

**FACTORS THAT INFLUENCE NON-ADHERENCE TO ANTIRETROVIRAL
THERAPY AMONG HIV AND AIDS PATIENTS IN CENTRAL PROVINCE,
KENYA**

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DECLARATION

This thesis is my original work and has not been presented for a degree or other awards in any other University.

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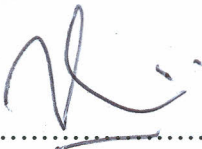
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DEDICATION

To my late loving mother, Miss Margaret Nyambura Wanjohi who taught me the value of discipline and hard work.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral Therapy
ARV	Anti- retroviral
ARVCER	Antiretroviral Community Education and Referral
CCC	Comprehensive Care Clinic
DAART	Directly Administered Antiretroviral Therapy
FDC	Fixed Dose Combination
FGD	Focus Group Discussion
HAART	Highly Active Anti-retroviral Therapy
HIV	Human Immuno Deficiency Virus
KAIS	Kenya AIDS Indicator Survey
KDHS	Kenya Demographic Health Survey
MCTC	Mother to Child Transmission
NGO	Non-Governmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Analogue Reverse Transcriptase Inhibitor
PEPFAR	President's Emergency Plan Aids Relief
PGH	Provincial General Hospital
PI	Protease Inhibitor
PLWHA	People Living With HIV and AIDS
PMTCT	Prevention of Mother to Child Transmission
TB	Tuberculosis
UNAIDS	United Nations Agency for International Development
USA	United States of America
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

DEFINITION OF TERMS

Adherence	Adherence to ART is taking all ARV pills in the correctly prescribed doses at the right time and in the right way observing any dietary restriction.
Age	this refers to the number of years that an individual has lived since date of birth.
AIDS	this refers to a progressive immune deficiency caused by infection of CD4+ T cells with the human immunodeficiency virus (HIV).
CD4+	this refers to an antigen maker of helper/inducer T cell that recognizes antigens bound in class II MHC protein.
Co-treatment	treatment of two or more infections simultaneously.
Incidence	the incidence of a disease is defined as the number of new cases that occur during a specified period of time in a population at risk for developing the disease.
Optimal adherence	proportion of those who take their medication $\geq 95\%$ of the time
Sub-optimal adherence	proportion of those who take their medication $<95\%$ of the time
Prevalence	this refers to the number of affected persons present in the population at a specific time divided by the number of person in the population at that time.
Undetectable viral load	when the virus is not detected in the blood after a laboratory test.
Viral load	levels of virus found in the blood per 10 milliliters (mls).

ABSTRACT

The main objective was to determine factors influencing non-adherence to Anti-retroviral therapy among HIV and AIDS patients. This cross sectional study was carried out at PGH Nyeri, Karatina District Hospital Nyeri and Thika District Hospital in Central Province Kenya. Data was collected using structured questionnaire with open and closed type questions where a total of 300 participants were interviewed. Three focus group discussions with 8 members each were conducted. Key informant interviews for health care providers were conducted and a checklist material was used to assess how well health facilities were equipped. Data was presented using charts, graphs and frequency tables. Data was analyzed using SPSS software version 11.50. Results show that the prevalence of non-adherence to ART was 26%. Factors that were significantly associated with non-adherence were age ($\chi^2 = 12.078, df = 5, p = 0.034$), household size ($\chi^2 = 121, df = 9, p = 0.0001$), occupation ($\chi^2 = 87.103, df = 7, p = 0.0001$), lack of food ($\chi^2 = 13.932, df = 2, p = 0.001$), level of education ($\chi^2 = 8.38, df = 3, p = 0.039$), co-treatment of HIV and other infections ($\chi^2 = 12.193, df = 4, p = 0.016$), ability to follow ART ($\chi^2 = 5.059, df = 1, p = 0.024$) and stigma ($\chi^2 = 10.526, df = 1, p = 0.001$). Some respondents believed in spiritual healing and therefore they abandoned ART. From FGDs it was found that transport cost and user fee for other medical services influenced non-adherence to ART. Other respondents preferred traditional medicine and this affected adherence to ART. Lack of appropriate paediatric formulations, unpalatability of some ARV drugs and dependence on caregivers influenced paediatric ART non-adherence. Facilities where the study was carried out were dispensing twice daily ARV regimen to their clients. Health care providers were committed to their work. Patients appreciated the care they received and generally felt better on therapy. It was concluded that the prevalence of non-adherence of 26 % (that is adherence level of 74%), was sub-optimal (less than 95%) but comparable to those in other developing countries. Based on these findings, to enhance ART adherence the study recommends to the government and other stakeholders to develop strategies to ensure food security in households with people living with HIV and AIDS. Intensify health education campaigns against stigma and promote family and community support for people living with HIV and AIDS. Develop adequate and appropriate paediatric ARV drugs formulations that are palatable. Ensure that all public health facilities have a functioning laboratory, adequate personnel and stock of ARV drugs.

CHAPTER ONE: INTRODUCTION

1.1 Background

The impact of HIV worldwide will be felt for decades to come. Promising developments have been seen in recent years in global efforts to address the AIDS epidemic, including increased access to effective treatment and prevention programmes (UNAIDS/WHO, 2006). However, the number of people living with HIV continues to grow, as does the number of deaths due to AIDS. Approximately 39.5 million people worldwide were living with HIV in 2006 (UNAIDS/WHO 2006). In 2007, new data showed global HIV-prevalence and the number of new infection had fallen, in part as a result of the impact of HIV programmes (WHO, 2007). In 2007, 33.2 million people were estimated to be living with HIV, 2.5 million people became newly infected and 2.1 million people died of AIDS worldwide. In low and middle income countries 3 million people were receiving ARV treatment by end of 2007 (UNAIDS/WHO, 2007, 2008).

Sub-Saharan Africa remained the most affected region in the global AIDS epidemic (WHO, 2005, 2006, 2007). More than two thirds (68%) of all people who are HIV-positive lived in Sub-Saharan Africa where more than three quarters (76%) of all AIDS deaths in 2007 occurred (UNAIDS/WHO, 2007). It was estimated that 1.7 million people were newly infected with HIV in 2007, bringing to 22.5 million the total number of people living with the virus in Sub-Saharan Africa (WHO, 2007). About 2.1 million people in Sub-Saharan Africa were receiving ART by end of 2007 (UNAIDS/WHO, 2008). Unlike other regions the majority of people living with HIV in Sub-Saharan

Africa (61%) were women (UNAIDS/WHO, 2007). Results from Kenya AIDS Indicator Survey (KAIS) indicate that 7.4% of Kenyan adults age 15-64 are infected with HIV.

According to the survey more than 1.4 million people in Kenya were living with HIV. Regional variation was significant: prevalence remains high in Nyanza at 15.3%, more than double the national prevalence estimate (NASCOP, MoH, Kenya, 2008, KAIS, 2007). Other provinces with rates similar to or higher than the national level are Nairobi (9%), Coast (7.9%), and Rift Valley (7.0%). Prevalence in Eastern is 4.7% and in Central, 3.8% of the adult population is infected. North Eastern province has the lowest adult HIV prevalence at 1% (NASCOP, MoH, Kenya, 2008, KAIS, 2007). The current data yielded an estimated national adult HIV prevalence of 5.1% in 2006, a reduction of 1.6% from 2003 (National AIDS Control Council Kenya, 2007). It indicated that national prevalence peaked at around 9% in 1997/1998. The current estimate of urban prevalence is about 8.3% and rural prevalence is 4.0% (NACC Kenya, 2007). The decline in prevalence since the late 1990s did not mean that the problem of HIV/AIDS was over. The number of people infected declined when the number of AIDS deaths exceeded the number of new infections (NACC Kenya, 2007). New infections occurred every day, especially among young people. In 2006 there were about 55,000 new adult infections (NACC Kenya, 2007).

The annual number of adult AIDS deaths reached a peak of about 120,000 in 2003. It would have stayed at roughly that level for the next three years but the increasing number of people receiving anti-retroviral therapy (ART) had reduced the annual number of

AIDS deaths to about 85,000 in 2006 (NACC Kenya, 2007). This implied that ART programs had averted about 57,000 deaths in 2006 (NACC Kenya, 2007). Levels of adherence below 95% have been associated with poor virological and immunological response (Paterson *et al.*, 2000; Orell *et al.*, 2003).

Adherence concerns have been one reason expressed by opponents of antiretroviral therapy in developing countries or resource poor settings (Stevens *et al.*, 2004; Gill *et al.*, 2005). In Kenya, the national HIV estimates for the year 2006 were: males HIV+ were 320, 000, females 614,000; people HIV+ in urban areas were 400, 000, in rural areas 534,000, adults 50 and above 55,000 and children 0-14 years old 102,000 (NACC Kenya, 2007). These figures illustrated the magnitude of the task to provide prevention, care and treatment, and support services for all who needed them.

These estimates show that: 1.5 million pregnant women needed counseling and testing each year to determine their HIV status, 68,000 needed treatment to prevent mother-to-child transmission of HIV, 23,000 children needed ART and 200,000 needed cotrimoxazole prophylaxis, 430,000 adults needed ART, 2.4 million orphans needed care and support from their extended families and communities (National AIDS Control Council Kenya, 2007). This strongly indicated the need to come up with strategies to maximize long-term ART adherence to ensure success as Kenya scale up ART programmes countrywide.

1.2 Statement of the Problem

To achieve effective treatment and realize the benefits of treatment, strict adherence to treatment instructions are very critical. Sticking to the treatment instructions for a long-term illness poses a great challenge to the patients (WHO, 2004). Just having medicine available cannot solve the HIV and AIDS problems. Worldwide, regardless of the illness or treatment many people do not take their medications correctly. A significant proportion of all hospital admissions are due to drug non-adherence. In a survey in U.S.A by Stone (2000), 21 % of AIDS patients who were on ARV drugs had missed a dose in 24 hours while 34 % had skipped a dose in 3 days.

Kenya has made tremendous strides in scaling up ART. However, anecdotal evidence is suggesting certain problems that contribute to defaulter rate, for instance it is said that some men use their partners ARVs irrespective of their status. A few patients may sell all or part of their ARVs for profit (NACC Kenya, 2008). There is a possibility that defaulter rate is high among the youth and children under care of elderly. In Kenya adherence is high but still sub optimal (UNAIDS/WHO 2006, NACC Kenya, 2007).

A study in Mombasa Kenya by Sarna *et al.* (2005) showed that ART adherence rate among patients under directly administered antiretroviral therapy (DAART) program was greater than 95% compared to sub optimal rates (< 95%) for patients who were not under DAART program. The Provincial General Hospital, District Hospitals, Sub-District Hospitals, Health Centres and Mission Hospitals in Central Province Kenya are dispensing ARV drugs (Republic of Kenya, MoH, 2005). However, DAART program is

not being implemented in other parts of country including Central Province. Therefore this study aimed at determining factors that influence non-adherence to ART among AIDS patients.

1.3 Study Justification

Despite patients' understanding the consequences of non-adherence to medication, adherence rates were sub optimal (WHO, 2004, Sharon *et al.*, 2006). Long-term adherence interventions are needed for durable effect, particularly in chronic diseases such as HIV (Sharon *et al.*, 2006). Antiretroviral therapy lowers viral load only when treatment regimen is fully adhered to. Human immuno deficiency virus (HIV) poses a unique challenge due to its rapid replication and mutation rates hence very high levels of adherence (greater than 95%) are required to achieve long-term suppression of viral load (Paterson *et al.*, 2000).

While it is known that patients in Lusaka Zambia used to skip treatment doses due to lack of food (Chishimba and Zulu, 2004) such information is lacking in the Kenyan population. This study was conducted at PGH Nyeri, Karatina District Hospital and Thika district Hospital where interventions such as Directly Administered ART have not been implemented. There was no documented information about ART adherence in Central Province. Nyeri district exhibited huge variations in poverty across divisions or locations. Nyeri town constituency is the poorest with a poverty incidence of 44%. However factors underlying such differences were not explored. Juja constituency in Thika district is the poorest contributing 7.5% to about one fifth (21%) of the poor in Central province

(Republic of Kenya, KNBS, MoP&Nat.Dev., KIHBS, 2005/2006). Therefore, this study provided information on prevalence and factors that influenced non-adherence to ART. The information will be useful to other scholars doing studies in this area and for planning interventions and effective strategies for maximizing long-term adherence to ART for successful treatment of HIV and AIDS.

1. 4 Research Questions

- i) What proportion of AIDS patients adhere to ART instructions?
- ii) Which socio-demographic and socio-economic factors influence non –adherence to ART among the AIDS patients?
- iii) Which social-cultural factors influence non-adherence to ART among AIDS patients?
- iv) How does treatment regimen and treatment of co-infections affect adherence to ART among the AIDS patients?
- v) How does health care facilities and health care providers influence adherence to ART among AIDS patients?

1. 5 Study Hypothesis

There are no factors that influence non-adherence to ART among AIDS patients.

1. 6 Objectives

1. 6 .1 Broad Objective

To determine factors that influence non-adherence to ART among AIDS patients.

1.6.2 Specific Objectives

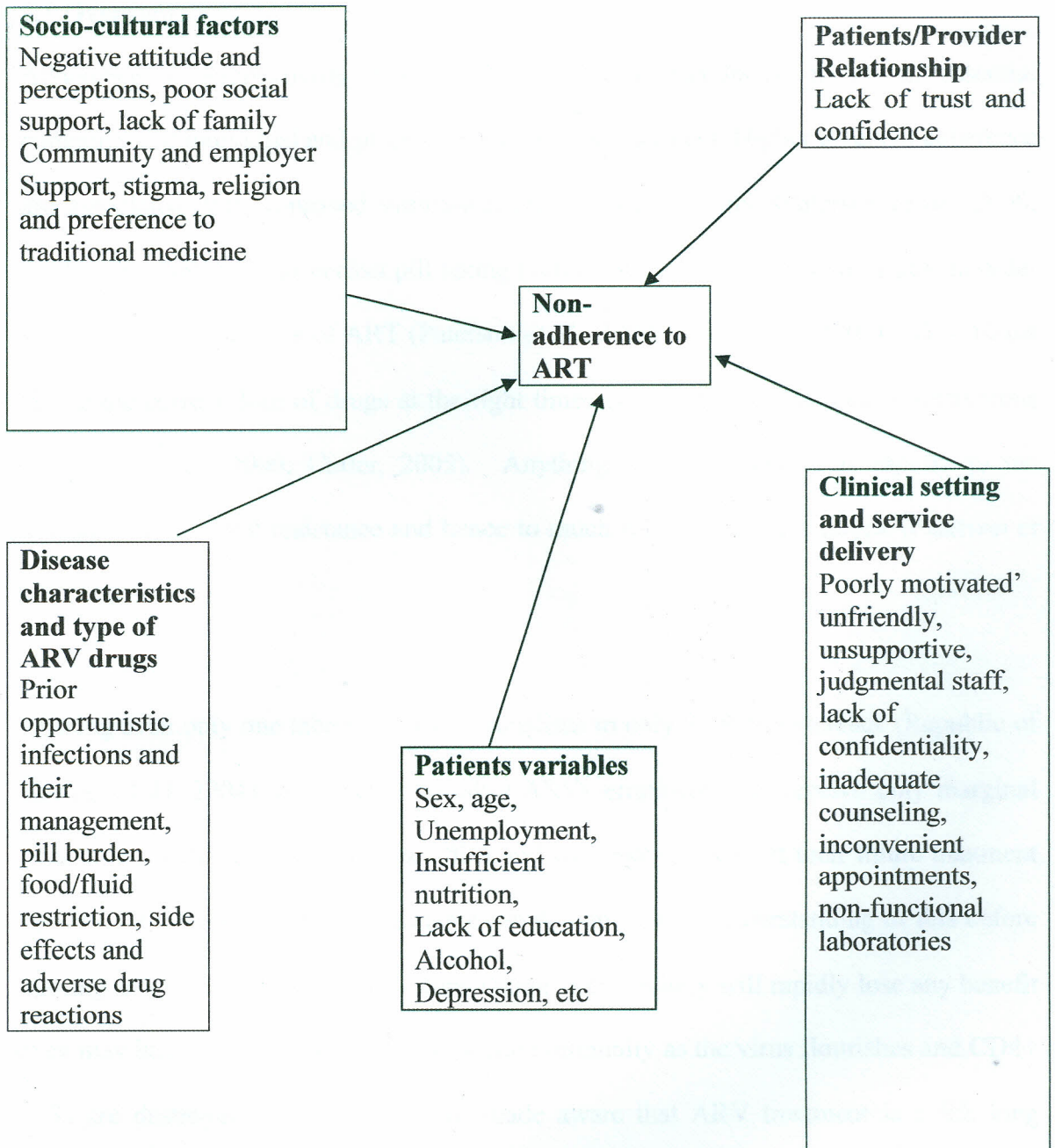
- i) To determine the proportion of AIDS patients that adheres to ART.
- ii) To identify socio-demographic and socio-economic factors that hinder adherence to ART among AIDS patients.
- iii) To determine social-cultural factors that influence adherence to ART among AIDS patients
- iv) To determine whether type of ARV drugs and treatment of co-infections affect adherence to ART among AIDS patients.
- v) To assess how health care facilities and health care providers influence adherence to ART among AIDS patients.

