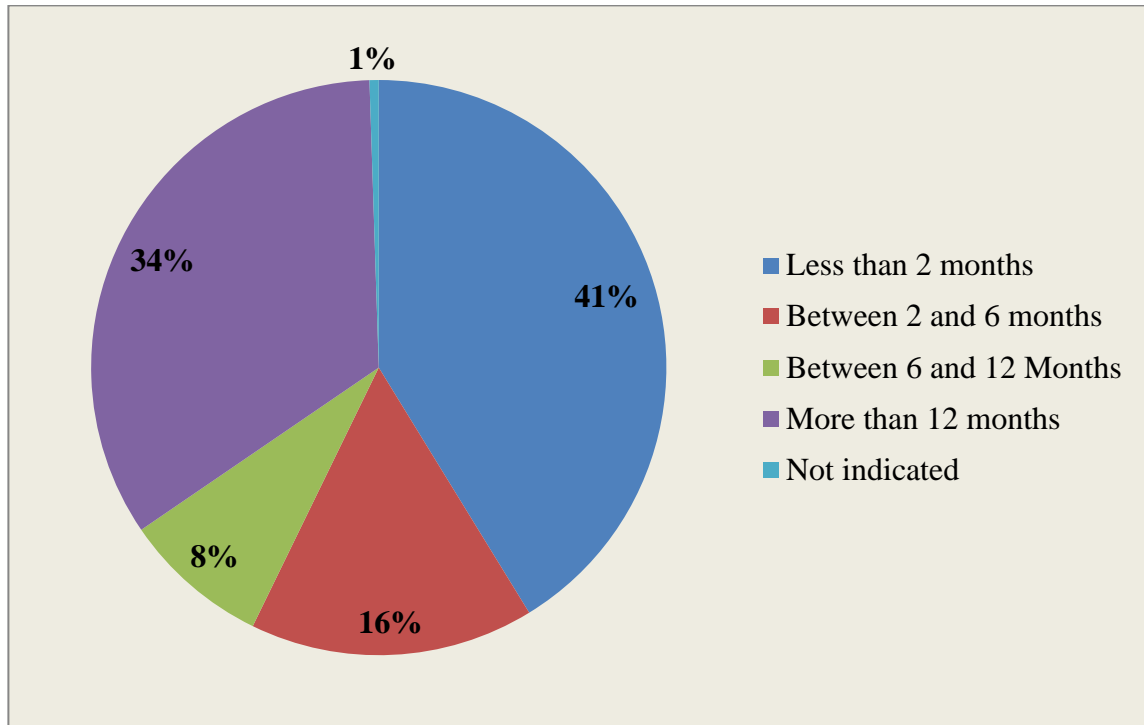


Figure 4.4: Duration on treatment by the time of death (N=586)

For cases, it was interesting to know the duration on treatment by the time of death. Of 194 patients who died, 80 (41.2%) had been on treatment for less than 2 months and this was the biggest number. Thirty one (16.0%) had been on treatment for the period ranging from 2 to 6 months, 16 (8.2%) had been on treatment for the period ranging between 6 and 12 months while 66 (34%) had been on treatment for more than a year. This is an indication that most patients started ART while in advanced stage of the disease as reflected by the level of baseline CD4, clinical stage, functional status and WHO clinical stage.

Causes of deaths were not indicated in 185 records; only 9 records had causes of death indicated. Causes of death recorded were TB, toxicity and others with 7, 1 and 1 record(s) respectively.

Information regarding places of death was also not available in most of the records (169). Only 25 (13.0%) records have places of death indicated of which 22 patients were recorded as having died in the hospital and three at home.

4.3 ANALYTICAL ANALYSIS

4.3.1 The association between risk factors and mortality of patients on ART in the Andara district

Table 4.17: The association between risk factors and mortality of patients on ART in the Andara district

| Risk factor | Chi-square value | Degrees of freedom | Sample size (n) | P-value | Conclusion |
|----------------|------------------|--------------------|-----------------|---------|----------------------------------|
| Sex | 16.382 | 1 | 586 | 0.000 | Significant positive association |
| Marital status | 8.9534 | 5 | 528 | 0.111 | No association |
| Employment | 17.7860 | 4 | 453 | 0.001 | Significant positive |

| | | | | | |
|---------------------|----------|---|-------------------|-------|----------------------------------|
| | | | | | association |
| Treatment supporter | 57.1963 | 3 | 576 | 0.000 | Significant positive association |
| Functional status | 122.5793 | 2 | 586 | 0.000 | Significant positive association |
| WHO clinical stage | 57.9134 | 4 | 559 | 0.000 | Significant positive association |
| CD4 count category | 21.9319 | 3 | 586 | 0.000 | Significant positive association |
| Hb level category | 38.2469 | 3 | 308 (278 missing) | 0.000 | Significant positive association |
| | | | | | |
| TB before ART | 106.6129 | 3 | 586 | 0.000 | Significant positive association |
| TB while on ART | 131.5209 | 3 | 577 | 0.000 | Significant positive association |
| Co-morbidities | 39.9366 | 7 | | 0.000 | Significant positive association |
| ART regimen | 53.3620 | 8 | 586 | 0.000 | Significant positive association |

Tables 4.17 and 4.18 indicate the association between risk factors at initiation with mortality and the magnitude of risk attached to each of the levels of risk factors on mortality respectively. Table 4.17 shows that sex is significantly (p -value=0.000) associated with mortality of ART patients at Andara hospital. There is no significant (p -value=0.111) association between marital status and mortality for ART patients. The table also indicates that there are significant associations between employment status (p -value=0.001), clinical staging (p -value=0.000), treatment support (p -value=0.000), functional status (p -value=0.000), ART regimen (p -value=0.000), TB before ART status (p -value=0.000), TB while on ART (p -value=0.000), co-morbidities (p -value=0.000), CD4 count level (p -value=0.000) and HB level (p -value=0.000) with mortality. These results highlight that with the exception of marital status; all the other survival risk factors at initiation of ART are significant and have great influence on the chances of death for patients on ART.