1.7 Limitation of the study

During data collection there was no reliable data for pill count that was kept at PGH Nyeri, Karatina and Thika District Hospitals that would have helped to calculate adherence level. This is a problem because proper and consistent pill counting is one of the objective methods of monitoring patient's adherence to ART in settings where electronic drug monitoring is not available like Kenya.

1.8 Conceptual Framework

Problem Analysis Diagram of Possible Factors Contributing to Non- Adherence to ART



Adopted from Chesney *et al.* (2000), Kgatlwane *et al.* (2005), Nakiyemba *et al.* (2005)

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview

Adherence to antiretroviral therapy (ART) is well recognized to be an essential component of individual and programmatic treatment success. Higher levels of adherence are associated with improved virological and clinical outcome (Paterson *et al.*, 2000; Orell *et al.*, 2003). Near perfect pill taking (values exceeding 95%) are desirable in order to maximize the benefits of ART (Paterson *et al.*, 2000; Gross *et al.*, 2001). This means taking the correct dose of drugs at the right times and observing any dietary restrictions (Paterson *et al.*, 2000; Carter, 2005). Anything less than this leads rapidly to the development of viral resistance and hence to much earlier treatment failure (Paterson *et al.*, 2000).

Missing even only one tablet in a week translates to only 92.8 % adherence (Republic of Kenya, MoH, 2004). A person who takes ARVs erratically will receive only marginal benefit, but will suffer similar side effect and will potentially limit their future treatment options. It is important that all patients can demonstrate an understanding of this before starting treatment. A patient who stops taking ARV entirely will rapidly lose any benefit they may have received in terms of increased immunity as the virus flourishes and CD4+ cells are destroyed. Patients must be made aware that ARV treatment is a life long treatment. Educating a patient effectively and assessing their understanding can be time consuming and labour intensive, but it is never time wasted. Simply giving a prescription at the first visit without sufficient adherence counseling is clinically negligent, but

unfortunately this is a common practice (Republic of Kenya, MoH, 2004). Antiretroviral therapy providers that do not seriously address the complex issue of adherence will fail in their objective of helping their patient. At the public level this may cause the development of multi drug resistant strains within the population they serve and which would have dire public health implications. Adherence is therefore central to the success of ART (Republic of Kenya, MoH, 2005).

Non-adherence to ART might involve a person missing one dose of a given drug, missing a dose of all the three drugs, missing multiple doses, not observing the time intervals, not observing the dietary restrictions, not taking the correct dose of any drug (KITSO Manual, 2000; Cater, 2005). Non-adherence can lead to poor clinical, immunological and virological outcomes. At an individual level the consequences of non-adherence include: incomplete viral suppression, continued destruction of the immune system and decrease of CD4+ cell count, progression of disease, emergence of resistant viral strains and limited future therapeutic option and higher cost for individual treatment which translates to higher program cost (Republic of Kenya, MoH, 2005). Proper education of patients before the initiation of and during ART is important for the success of adherence. Strategies such as education should cover basic information about HIV and its manifestations, the benefits and side effects of ARV medications, how the medications should be taken and the importance of not missing any doses. Adherence assessment should be combined with adherence counseling at each visit.

2.2 Highly Active –Antiretroviral Therapy (HAART)

Currently most effort is focused on reducing immediate risk by bringing about behavior change. But behavior change has been frustratingly difficult to achieve and sustain because the risks related to HIV and AIDS exposure are not always easy to control. In the past, it has been argued that in resource poor settings, either prevention or treatment must be prioritized. Prevention programmes have been funded at the expense of treatment programmes simply because prevention programmes are generally cheaper (UNAIDS/WHO, 2004). It is now clear that prevention, care, support and treatment of people affected by HIV and AIDS are mutually reinforcing elements of an effective response (Farmer *et al.*, 2001; Piot and Coll-Seck, 2001, UNAIDS/WHO, 2004).

Incorporating AIDS treatment into the established preventive measures only serves to fortify them. It must be acknowledged that ART though important, is only part of comprehensive treatment programme for HIV disease that includes voluntary counseling & testing (VCT), prevention and treatment of opportunistic infections and proper diet. They are essential for the success of therapy because they prevent re-infection and reduce the transmission between discordant partners. This is because, even with ART, low levels of viral replication* continue at concentration of viral load that is below the limits of detection (undetectable viral load). While the cure for HIV infection does seem far at the present moment, the enormous potential of these drugs to delay disease progression is undoubted.

Treatment and prognosis of HIV and AIDS improved dramatically between 1992 and 1995 with the development of protease inhibitors in 1992 and the subsequent introduction of highly active anti-retro-viral therapy (HAART). It is now agreed that optimal therapy for HIV and AIDS involves the combination of three or more anti-retroviral drugs (Sanford *et al.*, 1997; Grierson *et al.*, 2000). Anti-retro-viral drugs are broadly classified into the following groups:

- i) Nucleoside analogue reverse transcriptase inhibitors (NRTI).
- ii) Non-nucleoside reverse transcriptase inhibitors (NNRTI).
- iii) Protease Inhibitors (PIs) (Castro, 2005; WHO, 2005)

There is renewed sense of optimism that HIV could be transformed from a rapidly fatal disease to a manageable chronic illness. However, even among those on ARV treatment, drug side effects, co-morbidity, complexity of regimens, life-long pill taking and the quality of life that results from ART use may significantly limit the outcome of ART. Although currently available, ARV drugs are far from ideal, on-going pharmacological research may in future produce drugs that are less costly, easier to administer and fewer adverse effects and or resistance. Access to ARV drugs can motivate individuals to be tested for HIV and help to break the barriers of isolation and despair (Piot and Coll-Seck, 2001). Over the last few years the issue of making AIDS drugs more readily available to people in poor countries has received more attention from treatment advocates, policy makers, heads of states and the media. Faced with growing pressure for expanded access and the threat of competition from generic manufacturers several pharmaceutical companies have lowered the price of their brands of Anti-retroviral drugs.

2.3 Goals of Antiretroviral Therapy

From the point of view of patients, the primary goal of therapy is improvement of quality of life consequent to the reduction in morbidity, a result of treatment induced immune recovery. The goals of therapy can therefore be summarized as follows: improvement of the patient's quality of life, reduction of HIV related morbidity and mortality, restoration and or preservation of immunologic function and maximal and durable suppression of the viral replication (Republic of Kenya, MoH, 2005).

Patients' education to ensure long term adherence to treatment associated with treatment success should cover (i) why lifelong continuous treatment is necessary and the expected benefits of treatment (ii) adherence and its relation to treatment outcome (iii) drug resistance (iv) necessity for regular follow up (v) need to avoid non prescribed drugs including herbal medication whose interaction with ARV drugs are unidentified or undesirable (Republic of Kenya, MoH, 2005). Health providers should be able to: assess and prepare patients to ensure long-term adherence to treatment; use drugs rationally allowing for future treatment options; ensure regular and adequate monitoring of patients; manage complications of treatment and be able to change or discontinue treatment (Republic of Kenya, MoH, 2005).

2.4 Clinical benefits and risks of early and delayed treatment

Clinical benefits of early treatment include: control of viral replication easier to achieve; delay or prevention of immune system compromise; lower risk of resistance with complete viral suppression; possible decreased risk of HIV transmission (Republic of

Kenya, MoH, 2005). Positive impact of ARV treatment on health was demonstrated even in patients with advanced stages of HIV infection (Hung *et al.*, 2002). Antiretroviral therapy (ART) adherence is a strong predictor of biologic (virologic and immunologic) and clinical outcomes in HIV, including quality of life, HIV progression, hospitalization and death (Sharon *et al.*, 2006). The risks of early treatment include: greater cumulative drug related adverse effects; earlier development of drug resistance if viral suppression is sub optimal; limitation of future antiretroviral treatment options (Republic of Kenya, MoH, 2005).

Clinical benefits of delayed treatment include: avoidance of treatment related negative effects on quality of life and drug related toxicities; preservation of future treatment options; delay in development drug resistance associated with treatment failure; more time for the development of more potent, less toxic, and better studied combinations of antiretroviral drugs (Republic of Kenya, MoH, 2005). The risks of delayed treatment include: possible risk of irreversible immune system damage; the increased possibility of progression to AIDS; the increased risk of HIV transmission to others during a longer untreated period (Republic of Kenya, MoH, 2005)

2.5 Role of Counseling

It is rare that a physician is able to address all the concerns of a patient during the standard clinic visits. Optimal care should be capable of meeting both the medical and psychological needs of a patient. However; in reality studies have shown that care that meets all medical needs may fail to meet a clients emotional or social needs and vice

versa (Aldana *et al.*, 2001). It is therefore important that adequate time is set aside for counseling so that appropriate and informed decision on therapy and its implications are made by the patient (WHO, 2000).

All the positive messages initiated during the pre and post-test counseling should be reinforced during counseling for ART. The issues that can be discussed during counseling include financial considerations, drug information, emotional support, and disclosure and drug adherence. Counselors should also help patients to make decisions on prevention of transmission especially among discordant partners, decision about getting pregnant or entering marriage and decision about appropriate sexual behavior. All these are important in the overall outcome of treatment since they outline the expectations of both the caregivers and the patients.

2.6 Choice of Regimen

Maximal suppression of viral replication occurs only when combinations of anti-retroviral agents are used. No currently available agent is sufficiently potent to provide sustained suppression. Monotherapy yields incomplete viral suppression for a very limited duration of time and is only indicated for the prevention of mother to child transmission (WHO, 2000). Except in pregnant women where mono-therapy has been found to reduce MTCT by up to 70% (WHO, 1997), studies have shown that the use of only one drug results in the rapid development of drug resistance and treatment failure (WHO, 2004). Using two drugs provides a more durable effect but the most effective combination involves the use of at least three drugs (Grierson *et al.*, 2000). Combination

therapies that include protease inhibitors are associated with more significant and sustained reduction in viral load (Volberding, 1997). However Protease Inhibitors (PIs) have had several problems related to frequency of dosing, the intake of large number of drugs, food restrictions and multiple drug interaction that ultimately affect their tolerability.

2. 7 HIV and AIDS Treatment in World

One who is infected with HIV is likely to become sick with AIDS within 1-10 years, but if treated with Antiretroviral (ARV) medication their life can be prolonged (UNAIDS/WHO, 2006, 2007). As of December 2006, an estimated 7.1 million people living with HIV in low and middle-income countries urgently needed ARV medication. Of these only 2.015 million –barely one in four–were accessing the drugs (UNAIDS/WHO, 2006). Though shockingly small, this figure represents a great advance since 2003, when only 400,000 were receiving treatment (UNAIDS/WHO, 2006, 2007).

Never before in the history of the epidemic has so much money been available to finance treatment and care for people with HIV, and never before have life-saving antiretroviral medicines been so cheaply and plentifully available. However, everyday nearly 6000, people globally are dying from a disease which can be treated, but which all too often isn't (UNAIDS/WHO, 2006, 2007). “All by 2010” describes the goal of universal access to ARV treatment by the year 2010 meaning putting many more people on treatment than the 7.1 million currently in need (UNAIDS/WHO, 2006,2007). Since 1996, Brazil treatment effort has helped the country to prevent more than 60, 000 new cases of AIDS

and about 100,000 HIV related death over seven years representing about 50 % mortality (WHO, 2005). In 1997, an estimated 35,900 people were receiving treatment in Brazil. This increased to 55,600 in 1998; 105,000 in 2001; 140,000 in June 2004 and 183,000 in December 2005(WHO, 2006). At the end of 2006, around 180,000 were getting drugs, out of an estimated 210,000 in need (UNAIDS/WHO, 2006, 2007). Brazil is a particular success story and has the most advanced national HAART treatment programme in the developing world according to a 3 by 5 initiative statement. It has nation wide access to antiretroviral drugs (UNAIDS/WHO, 2006).

A study on antiretroviral therapy adherence in Brazil revealed that adherence prevalence was 75% (95% confidence interval 73.08-76.95). The factors that influenced non-adherence were: missed appointments, more complex regimes, a large number of pills (pills burden) and level of education (Nemes *et al.*, 2004).

2. 8 HIV and AIDS treatment Africa

At the end of 2005 only 1.3 million people in low and middle-income countries were receiving ARV medication. This was just 40% of the target. Across sub-Saharan Africa 1.34 million (28% of those in need) were on ARV treatment out of an estimated 4.7 million who needed it (UNAIDS/WHO, 2006, 2007).

There were estimated 270,000 people living with HIV in Botswana at the end of 2005. This gave Botswana a prevalence rate of 24.1% the second highest in the world. At the end of 2006 around 84,000 people were receiving ARV treatment, which was more than

95% of those in need. Botswana exceeded not only its 3 by 5 target of 30,000 by the end of 2005, but also the government's own target of 55,000 (UNAIDS/WHO, 2006,2007). A study in Botswana by Kgatlwane *et al.* (2005) showed ART adherence rate of 77% (95% confidence interval 73.1-80.89), which is comparable to that of developed countries.

At the end of 2005, there were one million people living with HIV in Uganda, according to UNAIDS data. The country's adult HIV prevalence fell from around 15% in the early 1990s to around 6.7% at the end of 2005 (UNAIDS/WHO, 2005)

Uganda ran one of the first pilot ARV programmes in Africa. It began in 1998 and aimed to see how an ARV programme could be set up and run in resource poor country. The 399 patients involved were responsible for paying for their treatment and bought their drugs at negotiated reduced prices. At the end of the two-year pilot, patients reported good adherence to treatment and virological and immunological response to ART were similar to those found in western countries (Byakika *et al.*, 2005; UNAIDS/WHO, 2005). Uganda exceeded a government target of 60,000 treatments by the end of 2005. The number had risen to 96,000 by the end of 2006, which was around 41% of those in need (UNAIDS/WHO, 2006).

Malawi has an adult HIV prevalence rate of 14.1%, which translates to 940,000 people infected. As of June 2004, only 3,760 people were reported to be receiving the drugs (UNAIDS/WHO, 2004). The government later set a target of 50,000 people on treatment by the end of 2005, which was less than the 3 by 5 goal of 65,000. Having missed both of these targets (only reaching 33,000) by the end of 2005, Malawi set another goal of

80,000 by June 2006. In the event it took another six months to reach 81,000 people on treatment, which was 41% those in need (UNAIDS/WHO, 2006)

The case for access of ARVs in South Africa has been the most high profile of all African countries. Data from the UNAIDS/WHO May 2006 report indicated that 5.5 million people were living with HIV at the end of 2005, which gives an adult prevalence rate of 18.8%. This means that South Africa has a high HIV prevalence than any other country in the world. In December 2004, the WHO estimated that 42,000-67,000 South Africans were receiving treatment. This figure rose to 178,000-235,000 by the end of 2005, 21% of the 983,000 people in need. This means that, despite being Africa's richest country, South Africa fell along way short of its 3 by 5 target. At the end of 2006 the number receiving treatment had grown to 325,000 or 33% of those in need, which is slightly above the average for Sub-Saharan Africa (UNAIDS/WHO, 2006, 2007)

2.9 Measurement of ART Adherence

Researchers who have tried to measure ART adherence have realized that there is no gold standard by which adherence can be quantified (Farmer, 1999). The many methods employed by different studies include: pill counting, electronic drug monitoring (EDM), pharmacy refill records, biochemical markers and other self reporting techniques such as visual analogue and recall method.

The relative accuracy of adherence measures ranks from physician assessment and self – assessment being the least accurate to pill counting being intermediate and EDM being

the most accurate (Gill *et al.*, 2005). Electronic drug monitoring more accurately predicts undetectable viral load (UDVL) than self-report or pill count. Its main advantages are that it provides data on the timing of doses taken and permits monitoring over long periods. Since adherence can be known precisely, the link between adherence levels and UDVL can be established with a high degree of confidence. Arsten *et al.* (2001) noted that patients whose EDM data indicated high adherence (above 90%) were far more likely to achieve UDVL than patients self-reporting the same level of adherence. Other studies had similar results on the relationship between UDVL and EDM-rated adherence.

Paterson *et al.* (2000) observed UDVL in 80% of those with above 95% adherence, while in a trial conducted by Kirkland *et al.* (2002) mean adherence was 94% with 85% of the patients achieving UDVL. However, no single measure is appropriate for all settings or outcomes. It has been found that the use of more than one measure of adherence allows the strength of one method to compensate for the weakness of the other and to more accurately capture the information needed to determine adherence levels (Vitolins *et al.*, 2000). Non-Adherence to ART can be influenced by various factors as follows

2.9.1 Patient factors

Patient factors include fear of disclosure and wanting to avoid taking medication in public places, feeling depressed, hopeless, or overwhelmed, having a concurrent addiction, forgetting to take medication at the specified time (Strace *et al.*, 2002; Castro, 2005; Mills *et al.*, 2006). Other barriers include being suspicious of treatment/medical establishment, wanting to be free of medication or preferring a natural approach (due to

treatment fatigue); feeling that treatment is a reminder of HIV status, wanting to be in control, not understanding treatment instructions, still having doubt or not being able to accept HIV status and lack of self worth (Castro, 2005; Nakiyemba *et al.*, 2005; Mills *et al.*, 2006). Low level of education may impact negatively on some patient's ability to adhere, while high level of education has a positive impact (Catz *et al.*, 1999; Rodriguez *et al.*, 2000; Abah *et al.*, 2004; Stone, 2004; Nakiyemba *et al.*, 2005). Belief about medication; there were eight reported barriers pertaining to beliefs/perceptions about medications: some common barriers in this category included: side effects (either real or anticipated), complicated regimens, and the taste, size, dosing frequency, and /or pill count. In other studies when individuals prescribed HAART felt healthy, adherence was often negatively affected (Castro, 2005; Mills *et al.*, 2006). Other barriers include doubting the efficacy of HAART, having a decreased quality of life; uncertainty of long-term effects and unwanted changes in body image (Mills *et al.*, 2006).

2.9.2 Financial constrains

Most studies conducted in poor settings overlook how direct and indirect economic burdens borne by patients affect their ability to access a steady supply of antiretroviral and take them on time. Such burdens may include absenteeism from work, the cost of elder or childcare during medical visits, the cost of transportation to a health center, being homeless, the cost of user fees, or the cost of tests and supplies (Castro, 2005). Although these costs may seem minimal to health professionals and decision makers, bearing these costs often translates into difficult household decisions about who eats, who works, or who goes to school.

In resource poor countries many people live below poverty line and there is often no medical insurance or disability pension for people living with HIV (Katabari, 2002).

2.9.3 Daily schedules

Nine common barriers were related to daily schedules and included: disruptions in routine or having a chaotic schedule, finding HAART too inconvenient or difficult to incorporate and difficulties coordinating adherence with work, family or care giving responsibilities at home (Castro, 2005; Mills *et al.*, 2006). Difficult to balance the numerous strict dietary requirements associated with HAART; sleeping through a dose; being away from home and not bringing medication, being too distracted or busy and having no time to refill prescriptions or other pharmacy related problems and difficulties with a particular dose the middle-of-day or early-morning dose (Castro, 2005; Mills *et al.*, 2006)

2.9.4 Interpersonal relationships

Interpersonal relationships can affect adherence behaviors. Lack of trust or dislike of a patient health care-provider, social isolation, negative publicity regarding HAART or the medical establishment, discouraging social network are impediment to ART adherence. Not living alone, having a partner, social or family support, peer interaction and better physical interactions and relationships are characteristics of patients who achieve optimal adherence (Williams and Friedland, 1997; Alice and Friendland, 1998; Motashari *et al.*, 1998; Castro, 2005; Mills *et al.*, 2006).

2.9.5 Impact of the drug regimen on ART adherence

Almost all of those who are on ART are on regimen of three or more ARVs (Grierson *et al.*, 2000). The likelihood of a patient's adherence to a given regimen declines with polypharmacy, the frequency of dosing, the frequency and severity of side effects and the complexity of the regimen (Williams and Friedland, 1997; Nakiyemba *et al.*, 2005). Poor adherence has also been associated with patients desire to avoid embarrassing side effects (like sweating) in certain situations such as on a date or at a job interview (Burgos *et al.*, 1998). Dietary restrictions add to the complexity of ART and often require adjustments in lifestyle. Patients can find their meal schedule compromised by ARVs that need to be taken on an empty stomach. This can be particularly difficult if workmates, family or friends are unaware of the patients HIV status (Grierson *et al.*, 2000; Nakiyemba *et al.*, 2005). Complicated regimens with rigid dosing intervals may also interrupt sleep. The physical aspects of a particular medication (for example taste, size or formulation) may also affect patient's ability to adhere (Nakiyemba *et al.*, 2005).

2.9.6 Clinical setting and service provision

The effect that the clinic setting has on ART adherence should not be underestimated. Clinic characteristics that impact on adherence include: proximity to the patients home or place of work; the expense of getting there, lengthy delays between appointments, clinic opening and closing times, long waiting times, lack of services such as child care, privacy, confidentiality, and unsympathetic or inconsiderate staff (Nakiyemba *et al.*, 2005).

2. 10 HIV and AIDS treatment in Kenya

More than 1.5 million people were infected with HIV in Kenya in 2005 but in the 2007 1.091 million people were living with HIV (WHO, 2005, 2007). Currently more than 172,000 Kenyans are on ARV treatment (NACC Kenya, 2008). Kenya was supporting the WHO and UNAIDS global initiative to provide ART to 3 million people with HIV/AIDS in developing countries by the end of 2005 (Kenya was one of the priority countries supporting the achievement of this effort). In October 2003 the WHO 3 by 5 team responded to a GOK request and conducted an initiative assessment mission to Kenya. The mission supported Kenya to identify how the rapid scaling up to ART services could be achieved (Republic of Kenya, MoH, 2001).

Kenya has shown high-level of political commitment to scaling up treatment and care alongside prevention efforts. State health officials had set the following target, progressively deliver effective ART reaching 50% (140,000 patients) by 2005 and 75% (200,000 patients) by 2008 so as to increase the quality of life and survival by 10 years, reduce HIV- related hospital admissions by 60 % and enhance significantly national prevention efforts (WHO, 2004). In Mombasa Kenya researchers from the Horizon Program and the International Center for Reproductive Health, in collaboration with Coast Province General Hospital (CPGH) conducted a study to find out how feasible Directly Administered Antiretrotherapy Therapy (DAART) would be in promoting adherence to ART (Sarna *et al.*, 2005).

They found out that despite challenges like time and resources involved in pre-packing the medication at CPGH to ensure drug security, staff shortages and costs of providing transportation to poor clients, DAART had positive impact (Sarna *et al.*, 2005).

Decentralizing the stocking and dispensing of antiretroviral (ARV) medications to peripheral sites in the community would normalize ARV delivery such that it would be like any other medication dispensed from peripheral health center pharmacies, thus doing away with pre-packing. Widening the network of health facilities that provide DAART support would serve to distribute the staff workload over more sites and move DAART services closer to patients' homes, thus reducing transportation problems (Sarna *et al.*, 2005). A shorter duration of DAART follow-up could reduce the costs to the health system and to clients and would increase the feasibility of intervention but would need to be evaluated. Directly Administered Antiretroviral Therapy offers a unique opportunity for close monitoring of patients receiving HAART. Directly Administered Antiretroviral Therapy also serves to enhance links between health service delivery and community resource networks, thereby facilitating access to care and support for HIV-infected individuals (Sarna *et al.*, 2005).

It is anticipated that by 2006, as a result of care and treatment related to ART, about 57,000 deaths were averted in Kenya. Donor support for care and treatment has been strong but despite good progress in the expansion of ART services, the task ahead is enormous. At a 0.2 % increase in prevalence as a result of ART, the effort is negligible but will increase in the future. Kenya has made tremendous strides in scaling up ART. It

is estimated that the need for second line ART will increase (UNAIDS 2006; NACC Kenya, 2008). In 2007, 172,000 patients were on ART compared to 60,400 in 2005 (NASCO database), equivalent to 35% of the 430,000 adults and 23,000 children requiring treatment (NACC Kenya, 2007). Of the 100,000 children who are HIV positive, 23,000 need ART but by 2007 only 13,000 children were receiving it. This was because of poor awareness on the part of parents and caregivers than non-availability of drugs. In 2005 only 4,000 children were on ART. From analysis of district data the male to female ratio for ART is 35%-to- 65 % (NACC Kenya, 2007). It is intended to have 209,000 adults and 20,000 children on ART by 2008 with 180,000 adhering to treatment.

Antiretroviral therapy has been delivered free since early 2005, but the user bears the cost of medical support services and transport. These additional costs are often inseparable financial burden, which causes patients to default on their treatment. Adherence rate is high but still sub optimal (NACC Kenya, 2008). A review of records for a 20-month period by NASCO suggests that 13% of the patients are either dead, transferring out or stopping ART. Only 5(3%) patients stopped ART voluntarily. However, the default rate could be particularly high among children who are under care of the elderly (NACC Kenya, 2007).

Research is urgently needed to determine patient-important factors for ART adherence in developing world settings. Clinicians should use this information to engage in open discussions with patients to promote ART adherence and identify barriers and facilitators within their own populations (Mills *et al.*, 2006)

CHAPTER THREE: MATERIALS AND METHODS

3.1 Overview of methodology

This chapter explains the methodology that was used in the entire study. The chapter looks at study area, study design, target and study populations, sampling techniques, research instruments, ethical considerations, data collection, data quality control, data management and analysis.

3.2 Study Area

The study was conducted at Provincial General Hospital Nyeri, Karatina District Hospital Nyeri and Thika District Hospital. Nyeri and Thika Districts are two of the seven districts of central province. Nyeri PGH had about 1000 HIV patients, Karatina District Hospital had about 950 HIV-patients and Thika District Hospital had about 1050 HIV patients who were on Antiretroviral Therapy (ART). In the year 2005 Nyeri District had HIV prevalence 5.3 % while Thika District had HIV prevalence of 7.6 %, which was the highest in Central Province (Republic of Kenya, MoH, 2005). The high HIV prevalence in Thika and Nyeri districts in the year 2005 means that high numbers of AIDS patients were eventually put on ART. However, there has been no documentation about ART adherence in Central province.

In 2007, Thika recorded a dramatic decrease in HIV prevalence contributing to the current 4.1% HIV prevalence in Central Province (NACC Kenya, 2007). The study sites captured Central Province because PGH Nyeri serves as a referral for majority of patients from Nyeri, Nyandurua and Murang'a Districts, Karatina District Hospital serves patients

from Nyeri and partly Kirinyaga Districts and Thika District Hospital serves patients from as far as Kiambu District and Maragwa District. Therefore the population of patients interviewed in this study was representative of Central Province.

3.3 Study Variables

3.3.1 Dependent variable was non-adherence to ARV treatment.

3.3.2 Independent variables were: sex, age, and marital status, household size, level of education, occupation, food, transport cost, treatment regimen and co-management of co-infections, socio-cultural factors such as attitude and perceptions, stigma, traditional medicine, religion, health care facility and health care providers.

3.4 Target Population

The target population was all HIV and AIDS patients.

3.5 Study population

The study population was AIDS patients on ART attending PGH Nyeri, Karatina and Thika district hospitals in Central Province.

3.6 Sample Population

The sample population was composed of more female AIDS patients on ART attending the selected public health facilities in Central Province. This was because males said they were busy and therefore participated much less in the study.

3.6.1 Inclusion Criteria

The inclusion criteria comprised of AIDS patients who had started ART and were willing to participate in the study. The benchmark of adherence was set at the day the patient was started on ARV treatment because even missing one dose of ARV drugs in a week translates to only 92.8% adherence, which is sub optimal (Paterson *et al*, 2000).

3.6.2 Exclusion Criteria

These were:

- i) AIDS patients who had not started ART
- ii) AIDS patients on ART who did not consent to participate in the study.

3.6.3 Ethical Considerations

These were:

- i) Permission to carry out the research study was sought from Kenyatta University and Ministry of Science and technology.
- ii) Informed consent was sought from all the study participants. For minors consent was sought from their parents or guardians.
- iii) Confidentiality, anonymity and privacy was fully guaranteed.

3.7 Study Design

A cross-sectional study design was used. The study design provided information about the presence and strength of associations between variables, permitting the testing of hypothesis about such associations. Both primary and secondary data was collected.

Primary data was collected through interviewing study participants, key informants (health care providers), and conducting focus group discussions and through observation. Secondary data was collected through reviewing medical records of the study participants after getting authority from health facilities' administrators and consent from study participants.

3.7.1 Sampling method

The sampling frame (patients' register) contained names of the AIDS patients on ART attending the health facilities. Provincial General Hospital Nyeri, Karatina District Hospital and Thika District Hospitals were selected conveniently. Patients in comprehensive care clinic meeting the inclusion criteria were selected using systematic random sampling method until the required sample size was obtained. The sampling interval was: $K = \text{Sampling frame (N)} / \text{Sample size (n)} = 1000 / 300 = 3$. The three health facilities, PGH Nyeri, Karatina District Hospital and Thika District hospital where the study was carried out, each had approximately 1000 registered AIDS patients who were on antiretroviral therapy (ART).

3.7.2 Sample Size

The sample was determined using following formula by Kothari (2003)

The assumptions were that the sample was representative; the sampling error was small, the sample was viable in the context of funds available for the research study, systematic bias was controlled in a better way and results from the sample study will be generalizable.

$$n = \frac{z^2 pq}{e^2}$$

Where z = standard variate (1.96) which correspond to 95% confidence interval
 p = proportion of HIV and AIDS patients on ARV treatment who did not
 adhere

$$q = 1 - p$$

e = acceptable error margin (precision of measurement)

$$p = 0.25$$

$$q = 0.75$$

$$e = 0.05$$

$$n = \frac{1.96^2 \times 0.25 \times 0.75}{(0.05)^2}$$

$$= 288 \approx 300$$

3.8 Methods of Data Collection

Both qualitative and quantitative methods of data collection were used.

3.9 Instruments of Data Collection (Research Tools)

Data for the quantitative part of the study was collected using structured questionnaire with both open and closed questions. The information that was collected included age, sex, marital status, household size, cost of transport, sufficient nutrition, level of education, occupation, knowledge, attitude, perception and practice on use of ARVs by health care providers and HIV patients.

Structured questionnaire provides data that is objective, scientific and reliable for hypothesis testing (Ong, 1993).

Data for the qualitative part of the study was collected using focus group discussion. The purpose of the focus group discussion was to identify difficulties that were being experienced by patients taking ART. In addition key informant interviews were conducted among health care providers in comprehensive care clinics. These were Clinicians, Nurses, Pharmacists and Social Workers. A checklist was used to assess how well health facilities were equipped.

3.9.1 Data Collection on Adherence

Researchers who have tried to measure adherence have realized that there is no gold standard by which adherence can be quantified (Farmer, 1999). This study had selected three measurement tools.

i) Two- day self report recall

Patients were asked how they took their medicines in the last two days. The two-day recall has the advantage of a short time-span, which means that memory of medicine intake is likely to be good. However patients may feel ashamed to report specific instances of non-adherence that occurred in the 48 hours prior to visiting the health facility, especially if they have to specify on the chart exactly when they failed to take a pill and then to explain why.

ii) One-month self report recall (10 cm long visual analogue scale)

ARV users were asked to indicate their adherence rate over the past month using a 10-centimetre long 'visual analogue' line. The beginning of the line indicated not taking the medications at all in the past month, while the end meant taking all of them as prescribed. The patient's mark was then measured using a 10 cm ruler and translated into percentages. In terms of desirability bias, the one-month visual analogue methods are likely to be better. By estimating the number of pills missed over a one-month period, patients are confronted less with each specific non-adherent event. The two-day self-report and one-month visual analogue recall methods have been found by Byakika and colleagues (2005) to be valid instruments for estimating adherence in a recent study in Uganda.

iii) Pharmacy pill count.