In addition, Table 4.17 shows the chi-square tests of association between the treatment outcome (death or alive) by the end of July 2011 with the different risk factors at initiation. It further indicates that there is a difference in socio-demographic, baseline and medical related factors between patients who died while on ART and patients who survived while on ART by the end of July 2011.

4.3.2 A logistic regression model to determine the odds of death for different risk factors

Table 4.18: A logistic regression model to determine the odds of death for different risk factors

| Risk factor | Odds Ratio | Std. Err. | z | P>z | 95% Conf. Interval | |
|----------------------------|------------|-----------|-------|--------------|--------------------|----------|
| Age group | | | | 0.493 | | |
| 15-19 | Ref | | | | | |
| 20-24 | 1.707004 | 3.755592 | 0.24 | 0.808 | 0.022882 | 127.3413 |
| 25-29 | 0.604459 | 1.294281 | -0.24 | 0.814 | 0.009094 | 40.17714 |
| 30-34 | 0.648067 | 1.393005 | -0.2 | 0.84 | 0.009594 | 43.77825 |
| 35-39 | 0.305647 | 0.661233 | -0.55 | 0.584 | 0.004403 | 21.21782 |
| 40-44 | 0.484804 | 1.057608 | -0.33 | 0.74 | 0.00674 | 34.87188 |
| 45-49 | 0.678502 | 1.507045 | -0.17 | 0.861 | 0.008728 | 52.74552 |
| 50+ | 0.743612 | 1.637096 | -0.13 | 0.893 | 0.00994 | 55.62953 |
| Sex | | | | 0.008 | | |
| Male | Ref | | | | | |
| Female | 0.254317 | 0.115021 | -3.03 | 0.002 | 0.104809 | 0.617093 |
| Marital status | | | | 0.086 | | |
| Single | Ref | | | | | |
| Married | 1.212703 | 0.611625 | 0.38 | 0.702 | 0.451287 | 3.258792 |
| Cohabiting | 1.741234 | 1.265846 | 0.76 | 0.446 | 0.41884 | 7.238783 |
| Widow | 2.173976 | 1.597652 | 1.06 | 0.291 | 0.514882 | 9.179135 |
| Divorce | 4.935958 | 3.859623 | 2.04 | 0.041 | 1.066063 | 22.85388 |
| Employment | | | | 0.210 | | |
| Employed | Ref | | | | | |
| Self-employed | 3.007179 | 5.144929 | 0.64 | 0.52 | 0.105161 | 85.99331 |
| Unemployed | 0.532932 | 0.334667 | -1 | 0.316 | 0.155647 | 1.824748 |
| Seasonal worker | 2.451493 | 6.345933 | 0.35 | 0.729 | 0.015347 | 391.6071 |
| Treatment supporter | | | | 0.004 | | |
| Yes | Ref | | | | | |
| No | 1.736601 | 0.939536 | 1.02 | 0.308 | 0.601427 | 5.014378 |
| Weight | 1.03154 | 0.017502 | 1.83 | 0.386 | 0.997791 | 1.066432 |
| Functional status | | | | 0.000 | | |

| | | | | | | |
|------------------------------|----------|----------|-------|--------------|----------|----------|
| Working | Ref | | | | | |
| Ambulatory | 3.314718 | 1.488369 | 2.67 | 0.008 | 1.374806 | 7.991927 |
| Bedridden | 57.57299 | 41.73505 | 5.59 | 0 | 13.9052 | 238.3749 |
| WHO clinical Stage | | | | 0.139 | | |
| Stage 1 | Ref | | | | | |
| Stage 2 | 0.556618 | 0.419025 | -0.78 | 0.436 | 0.127282 | 2.434146 |
| Stage 3 | 0.392222 | 0.301106 | -1.22 | 0.223 | 0.08711 | 1.766009 |
| Stage 4 | 0.432644 | 0.417182 | -0.87 | 0.385 | 0.065365 | 2.863601 |
| Baseline CD4 category | | | | 0.750 | | |
| Less than 50 | Ref | | | | | |
| CD4 count 50-99 | 0.146917 | 0.092026 | -3.06 | 0.002 | 0.043042 | 0.501471 |
| CD4 count 100-199 | 0.342832 | 0.20659 | -1.78 | 0.076 | 0.105233 | 1.116896 |
| CD4 count 200+ | 0.346345 | 0.238163 | -1.54 | 0.123 | 0.089988 | 1.333014 |
| Haemoglobin level | | | | 0.000 | | |
| Hb less than 8 | Ref | | | | | |
| Hb level 8-9.9 | 0.448095 | 0.296925 | -1.21 | 0.226 | 0.122273 | 1.642136 |
| Hb level 10-11.9 | 0.192673 | 0.133692 | -2.37 | 0.018 | 0.049453 | 0.750674 |
| Hb level 12-18.9 | 0.056138 | 0.045429 | -3.56 | 0 | 0.011493 | 0.274205 |
| TB before ART | | | | 0.881 | | |
| Yes | Ref | | | | | |
| No | 0.637741 | 0.327402 | -0.88 | 0.381 | 0.233161 | 1.744346 |
| TB while on ART | | | | 0.943 | | |
| Yes | Ref | | | | | |
| No | 0.672615 | 0.320534 | -0.83 | 0.405 | 0.264319 | 1.711613 |
| ART regimen | | | | 0.028 | | |
| D4T/3TC/EFV | Ref | | | | | |
| D4T/3TC/NVP | 0.558516 | 0.389602 | -0.84 | 0.404 | 0.14232 | 2.191823 |
| AZT/3TC/EFV | 0.522985 | 0.505365 | -0.67 | 0.502 | 0.078699 | 3.475458 |
| AZT/3TC/NVP | 0.1227 | 0.098647 | -2.61 | 0.009 | 0.02538 | 0.593181 |
| AZT/3TC/LPVr | ----- | | | | | |
| TDF/3TC/EFV | 0.64976 | 0.638383 | -0.44 | 0.661 | 0.094723 | 4.457079 |
| TDF/3TC/NVP | 0.280427 | 0.454284 | -0.78 | 0.433 | 0.011719 | 6.710333 |

The model in Table 4.18 was used to determine the risk factors for death in patients on ART and also to quantify the risks (odds of death) associated with each risk factor level given the different risk factors. Table 4.11 shows the different risk factors and how they contribute to the likelihood of death for someone who is in Andara and are on ART.

Sex is a significant risk factor and with males as the reference level, females are less likely to die compared to their male counterparts. Holding all other risk factors constant, females are around 74% less likely to die compared to males. This implies that men on ART in Andara are at higher risk of dying than women on the same treatment. For **marital status**, those who are divorced are significantly five times more likely to die during treatment as compared to singles for the study period. The widowed have also high chance of dying as compared to married people.

Employment status does not seem to have any significant effect on causing death among people on ART in the Andara district. Patients who were initiated on ART without a **treatment supporter** were twice at risk in comparison to patients who were initiated on treatment with supporters. This highlights the importance of initiating HIV patients on ART with a strong social support system as this reduces stigmatization and hence improves the survival prospects of HIV patients who are on ART. Patients who were initiated on ART with their **functional status** at ambulatory level were three times more likely to die compared to those who started when their functional status was still working; while those who were bedridden at initiation were 59 times more likely to die.

This indicates that it is critical for HIV patients to start on ART whilst their functional status is still in the working category. **TB disease** before and while on ART impacts negatively on survival prospects. Patients who were never diagnosed with the disease before treatment were 37% less likely to die whilst those who did not diagnose TB disease during treatment were 33% less likely to die in comparison to those who were diagnosed with the disease.

4.4 SUMMARY

This chapter focused on presenting the data analysis and research findings, and interpretations were made. Factors were described and discussed in relation to frequencies and percentages of distribution among patients who died and who survived while receiving ART by the end of July 2011, in the Andara district. Statistical significance of association with mortality of patients on ART was presented. A regression model which showed the strength of association in identifying factors that are significantly associated with mortality of patients on ART in the Andara district was presented. The study indicated that sex, functional status, having a treatment supporter and anaemia are significant risk factors associated with mortality in the Andara district. The study also revealed that the kind of ART regimen started was the protecting factor.

The next chapter will discuss these findings, conclusions and recommendations based on the findings.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

5.1 INTRODUCTION

The results of this study were presented in Chapter 4 following the descriptive and analytical analysis. Literature control was done to compare with findings of this study. In this chapter, conclusions as derived from the results and the hypothesis outcome are presented. Recommendations based on the findings are formulated and presented with focus on the research purpose and objectives and compare research findings with existing literature. Limitations of this study are also highlighted.

5.2 CONCLUSIONS

The purpose of this study was to explore, describe and analyse factors associated with mortality of patients on ART in the Andara district. Two objectives were formulated in order to achieve the purpose of this study. The first objective was to describe baseline socio-demographic and medical characteristics of patients on ART in the Andara district.

The second objective was to determine the independent risk factors associated with mortality of patients on ART in Andara. Therefore, conclusion is hereby presented based on these objectives.

5.2.1 Conclusions with regard to the first objective

First objective: To describe baseline socio-demographic and medical characteristics of patients on ART in the Andara district.

To reach the first objective, socio-demographic information, baseline information, co-morbidities and opportunistic infection information, medicine related information, treatment interruptions and adherence information and treatment outcome information were extracted from a standardized patient care booklet complimented by the electronic database, into the data abstraction tool developed by the researcher. Data were analysed using SPSS 17.0 to determine the distribution of these factors which characterized patients on ART in Andara , both who have died and who were still alive by the end of July 2011. This was achieved by applying descriptive analysis.

Conclusion:

Age

This study reflects that there was almost equal distribution in percentages of death among all age groups. The age groups between 15-19 (33.3%), 30-34 (37.1%) 44-49 (34.0%) and 70-75 (50%) seem to have the highest proportion of people dying from HIV/AIDS whilst on ART in the Andara district as indicated in table 4.1.

Although this study does not have a sustained trend of higher mortality as age increases, findings from a study conducted in Ethiopia indicated that older age has an increased

risk of death compared to young age groups. The numbers of co-morbidities increases with age, older patients have a higher mortality rate than do younger patients whilst age is inversely correlated with the time of AIDS diagnosis. Older age is significantly associated with shortened survival, suggesting that factors such as severity of complicating diseases or the capability of handling serious infections, rather than disease pattern, are responsible for the shortened survival (Balslev, Monforte, Stergiou, Antunes, Mulcahy, Pehrson, Phillips, Pedersen & Lundgren, 1997; Gadpayle et al 2012). These findings concur with the findings of the study conducted by Gadpayle et al, (2012) which reflected that old age is associated with rapid progression of HIV/AIDS and mortality.

Sex

There were more females than males in both the cases and the control groups. Reflection of this study could be as a result of the national distribution of HIV/AIDS patients which show that there is a higher proportion of females who are living with HIV/AIDS as compared to males statistics. Although there were more females on ART, this study indicated that more males died as compared to females. This phenomenon could also be attributed to mortality trends between males and females living with HIV/AIDS.

Findings from this study concur with findings from other studies where it was found that males receiving ART have high chances of dying compared to females and this could be attributed to poor compliance amongst males as well as the tendency amongst males to

start ART at a more advanced stage of the HIV/AIDS disease (Assefa and Wencheke, 2012; Chen, Yu, Harries, Bong, Kolola-Dzimadzi, Tok, King & Wang, 2008). In addition, studies conducted in Ethiopia showed that sex (male) is a predictor of mortality (Abose, 2011).

Marital status

Even though there were more married people in the study sample, more deaths were observed among the divorced and the widowed. Married people could have more support from their spouses than their divorced or widowed counterparts and could be more psychologically ready to adapt to the disease, and take their medicines correctly, as a result.