The pill-counts can be defined as the most 'objective' of the three approaches, measuring the actual number of pills left over since the previous refill. However, patients who fear the possible repercussions of revealing to the dispensing pharmacist that they have not achieved optimal adherence, may present fewer pills to the pharmacist than were actually left over. All three methods are likely to overestimate adherence.

The three methods were preferred so that one method could compensate the weaknesses of the other. However, for this study only the two-day self-report and one-month visual analogue recall methods were used to collect data on adherence because at PGH Nyeri,

Karatina and Thika district hospitals data on pharmacy pill counts could not be easily traced. Therefore the data reported on adherence and non-adherence is a mean of two-day self report recall and one month self report recall (10 cm long visual analogue scale).

3.10 Data Quality Control

Research instruments were pre –tested to increase the validity and reliability of the responses. Pre-testing was done on 10 respondents from Mbagathi District Hospital. These respondents were not included in the study sample. The research assistants were well trained before participating in the study. Regular cross checking, inspection and scrutinizing of information on the research instruments was done to ensure accuracy, relevance, completeness, consistency and uniformity of the data collected.

3.11 Data Management and Analysis

Data was sorted, coded, and entered into the computer using SPSS soft ware version 11.50. Data was presented using charts, graphs and frequency tables. Descriptive statistics such as mean, frequencies and percentages were used to describe and summarize the data. Both means, for optimal adherence and non- adherence rates for PGH Nyeri, Karatina and Thika district hospitals were calculated using data from two-day recall and one month self recall (10 cm long visual analogue scale). To calculate the average optimal adherence rate in the study area, the sum of all optimal adherence rates from the three health facilities was divided by three. Analysis of contingency tables was done and Chi-square statistic was used to test for association between variables and level of significance.

CHAPTER FOUR: RESULTS AND DISCUSSION

4.1 Overview of results and discussion

This chapter presents results of qualitative and quantitative findings. The section covers the following findings: Proportion of respondents not adhering to ARV treatment, Socio-demographic and Socio-economic information related to ART non-adherence, knowledge of the population on antiretroviral therapy (ART) and its influence on ART adherence, treatment regimen and co-management of HIV and other infections and how this affects ART adherence, Social-cultural factors that influence non-adherence to ART, health care facility (clinical setting) and services provided and how this influence non adherence to ART.

4.2 Determining Proportion of AIDS Patients on ARV who Adhered to Treatment

In this study, ARV users were asked to mark their adherence rate over the past month using a 10-centimetre long visual analogue scale. The beginning of the scale is associated with complete lack of adherence in the past month, while the end is associated with complete adherence. The patient's mark was then measured using a 10 cm ruler and translated into percentages. Then a two-day self-report recall was done. Pharmacy pill count: During data collection, pharmacy pill count records were not available at PGH Nyeri, Karatina and Thika District Hospitals. So there was no data to calculate optimal adherence using pharmacy pill count. This could be problematic because pharmacy pill count is a tool required to monitor patient ART adherence on every pharmacy refill visit. Therefore adherence was determined by the average of the adherence rate using 10-centimeter long visual analogue scale and the two-day self-report recall (Table 4.1)

Table 4.1 Distribution of Adherence Rate at PGH Nyeri, Karatina and Thika District Hospitals

Finding	PGH Nyeri n=100	Karatina D. Hosp n=100	Thika D. Hosp. n=100	Total % n=300	95% CI
Visual Line					
Adherence	53(53%) ^{a}	51(51%) ^{d}	53(53%) ^{g}	157(52%) ^{j}	47.74-56.26
Non-adherence	47(47%)	49(49%)	47(47%)	143(48%)	43.70-52.30
Two-day					
Adherence	96(96%) ^{b}	95(95%) ^{e}	97(97%) ^{h}	288(96%) ^{k}	94.05-97.95
Non-adherence	4(4%)	5(5%)	3(3%)	12(4%)	2.04-5.96
Average					
Adherence	74.5% ^{c}	73.5% ^{f}	75% ^{i}	74% ^{l}	73.04-75.96
Non-adherence	25.5%	26.5%	25%	26%	24.00-28.00

Average optimal adherence from the three health facilities was calculated as follows

$$\text{PGH Nyeri average ART adherence rate } c = \frac{a+b}{2}$$

$$\text{Karatina District Hospital average ART adherence rate } f = \frac{d+e}{2}$$

$$\text{Thika District Hospital average ART adherence rate } i = \frac{g+h}{2}$$

$$\text{Over all average ART adherence rate } l = \frac{j+k}{2} \text{ or } l = \frac{c+f+i}{3}$$

The mean non-adherence rate was 26 % (78) indicating that ART adherence rate was 74 % (222). This means that the level of ART adherence in the study area is sub-optimal (<95%){Figure 4.1}

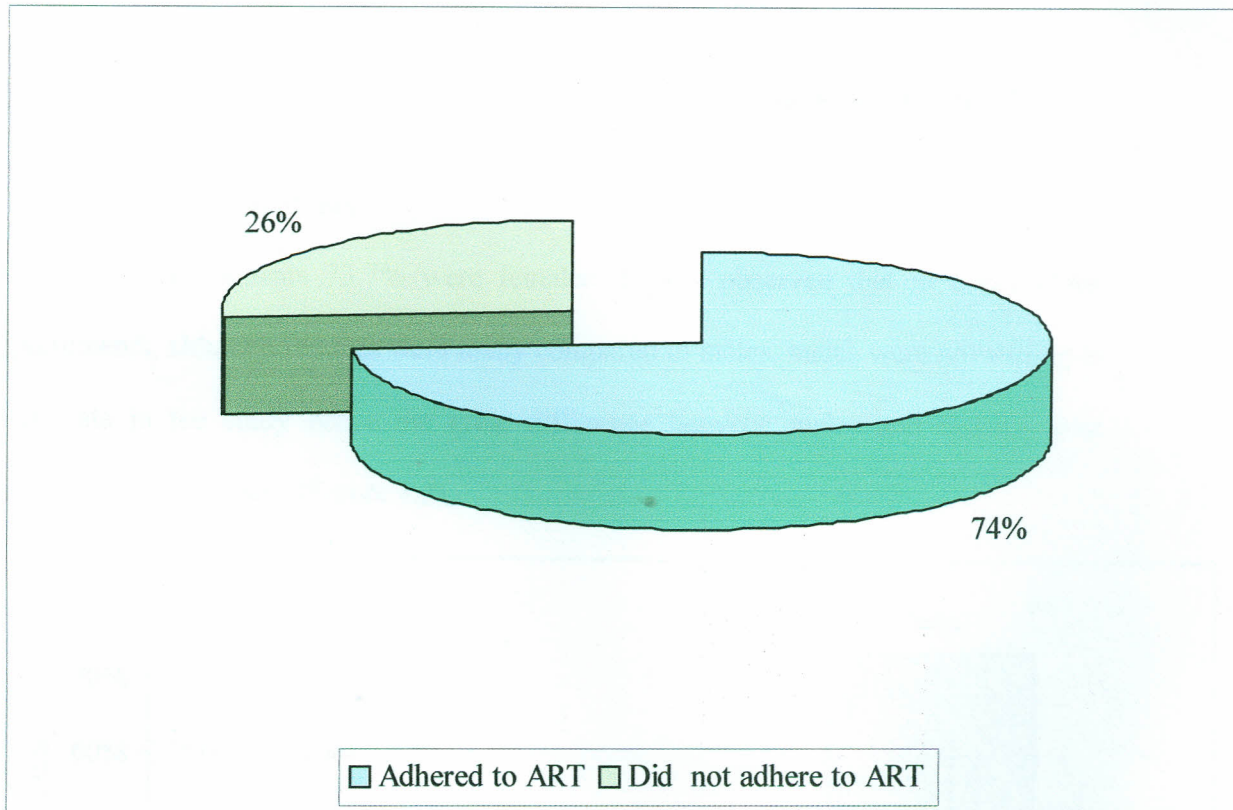


Figure 4.1 Distribution of respondents according to adherence to ART.

Antiretroviral therapy adherence rate in the study areas was relatively high 74% compared to findings of a study in developed countries on HIV- patients among whom ART adherence was 55 % (Mills *et al.*, 2006). The adherence rate (74%) found by this study was less than that found by Sarna *et al.* (2005) at Mombasa Kenya, which was greater than 95%. The finding by Sarna *et al.* (2005) was for patients on ART who were under Directly Administered Antiretroviral Therapy (DAART) program at Mombasa.

However, DAART program was not in use at PGH Nyeri, Karatina and Thika District Hospitals.

4.3 Socio-Demographic and Socio-economic factors related to adherence to ART.

4.3.1 Gender of respondents

Most of the respondents 73.7% were females. It was observed that in every clinic appointments, although females were many compared to males, males were not willing to participate in the study hence the great difference between males and females who participated in the study. (Figure 4.2)

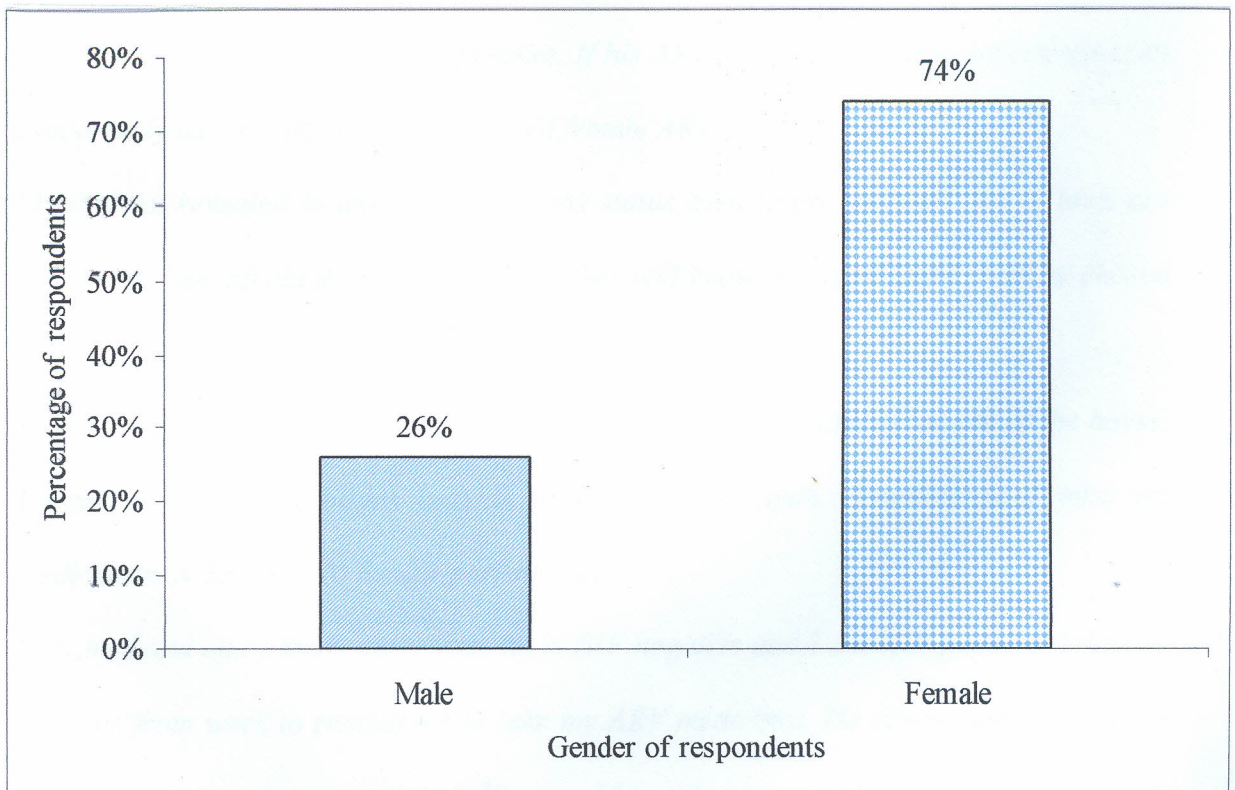


Figure 4.2 Distributions of respondents according to gender

Among female respondents 75.57% adhered to ART while among the male respondents 68.35% adhered to treatment indicating that females adhered more to ART than males. During the study males were found to be busier than females. They reported very early for clinic appointments since they had to go for job after that. For that reason many men were not willing to participate in the study. Those who participated disclosed that they often forgot to take ARV medicine especially the morning dose. However, no significant relationship between sex of respondent and adherence to ART ($\chi^2 = 1.56$, $df = 1$, $p > 0.05$). This finding was in contrast with finding by Abah *et al.* (2004) in South Africa where the sex of the respondent was found to influence adherence to antiretroviral therapy. From focus group discussions it emerged that men influenced a lot their spouses ART adherence for instance,

“My husband and I are both HIV positive, If his ARV stock gets finished before mine, he comfortably use my ARVs” (A 30 year old female ARV user).

“I have not revealed to any body about my status even to my husband. My in laws are very cruel, I am afraid if I tell my husband they will know and most likely I will be chased away. A 28 year old female patient commented”

“My husband is a drunkard he beats me up and sometimes he chases me out of the house. I have spent several nights outside in the cold. In such circumstance I miss my medication. A 32 year old female patient said”

“My husband and I know our status, he is HIV negative and I am HIV positive. Infact he calls me from work to remind me to take my ARV medicines. He always use condom for protection, he is very supportive. A 30 year old female patient commented”

4.3.2 Age of respondents

The respondents' age ranged from 18 to 60 and above years with a peak at age group between 30-39 years. Most of the respondents were within the reproductive age group of 15-49 years. Respondents within the age group 50-59 and those above 60 years old were 10 % and 6% respectively. There were 40 minors (children) whose parents and guardians were interviewed. This finding indicated that Majority of patients in age between 30-39 years were more aware of their status and were undergoing ART (Figure 4.3)

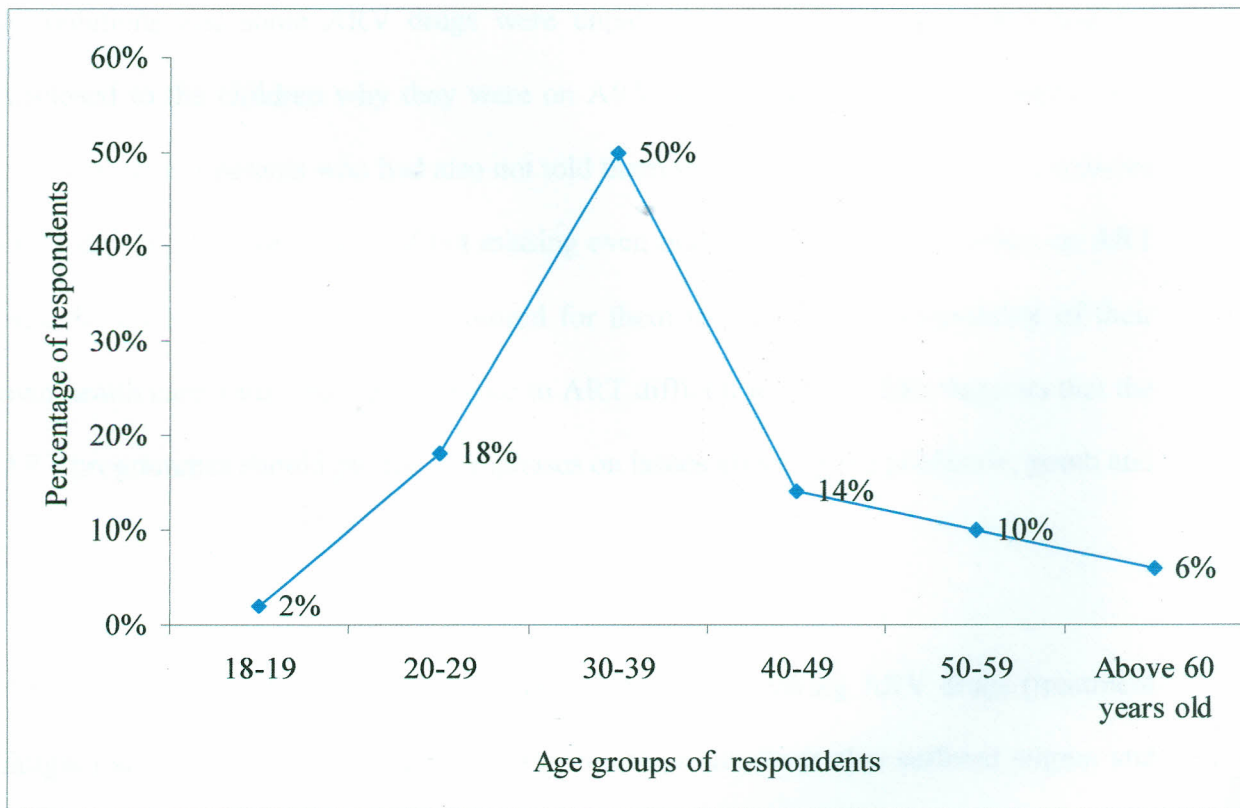


Figure 4.3 Distribution of the respondents according to age

Age of respondent influenced ART adherence ($\chi^2 = 12.078$, $df = 5$, $p < 0.034$). This finding agrees with the finding of Jones *et al.* (1999) and Abah *et al.* (2004) that age of

respondent influences adherence to ART. Adherence to treatment according to findings of this study was high (81%) among respondents in the age bracket 30-39 years. The trend showed that adherence to ART increased with increasing age and decreased as the age advanced beyond 60 years. This was because the youth suffered most from stigma and denial while the elderly had difficulties understanding and following ART instructions. In the current study Key informants revealed difficulties on ensuring paediatric ART adherence. Key informants mentioned shortages of appropriate paediatric formulations and some ARV drugs were unpalatable. Health care providers had not disclosed to the children why they were on ARV drugs medication. The children lived with their grand parents who had also not told them why they were taking ARV medicine every day and the importance of not missing even one dose. This made children on ART lack the understanding that they required for them to accept the responsibility of their own health care, thus making adherence to ART difficult for them. This suggests that the ART programmes should put more emphases on issues affecting the paediatric, youth and the elderly.