The findings for this study conform to the report by Gjanca (2004) which indicated that married people have significantly better health and a lower mortality than their single counterparts. It was further observed that widowed and divorced individuals were more likely to die than married people (Korenman and Goldman; Goldman, Korenman & Weinstein; Mineau, Smith & Bean in Gjanca, 2004). However, results from the study conducted in Ethiopia indicated that being single or unmarried is a strong predictor of mortality. This could be attributed to the fact that many women were on ART as compared to men, and usually men seek medical help late and start ART at an advanced stage of the HIV/AIDS. For HIV infected people, the researcher's assumption is that, divorced and widowed people may not have much needed emotional support since they

do not have spouses, thus rendering them vulnerable to poor conditions which in return, may lead to early mortality.

Similarly, a study in Ethiopia showed that single or never married people have high risks of dying, while findings on married people are consistent in that married people have a high survival rate (Abose, 2011).

Employment status

More people in the study were unemployed in comparison to other employment categories. The findings showed that more people who died came from the employed and unemployed categories, compared to the self-employed and seasonal employed categories. Thus, seasonal workers had the least percentage of death followed by the self-employed.

The study carried out in the US revealed that physically inactive patients at the initiation of ART are more likely to die (Marconi et al, 2010). Unemployment could be related to inactivity.

Baseline information

Availability of treatment supporter

The findings reveal that more people had **treatment supporters** at the starting of ART, yet it was interesting to learn that more people who died had treatment supporters. This is a rare scenario because treatment supporters are believed to contribute positively to

treatment outcome. This could be attributed to the fact that stigma and discrimination were very high at the beginning of ART (the period for this study), especially in the Andara district. Having a treatment supporter could have exposed patients to further stigma. This could be self-stigmatisation as the patient may think that the person who knows his/her HIV status will divulge that information to others.

Baseline weight

The evidence above concurs with findings from other studies which indicate that low weight at initiation of ART is an independent predictor of mortality (Alemu and Sebastián, 2010; Suthar, Granich, Mermin, & Van Rie, 2012; Worku, 2009). Weight alone does not determine a person's nutritional status. Nutritional status is determined by the BMI. This could not be done in this study because measuring of height for adults was not being routinely done at the beginning of ART era in Namibia. However, Abose (2011) indicated that studies conducted in Malawi and in Cameroon found that severely malnourished patients (BMI $<16\text{kg/m}^2$) are six times more likely to die than well-nourished patients, and that patients with a BMI $<15\text{kg/m}^2$ had a three times higher risk of dying.

It came out clearly from the study that many patients started ART with an **ambulatory functional status**, and that the majority of those who died had started ART with a bedridden functional status.

Other studies have revealed that patients who were working lived on average one year and two years longer than those in ambulatory and bedridden conditions respectively (Assefa and Wencheke, 2012)

This goes hand in hand with the **WHO clinical staging and CD4** count level. This study indicates that although many patients started ART in the WHO clinical stage 3, there was a high percentage of death among patients who started ART in WHO clinical stage 4 as well as those who had started ART with a CD4 count of less than 50 cell/mm³.

Assefa and Wencheke (2012) have demonstrated the common evidence in Ethiopia that patients who started ART in stage 1 survived longer than those that started ART in stage 2, 3 and 4.

This concurs with findings from a study done in rural Malawi where it was found that the WHO clinical stage 4, male sex, a baseline CD4 count of less than 50 cells/mm³ were independent determinants of death among patients receiving ART (Ferradini, Jeannin, Pinoges, Izopet, Odhiambo, Mankhambo, Karungi, Szumilin, Balandine, Fedida, Carrieri, Spire, Ford, Tassie, Guerin, Brasher. 2006).

Observation from a study conducted by Assefa and Wencheke (2012) indicate that patients who started ART with CD4 above 200/mm³ lived three years longer on average

than those that started ART with their CD4 count below 200/mm³. Other studies have established the same trend (Marconi et al, 2010).

It was evident that more patients started ART with an **Hb level** ranging between 8-11.9g/dL, but it came out that less people died from those who had an Hb of 12g/dL and above. Findings reflect clearly that more patients who were anaemic died.

The same findings are highlighted in the literature and other studies that a low Haemoglobin level is associated with poor nutrition and the advanced stage of HIV/AIDS and resultantly with the increased mortality of patients receiving ART (Takuva, Maskew, Brennan, Sanne, MacPhail, & Fox, 2013; Paton, Sangeetha, Earnest & Bellamy, 2006; Sieleunou et al, 2009; Stringer et al, 2006; Zachariah et al 2006).

Furthermore, the study revealed that more patients were **co-infected with TB and Hepatitis B** and both TB and Hepatitis B co-morbidities indicated increased percentage of mortality.

Findings of this study are in agreement with studies conducted in South Africa, Malawi, Jamaica and USA in terms of TB and HIV co-morbidities, which indicate that HIV co-infection with Tuberculosis or with Hepatitis C, is a great predictor of early mortality (Russell et al, 2010; Zacharia et al, 2006; Zacharia et al, 2009; Losina et al, 2007; Marconi et al, 2010). However, in Andara district Hepatitis B was the one identified

rather than Hepatitis C. This could be attributed to the fact that patients on ART in Namibia are routinely screened for Hepatitis B but not Hepatitis C (MoHSS, 2010a).

In addition, the findings of this study concur with studies done in different parts of the world (Castelnuovo et al 2009; Russell et al 2010, Zacharia et al, 2006; Losina et al, 2007). Abose (2011) reflected that a study conducted in Uganda showed that the death association with TB was high. The author further indicated that TB either before or during ART increases the patient's chance of dying. This may be due to the fact that TB kills nearly a quarter of a million people living with HIV each year and it is the number one cause of death among HIV-infected people in Africa, and a leading cause of death in this population worldwide (WHO, 2013). In addition, Mycobacterium TB is a virulent organism that can produce disease in HIV infected people at any stage even when the immunosuppression is minimal (Abose, 2011).

Medicine related information

Findings from this study further indicated that many patients were started on D4T/3TC/NVP and AZT/3TC/NVP **regimens**, yet more deaths were observed among patients started on the regimen containing EFV.

These findings are in concurrence with the findings of the study conducted in Ethiopia which has also reflected high mortality rates amongst patients who were started on EFV

based regimens (Abose, 2011). It was further indicated that most patients did not suffer from side effects after starting on ART.

Findings of this study are in agreement with a study carried out by Abose (2011) which showed that side effects or toxicity, new TB infections and clinical were some of the reasons for therapy change.

The results indicated that a big proportion of patients on ART in the Andara district had good level **adherence**, and among those who died a big proportion were from patients who had poor adherence level. The above evidence concurs with findings from other studies which demonstrated that adherence in resource-limited settings is equal or superior to that in resource-rich settings, possibly due to focused efforts on support groups and community acceptance of adherence behaviours (Nachega, Mills & Schechter, 2010). In addition, these findings are in line with what was found in Ethiopia where it was indicated that non-adherent patients had high mortality rates (Abose, 2011).

5.2.2 Conclusion with regard to second objective

Second objective: To determine the independent risk factors associated with mortality of patients on ART in Andara.

A case-control design was used to meet this objective. Cases were records of patients who started ART in the Andara district and who have died by the end of July 2011,

while controls were records of patients who had started ART in Andara during 01 August 2004 and 30 September 2009, and who were still alive by the end of July 2011. Analytical analyses were done on the sex, marital status, employment status, availability of a treatment supporter, functional status, WHO clinical staging, CD4 counts, Haemoglobin, TB before and while on ART, co-morbidities and ART regimen, using statistical tests of significant association, whilst using 95% confidence intervals, Odds ratios, chi-squares and p-values were calculated to determine the association of different factors and mortality and the strength of the association which exist. A multiple logistic regression analysis was done to determine the odds of death for different factors as discussed in Chapter 4.

Conclusion:

Age

The findings yielded that all **age groups** had more than a quarter of their populations dead by the end of July 2011. These are worrying trends for public health in the country. Those who were in the age group of 20-24 and taking ART treatment in Andara were two times more likely to be dead by the end of July 2011, compared to those who were on the same treatment regimen, but aged between 15-19. This could have negative economic implications for the country as this age group represents the highest percentage of the working force. All the other age groups were less likely to die during the period of study compared to those aged 15-19 years on ART in Andara. Overall the

different age groups are not significantly different from the 15-19 age group in terms of impacting on the outcome variable.

Sex

Sex was found to be a significant risk factor. According to this study, men were at a high risk of dying than females. High percentages of males died compared to females. This shows that mortality of males on ART due to HIV/AIDS is almost double that of females.

Marital Status

It was further established that **marital status** is a significant factor in this study. Divorcees and widowed are at more risk of dying than married patients.

Employment status was not found to have any significant effect on causing death in this study. Although it was indicated earlier that patients in the 20-24 age group are more likely to die, this seems not to have any effect on the employment status in this study.

Additional factors which came out as significantly associated with mortality in the Andara district are functional status, anaemia and having a treatment supporter. The study shows that the haemoglobin levels are very critical in determining the chances of survival for HIV/AIDS patients on ART in the Andara district. For treatment support, the patients who indicated that they had no treatment supporters during their initiation on ART are at a higher risk as compared to those who had treatment supporters. The odds

of death are 1.7366 for those without treatment supporters in comparison to those with treatment supporters. This shows that those without treatment supporters are 74% more likely to die as compare to those with treatment supporters. The percentages of patients who died increased with the clinical stage at which the patient started ART treatment. Out of those who started treatment while in clinical stage 4, more than half (56.1%) died before or in July 2011.

On **functional status**, bedridden patients are fifteen times more likely to die on ART treatment compared to those with working status whilst those in the ambulatory stage are three times more likely to die as compare to those with functional status. The **WHO clinical staging** is significant but stages 2, 3, and 4 are not statistically different in causing death for people on ART in the Andara district compared to stage 1.

This result indicates that if a baseline **CD4 count and haemoglobin** level as categories are included in the model, the risk associated with having no treatment supporter is highlighted. On baseline CD4 count, all the CD4 counts in the categories above 50 shows a more protective effect compared to those patients with a CD4 count below 50. The study indicates that starting ART with a low CD4 count risks chances of survival as compared to starting ART with high CD4 count. This goes hand in hand with the results for the clinical stages where a CD4 count of less than 50 is associated with the AIDS stage of the disease which clinically is diagnosed as stage 4. A CD4 count of more than 200 is associated with clinical stages one and/or two.

The same protective effect was also observed for haemoglobin levels above eight. A unit increase on weight will cause a 3% risk of death during the study period for the Andara district ART patients. This result on weight shows that small increments in the variable will not change the risk levels dramatically.

The study further found that patients with no history of TB disease and those who did not suffer from TB disease before and during the study period respectively, are at a lesser risk of dying as compared to those who suffered from the disease at any interval. The patients without a history of TB were 36% less likely to die and those who did not suffer from TB during the study period were around 33% less likely to die compared to those who had a history of TB and who suffered from the disease respectively before or during the study period. This shows that patients who are co-infected with TB have a higher chance of dying than those who are not co-infected.

It came out that the **ART regimen** started was a protecting factor. The treatment regimen shows that those who are started on ART with **D4T/3TC/NVP** are almost twice less at risk compared to those who are started on **D4T/3TC/EFV** and there is no significant difference on how these treatment regimens impact on the treatment outcome. All the other treatment regimens are more protective compared to **D4T/3TC/EFV**, with **AZT/3TC/NVP** and **TDF/3TC/NVP** being significantly more protective than **D4T/3TC/EFV**. The regimen containing EFV is the recommended regimen in both TB and Hepatitis B co-infections. This is an indication that patients who

were co-infected with TB and Hepatitis B, are likely to be the ones who were started on **TDF/3TC/EFV** and hence the significant association with death. The treatment regimen **AZT/3TC/LPVr** has no odds in this analysis because the sample size in this category was too small for the calculation of the odds ratio given the risk factors included in the model.