From focus group discussions some youth were tired of taking ARV drugs (treatment fatigue) and also suffered stigma and discrimination. Students also suffered stigma and discrimination. The elderly could not remember to take ARV drugs as instructed. These findings reveal that the adults in middle ages adhere much more than the paediatric, the youth and the elderly.

4.3.3 Marital Status of the Respondents

Forty seven percent of respondents were married, 21% were widowed, 21% were single, and 11% were divorced. This finding showed that majority of respondents were either widowed, single or divorced (Figure 4.4)

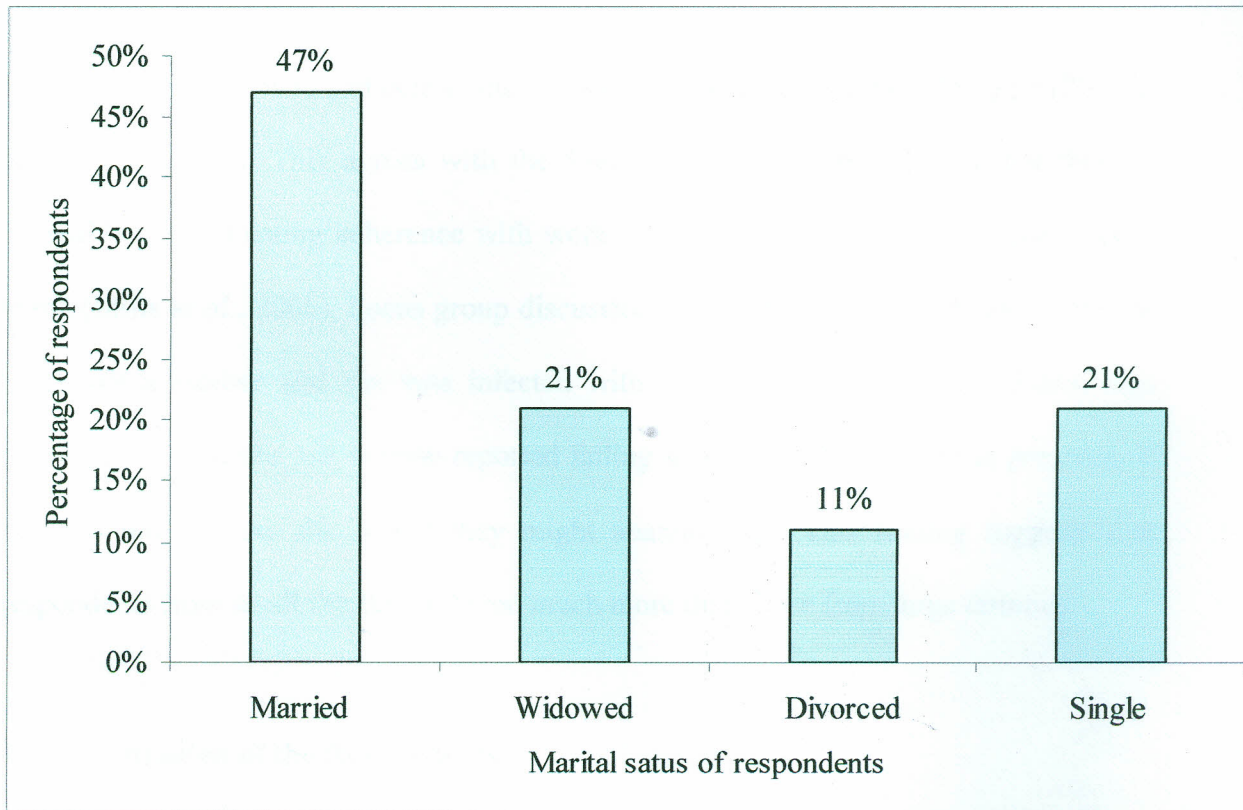


Figure 4.4 Distribution of respondents according to marital status

The results suggest that unmarried people more than any other category knew their HIV status and were undergoing ARV treatment. However, chi-square statistic revealed no significant relationship between marital status of respondent and adherence to ARV treatment ($\chi^2 = 0.62$, $df = 3$, $p > 0.05$). From focus group discussion it was found that many women who were either single or divorced had been chased away by their

husbands after knowing their HIV status. This discrimination greatly influenced non-adherence to ART. Four women who were discordant couples disclosed that their husbands were understanding and very supportive. This was because they had disclosed their HIV status and when counselled together they were able to adhere to ART.

Respondents (75%) who had below four young children adherence to ART ($\chi^2 = 120.552$, $df = 9$, $p < 0.0001$). This agrees with the finding of a study in Belgium that there is difficulties co-ordinating adherence with work, family or care- giving responsibilities at home (Mills *et al.*, 2006). Focus group discussion revealed that in households where the head was a mother and she was infected with HIV, disclosure to the children was difficult. For instance one woman reported failing to take ARV treatment in presence of her children because she feared they might abandon her. This finding suggests that respondents from small families adhered much more than those from large families.

4.3.4 Occupation of the Respondents

Seventy percent of the respondents were employed and 30% were not. This finding show that majority of respondents were employed (Figure 4.5)

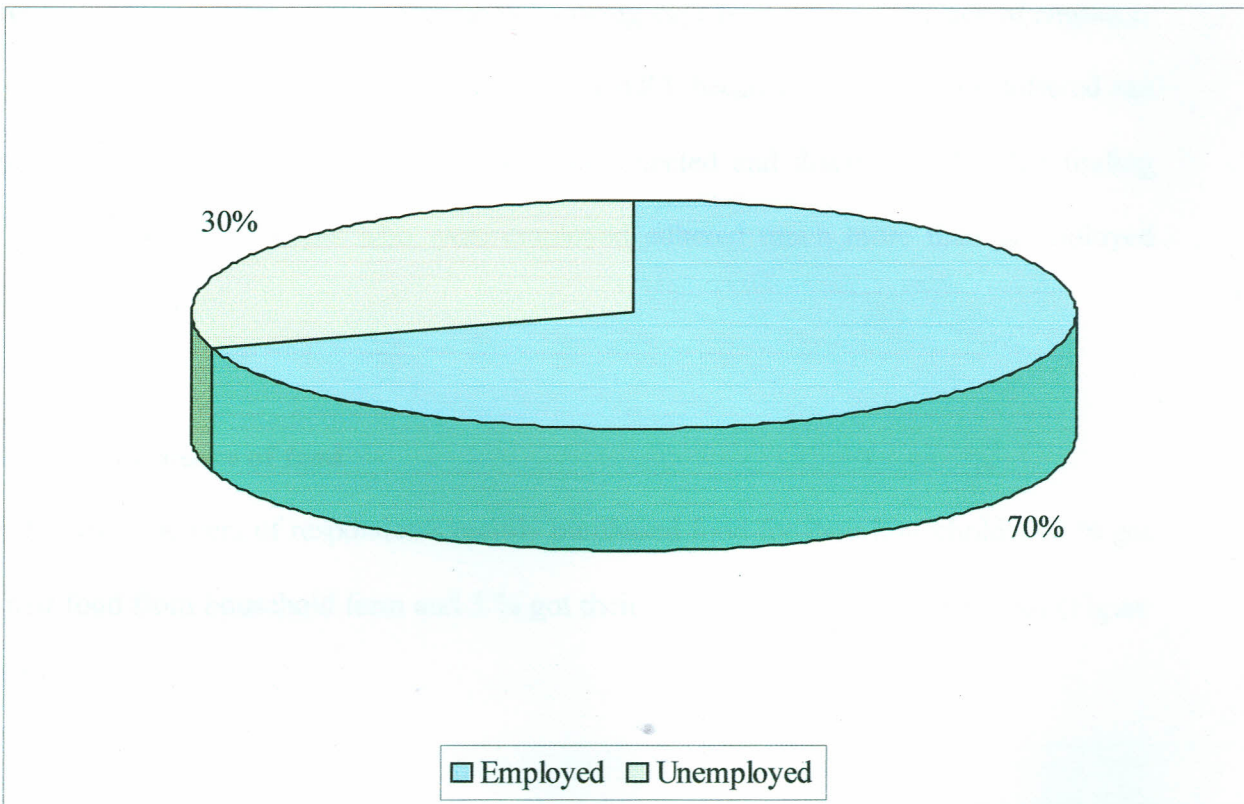


Figure 4.5 Distribution of respondents according to occupation

Respondents who were employed adhered to ART ($\chi^2 = 87.103$, $df = 7$, $P = 0.0001 < 0.05$). Although ART services at all government facilities were offered free of charge patients and health care providers felt cost of transport and health service user fees influenced ART non-adherence. This finding was supported by a study done on HIV-patients in Senegal and Botswana that user fees, not only deter people from accessing AIDS care, but also create an obstacle to ARV treatment adherence. In another context where ART is free, such as Costa Rica, transportation cost was associated with lower ART adherence (Castro, 2005). Focus group discussion found that those patients who were not employed had no other source of income. Some respondents were forced to

retire from work by their employer upon knowing their HIV status. This lack of employer support greatly influenced non-adherence to ART because those patients suffered not only from psychological torture but also felt rejected and discriminated. This finding indicates that respondents who were employed adhered much more than unemployed respondents.

4.3.5 Main source of food

Fifty seven percent of respondents mainly purchased food for their households, 40 % got their food from household farm and 3 % got their food from relatives and friends (Figure 4.6)

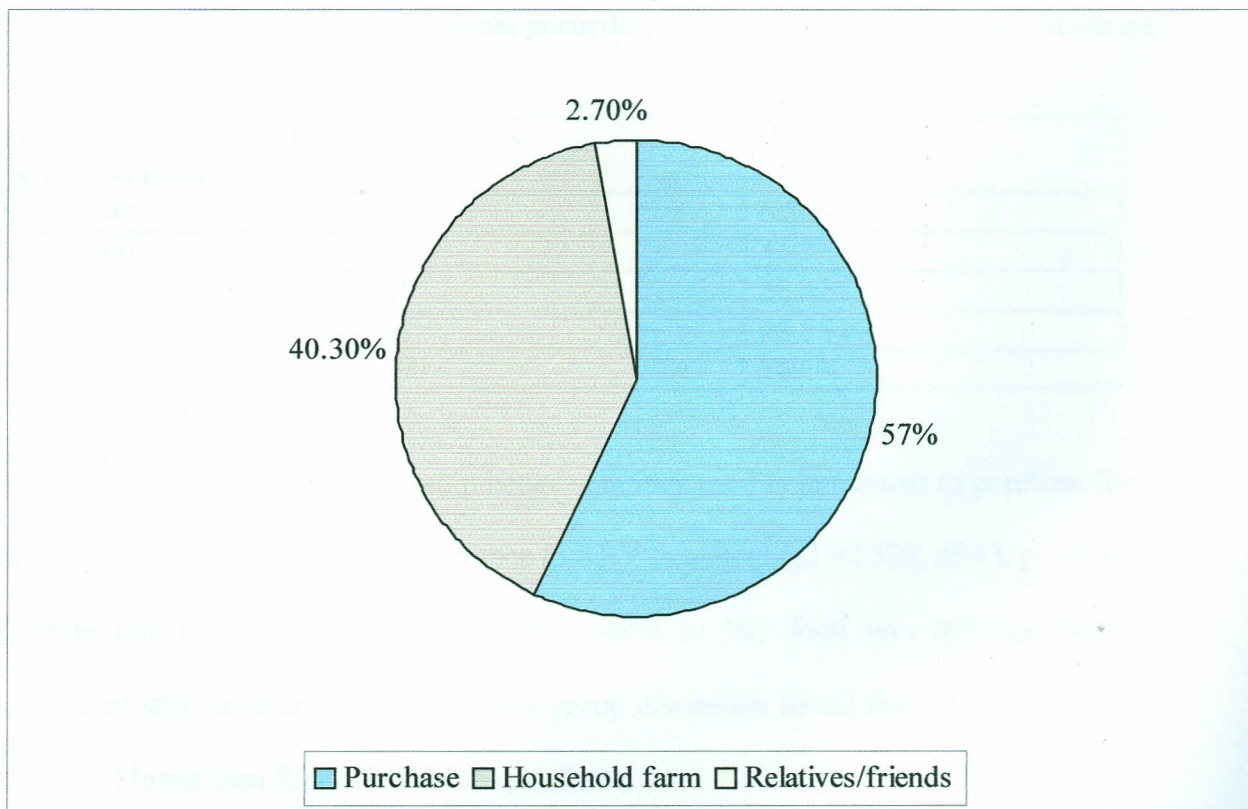


Figure 4.6 Distribution of respondents according to main source of food

No significant relationship existed between main source of food for the household and respondent's adherence to treatment ($\chi^2 = 0.694$, $df = 2$, $p = 0.707 > 0.05$). However, focus group discussion found that those who got food from their farm were able to adhere to ART than those who mainly purchased food because they were food secure.

4.3.6 Average Monthly Expenditure on Food

Forty five percent of respondents spent Kshs 3,000 to buy maize, beans, vegetables and milk, 29 % spent Kshs 6,000; 20 % spent Kshs 4,500 and 6 % spent Kshs 1500. This finding showed that those who got food from their farms spent less money on buying food because they were food secure and therefore more adhering to ART (Table 4.2).

Table 4.2 Distribution of respondents according to average monthly expenditure on food

Money spent to buy food by respondents	Frequency	Percent
Kshs 1500	19	6.3 %
Kshs 3000	134	44.7 %
Kshs 4500	61	20.3 %
Kshs 6000	86	28.7 %
Total	300	100 %

There was no significant relationship between money used in household to purchase food in one month and respondent's adherence to ARV treatment ($\chi^2 = 2.579$, $df = 3$, $p > 0.05$). Despite this finding implying that money spent to buy food was not significantly associated with adherence to ART; focus group discussion found that all patients in the study had lower than Kshs 10,000 in expenditure.