The multiple logistic regression model shows that if all the risks factors are put together as that was determined as significantly impacting on mortality using the bivariate analysis shown in Table 4.18, only five risk factors are returned. The five risk factors include sex ($p=0.008$), treatment supporter ($p=0.004$), functional status ($p=0.000$), ART regimen ($p=0.028$) and haemoglobin ($p=0.000$). The bivariate associations indicated that all the risk factors are significant, which implies that individually, each of the risk factors impact on mortality but when they are all put together, only five remain significant, showing that these are the most critical factors in causing mortality to people living with HIV/AIDS on ART in the Andara district.

The protective aspects are deduced from comparing different levels of a risk factor with the reference level, for example the entire ART regimen besides the reference is protective.

5.3 HYPOTHESIS OUTCOME

To direct the study, the null and alternative hypotheses were made. From the findings of this study, it is clear that mortality of patients on ART in the Andara district was associated with factors identified as: sex, availability of treatment supporter, baseline functional status, ART regimen initiated and haemoglobin levels.

The alternative hypothesis (H1) indicating that there is a **difference** in socio-demographic, baseline and medical related factors between patients who died and who survived while on ART by the end of July 2011 in Andara was accepted. This is based on the identified factors which are associated with mortality of patients on ART in the Andara district. It came out clearly that men are more likely to die than female. The findings yielded out that in the Andara district patients starting ART with treatment supporters are more likely to die as compared to their counterparts who start ART without treatment supporters. Additionally, it came out that patients starting ART with bedridden functional status are fifteen times likely to die as compared to patients starting ART with ambulatory functional status. The study further indicate that patients who start recommended ART regimen are not likely to die as compared to patients who were started on ART regimen non recommended as a first line treatment as per Namibian ART guideline. It also evident by the findings of the study that patients starting ART with low Hb are more likely to die as compared to patients starting ART with high Hb. Therefore the null hypothesis (H0) was rejected.

5.4 RECOMMENDATIONS

Different recommendations are derived based on the findings of this study. Given the wide involvement of different stakeholders in the ART program, key stakeholders who could act on these recommendations include Ministry of Health and Social Services and Catholic Health Services.

5. 4. 1 Recommendations to the Ministry of Health and Social Services

- ❖ A guideline on the revision of ART monitoring and evaluation tools should be developed by the National HIV/AIDS Monitoring and Evaluation (M&E) team, to guide the development and frequencies of revision of these tools.
- ❖ Ministry of Health and Social Services should attend to staff shortage to enable the national M&E division to continue with relevant research. This should be considered in the next financial year budget.

5. 4. 2 Recommendations to Catholic Health Services

- ❖ In-service training of health workers involved in ART data collection and data entry should be done on a quarterly basis to ensure that they understand the use of monitoring and evaluation tools. This will help to ensure that all variables are recorded in the registers, patient care booklets and eventually in the database.

- ❖ Quarterly support visits by National M&E Officer and Chief Medical Officer to operational level should be strengthened to provide technical mentorship and guidance in appropriate cases management following the national guideline.
- ❖ Collaboration between ART clinics and general hospital departments could be established to ensure continuity of care of patients receiving ART when being attended to in other departments at the hospital, by means of monthly meetings of the unit managers.
- ❖ Quarterly in-service training for HIV/TB collaborative activities for health workers could be improved to address TB-related morbidity and mortality among HIV patients.
- ❖ Staff to be given quarterly in-service training to capacitate them to provide adequate counseling to patients receiving ART and encourage them to disclose their status to their close relatives or partners. This will help them to reduce self-stigmatization and self-discrimination. Consequently, patients receiving ART will comply and adhere better to their treatment.

5. 4. 3 Recommendation to patients receiving ART

- ❖ Patients receiving ART should be counseled and encouraged to disclose their status to their closed relatives or partners. This will help them to reduce self-stigmatization and self-discrimination. Consequently, patients receiving ART will comply and adhere better to their treatment.

5. 4. 4 Recommendation to Andara Community

- ❖ It could be beneficial if Andara community members participate in community based support groups. This will contribute to the reduction of the stigma and discrimination towards HIV infected people in the community. The Social worker in partnership with the Peace Corps volunteer should lead the process and solicit for the involvement of other community based stakeholders such as youth groups, Total Control for Epidemic (TCE) groups and faith based organisations specifically Catholic AIDS Action (CAA).

5. 4. 5 Recommendation for further research

- ❖ Further research might be conducted to find out the root cause of low male attendance and then develop strategies to attract men.
- ❖ A national study on ART regimen could be done to guide the national technical advisory committee on ART which is responsible for updating the ART guideline on the preferred ART regimen in Namibia based on local scientific evidence.

5.5 LIMITATIONS OF THE STUDY

Limitations are restrictions or problems in a study that may decrease the generalisability of the findings (Burns and Grove, 2005). Following were limitations for this study.

5.5.1. Limitations with regard to generalisability

- ❖ Although the study sample was adequate for the Andara district, (100% for cases and 48% for controls) the population of the study was small. This makes it difficult to generalize the findings of this study to the Namibian population.

5.5.2. Limitations with regard to data sources

- ❖ This study was based on the analysis of secondary routine clinical data. The researcher had no control over how the original data was collected. Hence some data elements such as functional stage and adherence levels could have been interpreted differently by different clinicians.
- ❖ Missing data was a big challenge during this study. Clinicians only enter some data in the patients' health passports but do not update the patients' booklets. This phenomenon is common for longitudinal/follow-up data record keeping. These variables were excluded in the analysis.
- ❖ Some patients' files for cases (population was 100% sampled) could not be found.
- ❖ The data- capturing tools and the software used for ART in Namibia have evolved over time, thus data and variables collected may not have been consistent.

5.5.3. Limitations with regard to data abstraction tool

- ❖ The researcher did not conduct the pilot study. If the pilot study of the data abstraction tool was done, this could have helped the researcher to identify the

variables which were constantly missing such as longitudinal/follow up information which and could have adjusted the tool by removing longitudinal/follow up information section.

5.5.4. Limitations with regard to literature

- ❖ There is a general lack of primary sources on HIV/AIDS and ART; most of the literature reviews on HIV/AIDS and ART were based on studies available on the web and from journals.

5.6 CONCLUDING REMARKS

This study successfully achieved its purpose by exploring, describing and analysing factors associated with mortality of patients on ART in the Andara district. It is obvious from the findings of this study that factors associated with mortality of patients on ART in the Andara district are not different from the trends observed internationally. However, there is room for improving data-capturing and record keeping in the Andara district. The proposed recommendations could contribute to the strengthening of health systems in general and to the ART program in particular, and eventually to improved care of patients receiving ART not only in the Andara district but in all CHS health facilities and the Namibian public health system at large.

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Bedridden (B) 3

Not recorded (NA) 4

8. WHO Clinical stage at start of ART:

Stage I 1

Stage II 2

Stage III 3

Stage IV 4

9. Hemoglobin at the start of ART: _____

SECTION C: FOLLOW UP/LONGITUDINAL DATA

10. Weight at: 6months _____

12 months _____

18 months _____

24 months _____

11. Functional status:

At 6 months: W 1 A 2 B 3 N/A 4

At 12 months: W 1 A 2 B 3 N/A 4

At 18 months: W 1 A 2 B 3 N/A 4

At 24 months: W 1 A 2 B 3 N/A 4

12. WHO treatment stage at 6 months

At 12 months

At 18 months

At 24 months

13. Hemoglobin at 6 months _____

At 12 months _____

At 18 months _____

At 24 months _____

SECTION D: CO-MORBIDITIES AND OPPORTUNISTIC INFECTIONS

14. Suffered from TB before ART: Yes Y

No N

15. Suffered from TB while on ART: Yes Y

No N

16. Opportunistic infection in the first 6 months of treatment

Yes Y

No N

17. If yes to 24, which one:

Zoster 1

Pneumonia 2

Dementia 3

Thrush 4

Fever 5

Cough 6

Difficult breathing 7

| | | |
|-----------------------|--------------------------|----|
| IRIS | <input type="checkbox"/> | 8 |
| Weight loss | <input type="checkbox"/> | 9 |
| Urethral discharge | <input type="checkbox"/> | 10 |
| PID | <input type="checkbox"/> | 11 |
| Genital ulcer disease | <input type="checkbox"/> | 12 |
| Mouth ulcers | <input type="checkbox"/> | 13 |
| Other (Specify)_____ | <input type="checkbox"/> | 14 |

E. MEDICINE RELATED FACTORS

18. ART regimen prescribed at start up:

| | | |
|-----------------|--------------------------|--------|
| D4T/3TC/EFV | <input type="checkbox"/> | 1 |
| D4T/3TC/NVP | <input type="checkbox"/> | 2 |
| AZT/3TC/EFV | <input type="checkbox"/> | 3 |
| AZT/3TC/NVP | <input type="checkbox"/> | 4 |
| Other (Specify) | <input type="checkbox"/> | 5_____ |

19. Side effects experienced in the first 2 months of treatment

Yes Y

No N

20. If side effects experienced, which one?

| | | |
|----------|--------------------------|---|
| Nausea | <input type="checkbox"/> | 1 |
| Diarrhea | <input type="checkbox"/> | 2 |

| | | |
|---|--------------------------|----|
| Fatigue | <input type="checkbox"/> | 3 |
| Headache | <input type="checkbox"/> | 4 |
| Burning/Numb/Tingling | <input type="checkbox"/> | 5 |
| Rash | <input type="checkbox"/> | 6 |
| Anaemia | <input type="checkbox"/> | 7 |
| Abdominal pain | <input type="checkbox"/> | 8 |
| Jaundice | <input type="checkbox"/> | 9 |
| Fat changes | <input type="checkbox"/> | 10 |
| CNS (dizzy, anxiety, nightmare, depression) | <input type="checkbox"/> | 11 |
| Lactic acidosis | <input type="checkbox"/> | 12 |
| Other (Specify) | <input type="checkbox"/> | 13 |

21. Side effects experienced anytime after 2 months

Yes Y

No N

22. If side effects experienced, which one?

| | | |
|-----------------------|--------------------------|---|
| Nausea | <input type="checkbox"/> | 1 |
| Diarrhea | <input type="checkbox"/> | 2 |
| Fatigue | <input type="checkbox"/> | 3 |
| Headache | <input type="checkbox"/> | 4 |
| Burning/Numb/Tingling | <input type="checkbox"/> | 5 |
| Rash | <input type="checkbox"/> | 6 |
| Anaemia | <input type="checkbox"/> | 7 |

| | | |
|---|--------------------------|----|
| Abdominal pain | <input type="checkbox"/> | 8 |
| Jaundice | <input type="checkbox"/> | 9 |
| Fat changes | <input type="checkbox"/> | 10 |
| CNS (dizzy, anxiety, nightmare, depression) | <input type="checkbox"/> | 11 |
| Lactic acidosis | <input type="checkbox"/> | 12 |
| Other (Specify) | <input type="checkbox"/> | 13 |

F. TREATMENT INTERRUPTIONS

23. ART treatment interruptions: Yes Y

No N

24. If treatment was interrupted, what was the cause of interruption?

Stopped by clinician 1

Patient was lost 2

25. If treatment was not stopped by clinician, what was the reason for stopping:

Toxicity/side effects 1

Share with others 2

Forgot 3

Felt better 4

Too ill 5

Stigma, disclosure or privacy issues 6

Medicine stock out—dispensary 7

- Patient lost/ran out of pills 8
- Travel problems 9
- Alcohol 10
- Depression 11
- Lack of food 12
- Other (Specify _____) 13

G. THERAPY CHANGES

26. Therapy substituted within first line: Yes Y
No N

27. Reason for substitution within first line:

- Toxicity/side effects 1
- Pregnancy 2
- Risk of pregnancy 3
- New TB 4
- New drug available 5
- Drug out of stock 6
- Other (Specify) _____ 7