4.3.7 Number of meals taken in a day

Majority of respondents 71 % were able to afford three meals in a day. Those who could afford two and one meal in a day were 27 % and 2 % respectively. This means the underlying population was food secure (Figure 4.7)

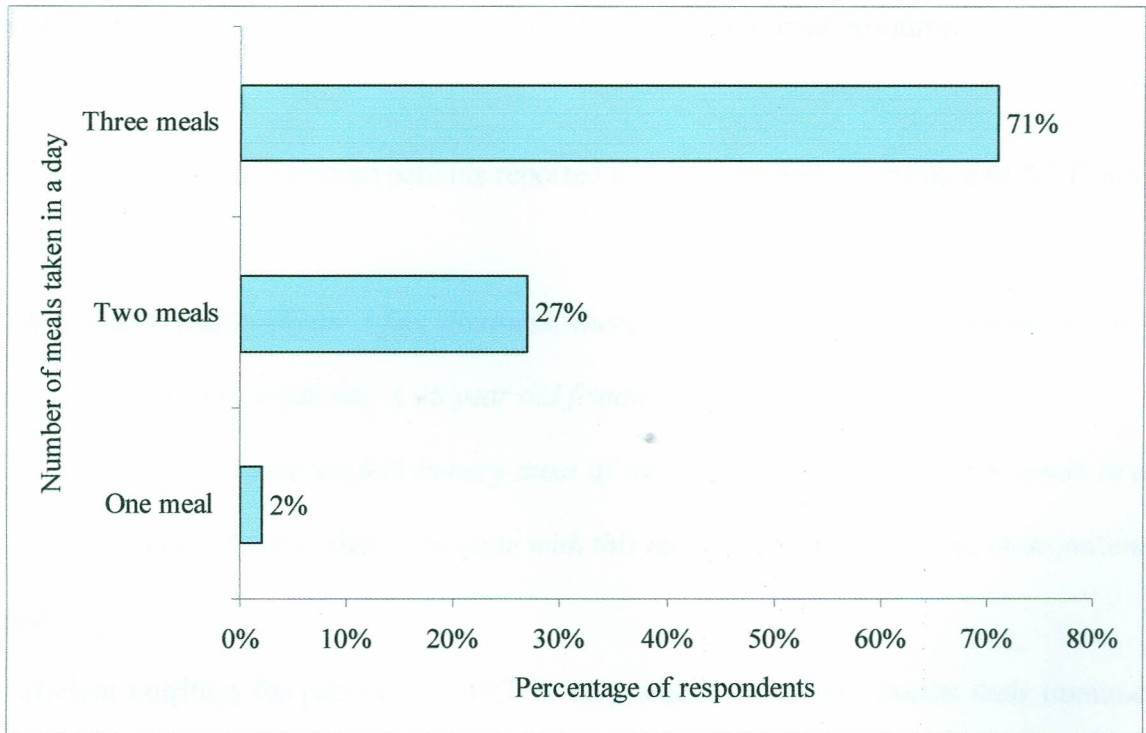


Figure 4.7 Distribution of respondents according to number of meals taken in a day.

Respondents who could afford three meals in a day adhered to ART ($\chi^2 = 13.932$, $df = 3$, $p = 0.001 < 0.05$). This level of adherence was close to the average optimal adherence rate (74%) in the study area. This finding suggests that lack of enough food influenced non-adherence to ART. The more meals one could afford in day the more that patient adhered to ART. Patients reported that when they take their treatment having not eaten any food they suffered from dizziness and therefore it was difficult to take ARV medicine without food. Infact among respondents who could only afford one meal a day 71% did

not adhere to ARV treatment. This finding was supported by a study on HIV-patients in Lusaka Zambia who used to skip treatment doses due to lack of food (Chishimba and Zulu, 2004). In the three study sites, PGH Nyeri, Karatina and Thika District Hospital, health workers expressed concern about the expected increase in numbers of patients to be treated, which results in straining existing facilities and human resources.

From focus group discussions patients reported that lack of food contributed to ART non-adherence.

“Once I take this medicine I feel dizziness, therefore when I have not taken any meal I can hardly take this medicine. A 36 year old female patient quipped”.

“These medicines make me feel hungry most of the time I can even take four meals in a day when there is food so that I can cope with this medication. A 40 year old male patient said”.

Sufficient nutrition for patients on ART is very crucial because it boosts their immune system, which helps them to cope with medication. That way the patient is able to tolerate the side effects especially the undesired side effects.

4.3.8 Level of education attained by respondents

Most respondents (61 %) had attained primary level of education and 28 % had attained secondary level of education. The respondents who had attained college education were 4 % and those who had no formal education were 7 % (Figure 4.8).

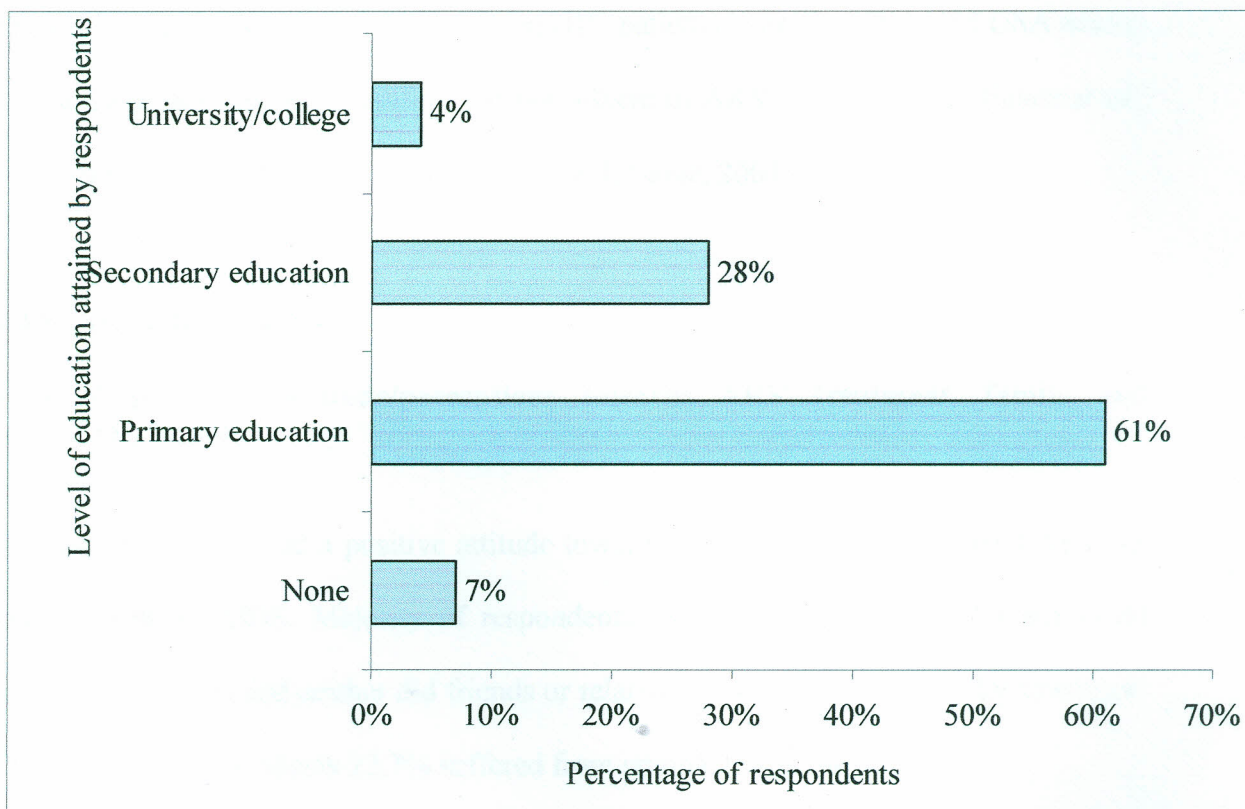


Figure 4.8 Distribution of respondents according to level of education attained.

A significant relationship between level of education and adherence to ARV treatment ($\chi^2 = 8.38$, $df = 3$, $p < 0.039$). Seventy eight percent of respondents who had attained form four level of education adhered to ART while 77% of those who had attained college and university education adhered to treatment. The study found high levels of education increased the patient's adherence to ART. The likely reason is that those patients could easily understand and follow ART. Fifty two percent of respondents who had no formal education had difficulties adhering to ART.

These findings are supported by studies on HIV-patients in South Africa and USA among whom those who lacked education did not adhere to ARV treatment (Rodriguez *et al.*, 2000; Wolf and Cecilia, 2001; Abah *et al.*, 2004; Stone, 2004).

4.4 Social cultural factors

4.4.1 Respondents attitude/perceptions towards ARV treatment, family and community support.

All patients (100%) had a positive attitude toward ART and they all approved ART for management of AIDS. Majority of respondents 77.3 % said that they did not avoid friends or relatives and neither did friends or relatives avoid them during ARV treatment. The rest of the respondents 22.7% suffered from stigma. (Figure 4.9)

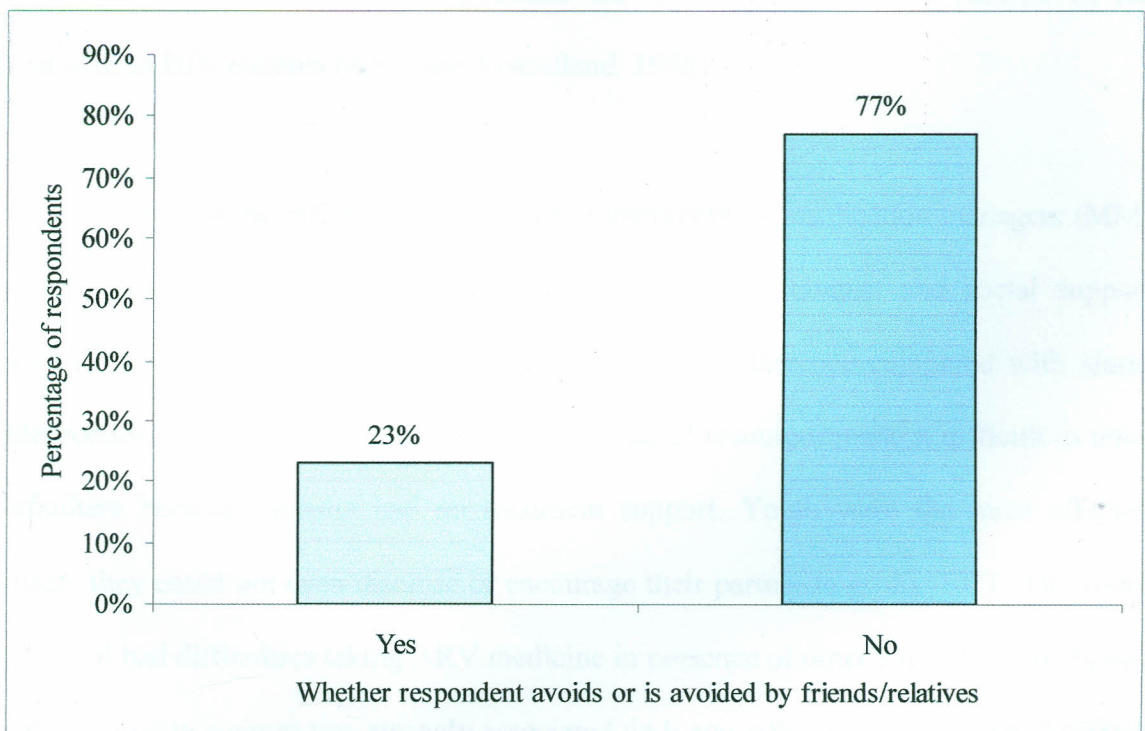


Figure 4.9 Distribution of respondents according to whether they suffered from stigma or not

This was an indication that stigma was still high in the study area. A significant relationship existed between stigma and adherence to ART ($\chi^2 = 10.526$, $df=1$, $p=0.001 < 0.05$). This finding was supported by another study on AIDS patients among whom 67.65% reported fear of disclosure (Mills *et al.*, 2006).

At one study site one respondent mentioned that having a cordial relationship with health care provider really improved her adherence treatment. Respondent who were open and had told friends and family members their HIV-status were supported during ARV treatment. Employers were also not supportive. Respondents who were supported adhered to ART ($\chi^2=300$, $df=8$, $p=0.0001 < 0.05$). This finding agrees with studies in USA and Belgium that positive interpersonal relationship made adherence to ARV treatment successful (Mills *et al.*, 2006). The use of family members and peers to enhance ART adherence has emphasized the importance of social support in the treatment of HIV patients (Alice and Friendland, 1998).

A study to assess the efficacy of 2 adherence interventions, medication managers (MM) and medication alarms (ALR) found that more frequent contact and social support provided by MM intervention resulted to better ART adherence compared with alarm intervention (Sharon *et al.*, 2006). Stigma and lack of resources made it difficult to trace defaulters because patients had no treatment support. Youth were the most affected group; they could not even disclose or encourage their partner to go for VCT. The youth in school had difficulties taking ARV medicine in presence of other students. Poor family and community support was strongly associated with non-adherence to ART ($p=0.0001 < 0.05$).

Women were the most affected group in this case; majority said that their in-laws blamed them and persuaded their sons to divorce them.

Focus group discussion found that some patients at one point had preferred traditional medicine because of the belief that traditional medicine could cure HIV, which is not true. These patients could alternate ARV drugs and traditional medicine or abandon ARV medicine and take traditional medicine for sometime. This was dangerous because of drug interactions. Three patients said that they consulted spiritual healers, they were prayed, believed they got healed and abandoned ARV treatment. They later got very ill and resumed to ARV treatment but they had already defaulted. Therefore religion also influenced non-adherence to ART.

4.5 ARV treatment regimen and co-treatment of HIV and other infections

4.5.1 Knowledge about benefits of ART

Majority of respondents 79.3 % knew that ARV treatment reduces the viral load and therefore prevent progression to AIDS. Sixteen percent of respondents said ARV treatment cures HIV and AIDS disease while 3.3 % said ARV treatment reduces pain. Only 1 % of respondents said they didn't know any benefit of ARV treatment (Figure 4.10).

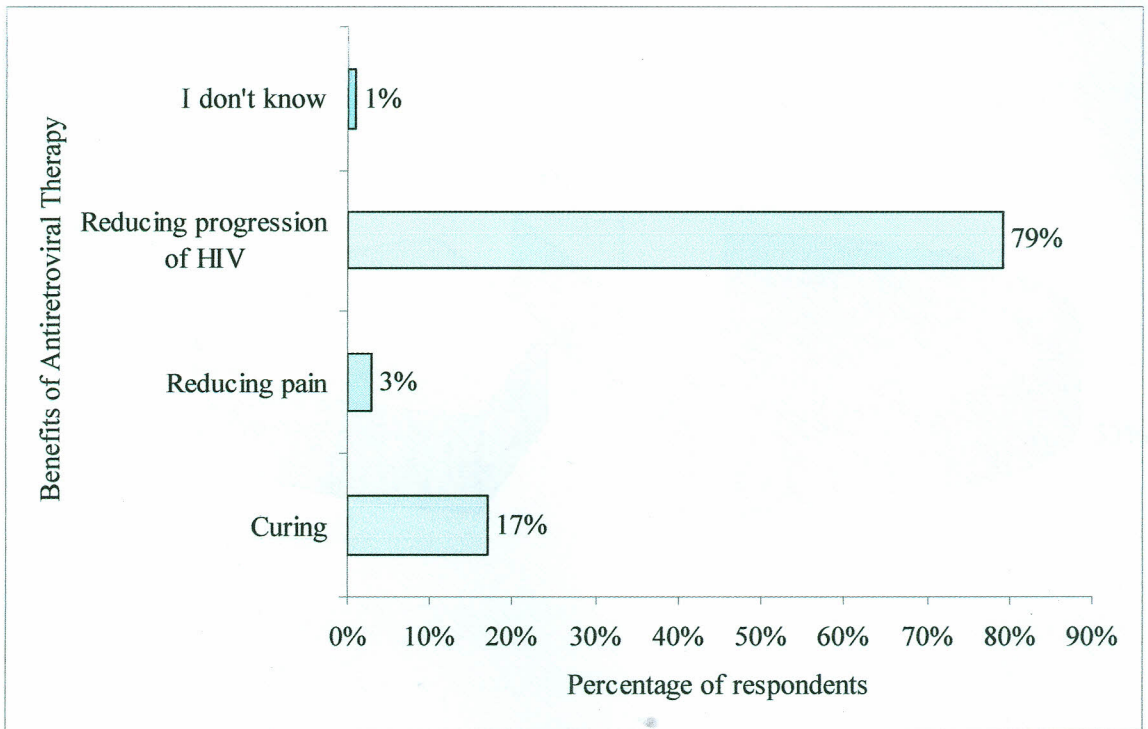


Figure 4.10 Distribution of respondents according to knowledge on benefits of ART

Respondents demonstrated substantial knowledge about ART. However, no significant association existed between knowledge about ART and adherence ($p > 0.05$). This was because despite patients knowing the benefits of ART and the importance of adherence there were other factors like stigma, missed clinic appointments that made them to default.

Most respondents 53.3 % were optimistic towards ART and admitted that their CD4+ count (indicated on patients card) improved after taking ARV drugs for at least one month; 41.7% said they had no more frequent sickness. Five percent of respondents were guardians or parents of HIV positive children and they mentioned normal growth of the child as a benefit of ART to the child (Figure 4.11)

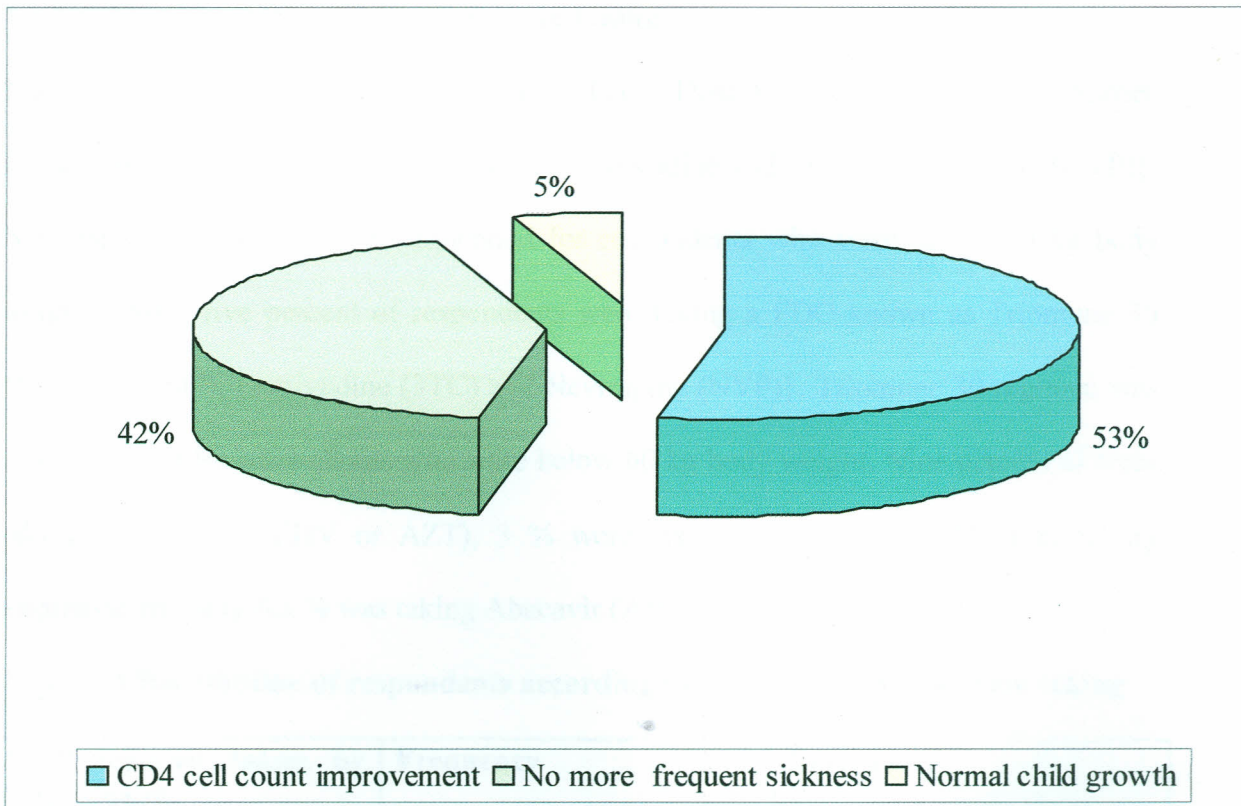


Figure 4.11 Distribution of Respondents by gained benefits of ART

This finding shows that respondents' perception of ARV treatment was very positive.

One percent of respondents who were pregnant knew that ARV drugs could prevent transmission of HIV from mother to child during pregnancy. This finding indicates that respondents were educated and believed that ARV could bring about prevention of mother to child transmission of HIV (PMTCT). Focus group discussion revealed that use of ARV treatment for PMTCT was understood by pregnant women as a new hope for one to deliver a HIV negative child. This encouraged them to adhere to ART.

4.5.2 ARV regimen the respondents were taking

Majority of respondents 46 % were taking Fixed Dose Combination of ARV regimen known as Nevilast 40 {Stavudine (dt4), Lamivudine (3TC) and Nevirapine (NVP)}. Nevilast 40 regimen was recommended for respondents who were above 60 kg body weight. Thirty five percent of respondents were taking a FDC known as Triomune 30 {Stavudine (dt4), Lamivudine (3TC) and Nevirapine (NVP)}. Triomune 30 regimen was recommended for respondents who were below 60 kg body weight. Nine percent of were taking Zidovudine (ZDV or AZT), 3 % were taking Tenofovir, 0.7 % were taking Lopinavir and only 0.3 % was taking Abacavir (ABC) (Table 4.3).

Table 4.3 Distribution of respondents according to ARV regimen they were taking

ARV regimen taken by Respondents	Frequency	Percent
Nevilast 40	139	46.3 %
Triomune 30	105	35.0 %
Evafirenze (EFZ)	15	5.0 %
Tenofovir	10	3.3 %
Zidovudine (ZDV or AZT)	28	9.3 %
Abacavir (ABC)	1	.3 %
Liponavir/ritonavir	2	.7 %
Total	300	100.0 %

No significant relationship existed between type of ARV drugs the respondent was taking and adherence to ART ($p > 0.05$). However, focus group discussion revealed that patients had difficulties adhering to the ARV regimen efavirenze for example one 35 years old lady said

“It is difficult to take efavirenze during working days it makes me feel sleepy. My boss became so curious what was the matter because I used to feel sleepy on daily basis and sweat excessively some times. I opted to be skipping the dose than disclose my status”

“Efavirenz tablets are big and very uncomfortable, you feel like they can choke you or as if they have stuck in the throat. Sometimes I deliberately avoid them. A 27 year old female ARV user”. These findings were supported by a study on AIDS patients in Uganda (Byakika *et al.*, 2005). Fixed dose combination had reduced the number of pills per dose the patient was supposed to take per day and this enhanced ART adherence.

4.5.3 Doses of treatment regimen missed by respondents

Thirteen percent of respondents missed a dose or more of Nevilast 40, 8.3 % missed a dose or more of Triomune 30, 1.3 % missed a dose or more of Efavirenze, 1% missed a dose or more of Tenofovir, and 2.3% missed a dose or more of Zidovudine (ZDV or AZT). Only 0.3% of respondents missed a dose or more of Abacavir. Majority of respondents 74% did not miss any treatment dose (Table 4.4).

Table 4.4 Distribution of respondents according to doses of treatment regimen they missed

Treatment regimen taken by respondents	Frequency of doses missed	Percent
Nevilast 40	38	12.7 %
Triomune 30	25	8.3 %
Efavirenze	4	1.3 %
Tenofovir	3	1.0 %
Zidovudine (ZDV or AZT)	7	2.3 %
Abacavir (ABC)	1	.3 %
No treatment dose missed	222	74 %
Total	300	100.0 %

This finding shows that most people missed Nevilast 40. It was not known why most people missed this ARV drug.

4.5.4 Reason(s) for missing dose(s) of ARV treatment regimen

Majority of respondents 18.7 % who did not adhere to treatment said that they forgot to take ARV drugs, 2 % said that they missed their treatment doses due to fear of stigma or disclosure, 1.3% said they missed ARV doses because they were very ill, 1% respondents mentioned pill burden as the cause of them to miss their treatment doses. The rest of respondents who missed treatment doses 1% said they felt better and therefore they missed treatment doses. Those respondents who missed treatment doses due to alcohol abuse were 0.3% and those who missed treatment doses due to side effects were 0.7 %

Table 4.5)

Table 4.5 Distribution of respondents according to reason(s) for missing treatment dose(s)

Reason(s) for missing treatment dose(s)	Frequency	Percent
Developed toxicity/side effect	2	.7 %
Forgot to take ARV	56	18.7 %
Felt better	3	1.0 %
Too ill	4	1.3 %
Fear of stigma/disclosure	6	2.0 %
Stock finished	3	1.0 %
Drunk alcohol	1	.3 %
Pill burden	3	1.0 %
Did not miss any dose	222	74 %
Total	300	100.0 %

This showed that respondents had various reasons that made them miss treatment doses.

A significant relationship existed between reasons for missing treatment doses and adherence to ART ($\chi^2 = 300$, $df = 8$, $p < 0.0001$). This association was statistically very strong. The factor that mostly influenced non-adherence to ART was forgetting (18.7%). Patients said they were busy and therefore easily forgot to take ARV drugs especially the

morning dose. This finding indicates that if there is a single dose per day ARV regimen and then patients are encouraged to choose a convenient hour for taking ARV medication in the evening; then a simple reminder like alarm clock can greatly improve adherence to ART.

This finding was supported by studies on AIDS patients in USA, Canada, Belgium, Brazil and Botswana that showed forgetfulness, fear of side effects, feeling better, feeling too sick and pill burden as reasons for ART non-adherence (William and Fournery, 2000, Mills *et al.*, 2006). From focus group discussion, some respondents mentioned that once they started ARV treatment the urge for sex increased.

“Once I knew my status I decided to abstain, but since I started taking these ARV medicines my libido (urge for sex) has really gone up. It is a challenge. Some times I opt not to take these ARV medicines. I don’t know what to do. A 38 year old female respondent said”. Other patients felt they needed to take a break from ARV medication (treatment fatigue). They said they felt better and abandoned ARV medicines.

4.5.5 Source of ARV drugs

Majority of respondents 92% said that government health facilities are the source of ARV drugs. Five percent said that they would get ARV drugs from a chemist in case their ARV drugs got finished, 1.7 % said that they would get ARV from a friend, 1.7% said that they could get ARV drugs from mission hospitals (Figure 4.12).

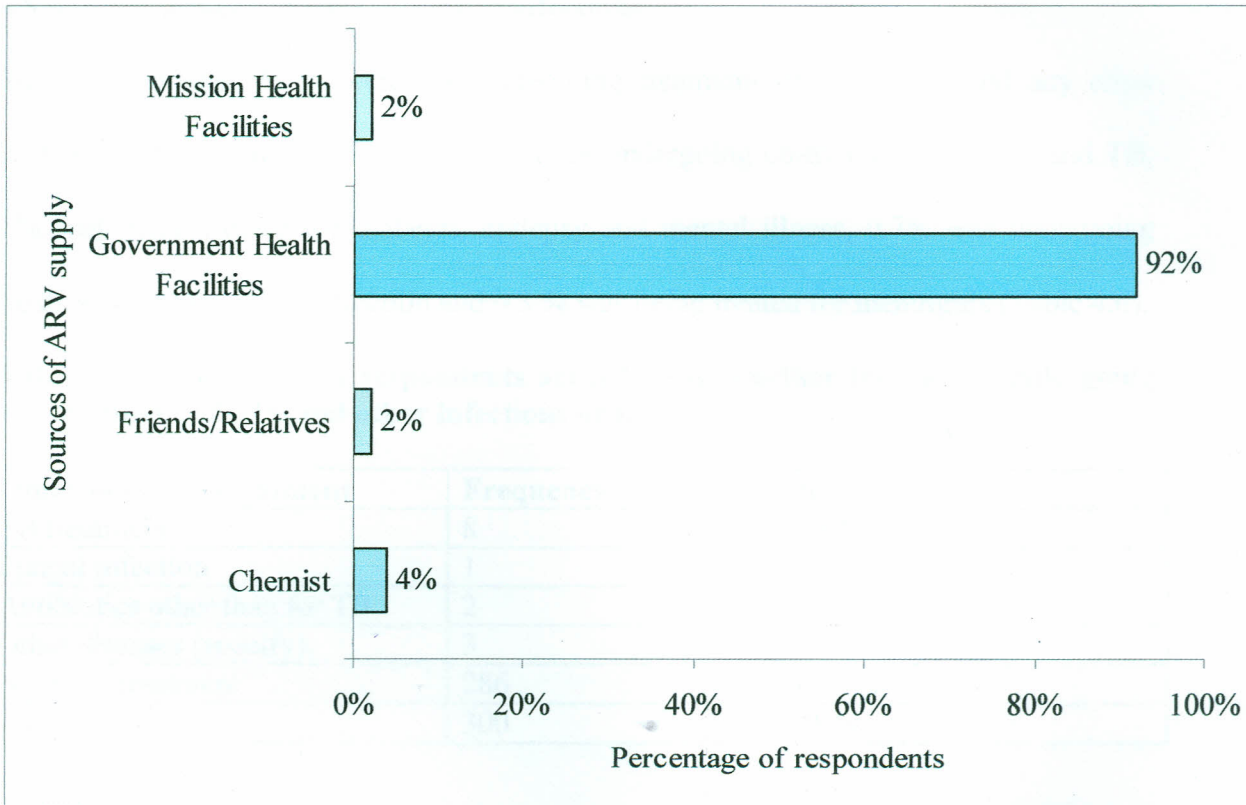


Figure 4.12 Distribution of respondents according to knowledge on source of ARV drugs supply

This finding indicated that majority 92% of respondents were aware of where they should get their ARV medication. Therefore ARV re-supply was not a problem to patients. No significant association existed between the knowledge about where to get ARV supply and adherence to ART ($p > 0.05$). Focus group discussion found that some couples would share ARVs for instance a husband would take partner's ARVs irrespective of his status. This jeopardised adherence to ART.

4.5.6 Co-treatment of HIV and other infections

Most respondents 95 % were not undergoing treatment of both HIV and any other infection. Three percent of respondents were undergoing co-treatment of HIV and TB, 1% was being treated for diabetes, epilepsy and mental illness, 0.7% was undergoing treatment against fungal infection and 0.3 % was being treated for meningitis (Table 4.6).

Table 4.6 Distribution of respondents according to whether they were undergoing Co-treatment of HIV and other infections or not

Other infection treatment	Frequency	Percent
TB treatment	8	2.7 %
Fungal infection	1	.3 %
Antibiotics other than for TB	2	.7 %
Other diseases (specify)	3	1.0 %
No other treatment	286	95.3 %
Total	300	100%

This finding implied that majority 95% had no other infections. A significant association existed between treatment of both HIV and other infections and adherence to ART ($\chi^2 = 12.198$, $df = 4$, $p = 0.016$). Fifty percent of respondents who were undergoing co-management of HIV and TB did not adhere to ART and they mentioned pill burden as the reason. Three respondents who were undergoing mental treatment, epilepsy and diabetes respectively had difficulties adhering to ART. Epileptic patients could not adhere to ART because when epileptic seizure occurred close to the hour of taking ARV medicines the patient could hardly take ARV medicine even after the epileptic seizures. Patients who were mentally ill also did not adhere to ART because of depression.

4.6 Health care facility and health care providers influence on adherence to ARV treatment

Majority of respondents 98.7% said that they were able to follow their ARV treatment, 98.3% said that they knew the importance of following the course of treatment strictly and only 1.7% said that they didn't know the importance of strictly following the course of ARV treatment. Majority of respondents 99% admitted that they were counselled especially before they were started on ARV treatment, 1% said they were not counselled. Almost all respondents 99.7% agreed that it was important for HIV- patients to be counselled as they continue with ARV treatment because it helped to improve ART adherence. Majority of respondents 96.7 % said that privacy was maintained during consultations and only 3.3 % said privacy was not maintained. This finding showed that health care providers adequately informed their patients regarding ARV medication.

A significant relationship existed between ability to follow ARV treatment and adherence ($\chi^2 = 5.059$, $df = 1$, $p = 0.024 < 0.05$). This was because of information that the respondents were getting from healthcare providers. Respondents knew the importance of following the course of treatment, side effects that could result from medications, what to do to ensure ART adherence, importance of counselling before starting and during treatment and importance of privacy during consultation. These findings were confirmed by observation and focus group discussion. These findings were supported by another study done on HIV patients and health care providers where exit interviews, observation, focus group discussion and key informant interviews demonstrated that, patients who were adequately informed about antiretroviral therapy adhered to ART (Abah *et al.*, 2004).

Lack of infrastructure influenced non-adherence to ART. For example patients mentioned congestion and lack of privacy at pharmacy. Key informants mentioned lack of proper functioning laboratory and insufficient counselling rooms. Workload made health care providers unmotivated and this influenced non-adherence to ART. Although statistical analysis did not reveal clinical setting and services provided as very strong factors that influence non-adherence to ART; focus group discussion revealed that poor clinical setting and poor service delivery strongly influenced non-adherence to ART. The following findings (4.6.1 - 4.6.7) below were obtained from observation and exit interviews.