28. Therapy switched to second line: Yes Y
No N

29. Reason for switching to second line:

- Toxicity/side effects 1

- Pregnancy 2
- Risk of pregnancy 3
- New TB 4
- New drug available 5
- Drug out of stock 6
- Clinical treatment failure 7
- Immunological failure 8
- Virological failure 9
- Other (Specify) _____ 10

H. ADHERENCE INFORMATION

30. Adherence level:

- At 6 months: Good 1 Fair 2 Poor 3 Not recorded 4
- At 12 months: Good 1 Fair 2 Poor 3 Not recorded 4
- At 18 months: Good 1 Fair 2 Poor 3 Not recorded 4
- At 24 months: Good 1 Fair 2 Poor 3 Not recorded 4

I. TREATMENT OUTCOMES

31. Treatment outcome by July 2011:

- Alive 1
- Died 2

32. If died, duration on treatment by the time of death _____

33. If died, cause of death:

TB 1

GE 2

Pneumonia 3

Anaemia 4

Meningitis 5

Hepatitis 6

Others (Specify) 7

Unknown 8

34. If died, place of death

Hospital 1

Home 2

ANNEXURE B: APPROVAL OF THE STUDY BY UNAM

UNIVERSITY OF NAMIBIA

Private Bag 13301, 340 Mandume Ndemufayo Avenue, Pionierspark, Windhoek, Namibia



FACULTY OF MEDICAL AND HEALTH SCIENCES

**Letter of permission:
Post graduate students**

**To: Post graduate students
From: Dr K. Hofnie-//Hoëbes**

Date: 7 June 2011

Dear Student: Ms Emmy-Elsie Hango (Student number: 9115730)

The post graduate studies committee has approved your research proposal.

Factors associated with mortality of patients on Antiretroviral therapy at Andara District, Kavango Region

You may now proceed with your study and data collection.

It may be required that you need to apply for additional permission to utilize your target population. If so, please submit this letter to the relevant organizations involved. It is stressed that you should not proceed with data collection and fieldwork before you have received this letter and got permission from the other institutions to conduct the study. It may also be expected that these organizations may require additional information from you.


Please contact your supervisors on a regular basis.

[Handwritten signature]
Dr K. Hofnie-//Hoëbes

UNIVERSITY OF NAMIBIA
Faculty of Medical and Health Sciences
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WINDHOEK, NAMIBIA
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**ANNEXURE C: APPROVAL LETTER BY MINISTRY OF HEALTH AND
SOCIAL SERVICES**

9 - 0/0001



REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

| | | |
|--|---|--|
| Private Bag 13198 Windhoek Namibia | Ministerial Building Harvey Street Windhoek | Tel: (061) 2032510 Fax: (061) 227786 E-mail: eshaama@mhss.gov.na |
| Enquiries: Ms. E.N. Shaama | Ref.: 17/3/3 | Date: 08 July 2011 |

OFFICE OF THE PERMANENT SECRETARY

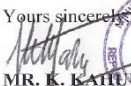

Ms. Emmy E. Hango
P.O. Box 1714
Windhoek

Dear Ms. Hango

Re: Factors associated with mortality of patients on antiretroviral therapy at Andara District, Kavango region

1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
 - 3.1 The data to be collected must only be used for completion of your MPH Degree;
 - 3.2 No other data should be collected other than the data stated in the proposal;
 - 3.3 A quarterly report to be submitted to the Ministry's Research Unit;
 - 3.4 Preliminary findings to be submitted upon completion of study;
 - 3.5 Final report to be submitted upon completion of the study;
 - 3.6 Separate permission should be sought from the Ministry for the publication of the findings.

Yours sincerely,

MR. K. KATHURE
PERMANENT SECRETARY

"Health for All"

ANNEXURE D: PERMISSION LETTER BY CATHOLIC HEALTH SERVICES



CATHOLIC HEALTH SERVICES

17 Jan Jonker Road, PO Box 11525, Windhoek, Namibia
Tel: (061) 224798/225265/259554/259847. Fax: (061) 248126. e-mail: health@ncbc.com.na

ASSOCIATION INCORPORATED UNDER SECTION 21

Enquiry: Sister Angela Bock

Date: 24-10-2011

OFFICE OF THE DIRECTOR OF HEALTH

SHALOM!

DEAR EMMY,

RE: PERMISSION TO CONDUCT A STUDY IN ANDARA HEALTH DISTRICT


AT THIS POINT IN TIME, WE FIND NO OBJECTIONS WITH YOUR PROPOSED STUDY. THE STUDY ENTITLED "FACTORS ASSOCIATED WITH MORTALITY OF PATIENTS ON ANTIRETROVIRAL THERAPY AT ANDARA DISTRICT, KAVANGO REGION".

OBJECTIVES OF THE STUDY BEING:

- TO EXPLORE AND ANALYZE FACTORS ASSOCIATED WITH MORTALITY IN PATIENTS ON ART IN THE ANDARA DISTRICT
- TO COMPARE FACTORS ASSOCIATED WITH EITHER THE DEATH OR SURVIVAL OF THOSE PATIENTS.

WE WISH YOU ALL THE BEST WITH YOUR STUDY.

SINCERELY YOURS,


SISTER ANGELA BOCK, O.S.B.
DIRECTOR OF HEALTH
CATHOLIC HEALTH SERVICES

Directors: Archbishop L. Nashenda, Bishop J. Shikongo, Bishop P. Pöllitzer, Sister A. Donadilla,
Sister S. Endjala, Sister M. Shetunjenga, Sister Dr. I. Iita, Sister A. Mattkarathundiyl

District Hospitals: Andara, Nyangana, Oshikuku, Rehoboth
Health Centres: Aroab, Bunya, Okatana, Sambyu, Tondoro
Clinics: Anamulenge, Ilyateko, Mayara, Mbambi, Old Bagani, Oshitutuma, Shinungwe