4.6.1 Health Care Facility

The P.G.H Nyeri, Karatina District Hospital and Thika District Hospital had a treatment guideline (from NASCOP). The P.G.H Nyeri, Karatina District Hospital and Thika District Hospital Comprehensive Care Clinics had functioning diagnostic laboratories. The criteria for starting ART in all the three health facilities were HIV positive, a CD4 count of less than 200 and weight loss >10% of body weight, unexplained diarrhoea > 1 month, unexplained fever > 1 month, oral candidiasis, oral hairy leukoplakia, pulmonary TB in the past year, recurrent bacterial infection for instance pneumonia and having been bedridden <50% of the day for the past month (WHO stage 3) or having HIV wasting syndrome, pneumocystis carinii pneumonia, mucocutaneous herpes simplex > 1 month, extrapulmonary TB, atypical TB, Kaposi's Sarcoma, Candidiasis of the Oesophagus, Toxoplasmosis of the brain, Extrapulmonary Cryptococcosis, Disseminated Mycosis, Non-typhoid salmonella septicaemia, Lymphoma, Cryptosporidiosis with diarrhoea > 1

month, Cytomegalovirus infection outside liver, HIV Encephalopathy ,Progressive Multifocal leucoencephalopathy and having been bedridden > 50% of the day during the last month(WHO stage 4) of AIDS (Republic of Kenya, MoH, 2004).

All the three comprehensive care clinics had preparedness to ARV treatment program. These programs worked with PLWHAs on an individual basis. All the three comprehensive care clinics required a proof of adherence to prophylaxis against opportunistic infections, usually cotrimoxazole and in some cases isoniazid. The three comprehensive care clinics had a pharmacist. In the three study sites the clinic ran daily, the patients were counselled, prescriptions were filled and the pharmacist dispensed ARVs on daily basis but no reliable data was kept on pill count.

Counselling was conducted at the three comprehensive care clinics by clinicians or by a trained HIV counsellor. The three study sites had a nutritionist who offered counselling on dietary needs to PLWHAs. At PGH Nyeri and Karatina District Hospital there was shortage of rooms for counselling. ARVs were dispensed free of charge in all the three comprehensive care clinics where the study took place but other medical services like laboratory services were offered at a user fee.

At the time of the study, there were no ARV drugs stock outs reported over the past two months. The three study sites were dispensing ARV drugs whose dose was one tablet twice a day. At Thika District Hospital there was a problem of storage for ARV drugs at pharmacy but rooms for counselling and consultation were adequate.

4.6.2 Quality of Care

Perceived quality of care may be a crucial issue for PLWHAs to have long term ART adherence. In this study data was collected on quality of care from sources such as in-depth interview and exit interview with PLWHAs and observation on health worker – PLWHAs interaction.

4.6.3 Privacy

In the three health facilities where the study was carried out, PLWHAs privacy was respected. Privacy was observed during consultations. However, in the three study sites PLWHAs complained about privacy at the pharmacy. They said that they were exposed to all other patients from other clinics waiting at the pharmacy for medicines. They feared that somebody who knew them might suspect that they were suffering from HIV and disclose to other people. This fear was an indicator that stigma was still high in the study area. This finding was supported by focus group discussion where respondents confessed suffering from stigma and discrimination even at home. At Karatina District Hospital PLWHAs had porridge or tea together as a way of improving social support. They felt knowing, supporting and sharing experiences with each other made it easier to adhere to ART. Clearly the importance of privacy depend on the over all set of the ARV treatment centre.

4.6.4 Respectful treatment.

Almost all interviewed PLWHAs expressed their satisfaction about the way they were treated by the health workers as one female responded on the question how she felt being

treated by health staff: *“good! good, all care providers; they are very kind and caring to you”*. They were welcomed in a friendly way, felt they can express their concerns and asked questions they wanted to have answered. For example one PLWHA who had missed a dose questioned the health worker about the risk of treatment failure due to non-adherence.

4.6.5 Information given to PLWHAs

Informing PLWHAs about ARV treatment and related issues is supposedly of major influence in enabling them to be more adherent. In this study information given to the first-time- visiting PLWHAs was observed in health –worker PLWHAs interactions and questioned in the exit interview as well. In particular PLWHAs were asked whether the health workers provided them with information about medications, importance of continuous following of ARV treatment regimen, when and how to take medicines, what possible interactions may occur, what possible side effects may occur, what to do when they forget to take medicine, and where to get ARV re-supply. Majority of respondents interviewed said that they got adequate amount of information and they responded to questions adequately.

4.6.6 Waiting time

Another quality of care of crucial importance to maintaining high ART adherence levels over a long period of time is avoidance of long waiting time. The observation showed that waiting time ranged between 30-60 minutes. Some respondents reported that waiting time needed to be minimized.

4.6.7 Efforts to enhance adherence

The three study sites (PGH Nyeri, Karatina and Thika District Hospitals) had conducted several measures to enhance adherence to ARV treatment. Written information (leaflets) was available in all the three clinics. Follow-up program was monthly clinical reviews. The three clinics kept a diary of appointment and at Thika District hospital they were taking telephone contacts with aim of using phone calls and short messaging. This was only done when financial resources were available. Pharmacists and counsellors advised patients to be using an alarm clock as a reminder. Health workers reported that some patients deliberately gave wrong contacts in efforts to avoid follow up. The same patients hesitated to identify any treatment supporter. This was an indicator of fear of disclosure due to stigma. This together with lack of resources made it difficult to trace defaulters. At the three study sites, health care providers despite the huge workload provided high quality counselling. From the observation of 8 counselling sessions it was noted that most patients were welcomed in a friendly manner and were listened to carefully. A middle aged PLWHA expressed his feeling during the interview: “...*they are really very caring...*” Results from exit interviews with 10 PLWHAs also supported this finding. Most of them were satisfied with the services and said that they respected and trusted the health care providers.

Interviews with health care providers indicated that most of them were extremely enthusiastic and passionate, though some health care providers complained about the heavy workload, salary delay and inadequate recognition by the government about extra work done. Health care providers expressed their hope that the government would assist

in creating a more enabling environment for ARV treatment by providing community sensitising programme, to positively influence the support system that PLWHAs under ARV treatment need. Health care providers suggested that the NGOs dealing with HIV and AIDS should link up with government comprehensive care centres to maximize on service delivery.

CHAPTER FIVE: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Overview of summary, conclusions and recommendations

This chapter sums up the findings of the research; outlines the implications of the study findings; conclusions based on the research findings; recommendations and suggestions for further research.

5.2 Summary of findings

The study set out to establish the factors that influence non-adherence to antiretroviral therapy among AIDS patients. The study demonstrates that the research questions and objectives had been met. The study findings indicated that the level of adherence (74%) in Central Province, Kenya is sub optimal (less than 95%). Patient factors such as age, household size, alcohol use, occupation, education and social economic and cultural factors such as poverty, transportation cost, cost of food, absenteeism from work, stigma and discrimination, denial, lack of family support, community and employer support, preference to traditional medicine, belief in spiritual healing (religion) profoundly influenced non -adherence to ART.

Management of co-infections influenced negatively adherence to ART. Antiretroviral regimen that is number of drug regimens per day, number of pills per regimen and therapeutic class composition of drug regimen influenced non-adherence to ART. However fixed doses combination of ARV have improved adherence to ART. Health care infrastructure and quality of relationship with health care providers determined whether patients adhered to ART or not.

Efforts to enhance adherence to ART by both patients and health care providers were met by challenges that limited their success. Patients lacked economic power to consistently meet their basic needs. The need to coordinate ART adherence and family, work responsibilities at home and at work place and maintain a cordial interpersonal relationship made it difficult for patients to achieve successful ART adherence. Lack of motivation among health care providers due workload; lack of recognition by government for extra work done; lack of capacity building and poor infrastructure made it difficult for health care providers to address the challenges of ART adherence particularly among the youth, pediatric and the elderly.

To improve adherence to ART, health care providers recommended that: NGOs dealing with HIV and AIDS should link up with government health facilities to ensure success of ART programmes; monitoring and evaluation of ART programs should target at making pill counting system operational, improving defaulter tracing systems; government should set up youth friendly programs and continue educating patients and community to eradicate stigma and discrimination which is still a huge obstacle to success of HIV prevention and treatment programs. Patients recommended that: the government should provide food and transport for those genuinely in need and provide income-generating activities among AIDS patients. They also requested the government to provide pharmacy at comprehensive care centers to ensure privacy.

5.3 Conclusions

- i) Level of adherence (74%) was sub-optimal but comparable to other developing countries.
- ii) Taking ARV drugs without eating any food made patients suffer from side effects thus making them avoid taking the medication.
- iii) Stigma, discrimination, lack of family and community support are huge obstacles to ART adherence.
- iv) Co-treatment of HIV and other infections remains a major challenge. Type of ARV drug influenced ART adherence.
- v) Shortage of appropriate paediatric formulations and unpalatability of some ARV drugs influenced pediatric ART non-adherence.
- vi) Health facilities with functioning laboratory, adequate personnel and stock of ARV drugs enhanced ART adherence.

5.4 Recommendations

To enhance ART adherence the study recommends to the Ministry of Medical Services, Ministry of Public Health and Sanitation and other stakeholders to:

- i) Develop strategies to ensure food security in households with people living with HIV and AIDS.
- ii) Intensify health education campaigns against stigma and promote family and community support for people living with HIV and AIDS.
- iii) Develop adequate and appropriate paediatric ARV drug formulations that are palatable.

- v) Ensure that all public health facilities have a functioning laboratory, adequate personnel and stock of ARV drugs.

5.5 Suggestion for Further Research

- i) There is need for a study on co-treatment of AIDS and other infections.
- ii) Determine why ARV (Nevilast 40) is skipped by most respondents.

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APPENDIX I

Consent Form

Hello, my name is Nyambura Anthony Wanjohi. I am a Master of Public Health student at Kenyatta University, Nairobi. Today I am here to carry out a study on treatment among HIV- patients. The information you give is important and therefore kindly be sincere in your responses. I assure you that the information you give will be handled with total confidence and at no time will you be required to identify yourself by name. To participate you must have started treatment. Kindly answer the questions as completely and as clearly as possible. You are free to choose either to participate or not to participate.

Do you agree to participate in the study? No [] Yes []

If Yes,

Signature.....Date.....

APPENDIX II

QUANTITATIVE DATA COLLECTION TOOL (STRUCTURED QUESTIONNAIRE)

Structured interview guide for the HIV and AIDS patients who are on treatment.

(A) Basic Information

1. Date of interview. _____
2. Study site. _____
3. Code of the interview

(B) Socio-Demographic Information

4. Sex/ Gender of participant (1) Male [] (2) Female []
5. Age in years:
 - (1) 18-20 years []
 - (2) 20-29 years []
 - (3) 30-39 years []
 - (4) 40-49 years []
 - (5) 50-59 years []
 - (6) 60+ []
7. What is your current marital status?
 - 1). Single (not married and not living with a partner) []
 - 2) Married (monogamous/polygamous) []
 - 3). Separated (currently not living together but not divorced) []
 - 4) Divorced []
 - 5) Widowed/ widower []
 - 6) Co-habiting (not married but lives with a partner) []
- 8). Number of children.....
 - 8.1 Age of the last born.....

(C) Socio-Economic Information

- 9). what is/was your main occupation in the last month?
 - 1) Student []
 - 2) Employed full time []
 - 3) Employed part time []

- 4) Business/self employed. []
- 5) Sick leave []
- 6) Voluntary retirement []
- 7) Involuntary retirement []
- 8) Unemployed []
- 9) Others (specify)..... []

(D) Food and Nutrition Security.

10) What is the main source of food for your household?

- 1) Purchase (market/grocery) 4) Welfare/NGO support []
- 2) Household farm/garden 5) Other (specify).....
- 3) Relatives/friends

11). What percent of food currently consumed is from the source mentioned above?.....% []

12). About how much money in Kenya Shillings do you usually spend on buying food for one day in your household?....., don't know []

13). How many meals do you afford to take in day? (1) One [] (2) Two []
 (3) Three []

(E) Level of Education and Knowledge on ARV drugs

14). What is your level of education?

- 1) None []
- 2) Primary education Std 1- 8 []
- 3) Secondary education form I- IV []
- 4) University/college education []
- 5) Adult education []

15). In your own view what are ARV drugs used for?

- 1) Curing []
- 2) Reducing pain []
- 3) Reducing progression of HIV []
- 4) I don't know []

(F) Treatment Regimen and Co-management.**Level of adherence**

Instructions to the study participant: Now I would ask questions on how you have been taking the ARV medications in the past one-month. Please be aware that everyone misses doses in some time. Be assured that this information will neither change the way you receive ARV medications from the treatment center nor your opportunity to participate in this study.

16) Which ART drugs are you currently taking?

1) Stavudine (d4T)	1) No	2) Yes
2) Lamivudine (3TC)	1) No	2) Yes
3) Efavirenze (EFZ)	1) No	2) Yes
4) Nevirapine (NVP)	1) No	2) Yes
5) Tenofovir	1) No	2) Yes
6) Zidovudine (ZDV or AZT)	1) No	2) Yes
7) Abacavir (ABC)	1) No	2) Yes
8) Didanosine (ddl)	1) No	2) Yes
9) Lopinavir/Ritonavir	1) No	2) Yes
10) Other (specify)		

17) Many people find it hard to remember to take every single dose, in the last two weeks, how many doses have you missed?

Name of ARV drug	Number of doses missed
1	
2	
3	
4	
5	

18) What things can make it hard for you to remember your tablets?

- 1) Developed toxicity/ side effect []
- 2) Forgot to take ART []
- 3) Felt better []
- 4) Too ill []
- 5) Fear of stigma/disclosure []
- 6) Stock was finished []
- 7) Drunk alcohol []
- 8) Too many pills/ pill burden []
- 9) Other (specify) _____.

19). Where can ARV drugs be obtained?

- 1) Chemist/ pharmacy []
- 2) Friends/ relatives []
- 3) Government Health central, hospitals and clinic []
- 4) Mission hospitals/clinics []
- 5) Don't know []
- 6) Other specify _____.

20). What other drugs (besides anti-retroviral) are you currently on (tick as appropriate)

Tick	Drug	How many times per day
1	Pain killers	
2	Appetitive stimulants/vitamins	
3	Sleeping pills	
4	TB treatment	
5	Antibiotics(other than for TB)	
6	Fungal infection treatment	
7	Others specify.....	

(G) Practice of Health Care Providers and Patients on ART

21). Are you able to follow ARV therapy regimen? No, [] Yes, []

22). Were you told the importance of completing the full course of treatment?

No, [] Yes, []

23). Were you told about the side effects and interactions of these drug(s) given?

No, [] Yes, []

24). Have you received any counseling during your treatment? No, [] Yes, []

25). Do you think counseling is useful for HIV patients on treatment? No, [] Yes, []

26). Was privacy maintained during consultation? No, [] Yes, []

(H) Social-Cultural Factors

Attitude/ perceptions towards ART

27). What is your opinion regarding ART therapy 1) Approve [] (2) Disagree []

(3) Undecided []

28). If disapprove what are the reasons?.....

29). Do you avoid friends or relatives because of your illness? No, [] Yes, []

30). In the last one month did you have any family or community member who supported (reminded or encouraged) you to take your ARV medications? No, [] Yes, []

31). If yes, who was the person who supported you?

(Check one response only)

1) Spouse []

2) Immediate member of family (specify) []

3) Nurse []

4) Doctor []

5) Social Worker/Community Health Worker []

6) Friend []

7) Other specify.....

32). Do you think that ARV will have a positive effect on your health? No, [] Yes, []

33). What benefits have you gained from using ARV drugs (1) Gained more weight/energy [] (2) No more frequent sickness [] (3) Child grows normally now []

34). Do you think ARV drugs can prevent the child you are expecting from HIV infection No, [] Yes, []. Only for pregnant women.

Thank you for taking time to participate in this interview

APPENDIX III**FOCUS GROUP DISCUSSION (FGD) GUIDE.**

I would like to inform you (participants) that your participation will be tape recorded. The information obtained will be treated in absolute confidentiality and will be used only for purpose of this study.

- 1) What would say is anti-retroviral therapy?
- 2) Are there any benefits patients obtain from using anti-retroviral therapy?
- 3) Everyone sometimes misses treatment doses, what do you think makes one to miss treatment doses?
- 4) Is it good to have privacy during consultation?
- 5) What social-cultural factors do you think hinder one from following treatment as required?
- 6) Are there problems at family level you think hinder you from taking your treatment property?
- 7) One needs a lot support when undergoing treatment, have you ever been supported by any one. If yes who is that person?
- 8) What would you like to be done to improve service delivery in comprehensive care clinic

APPENDIX IV

QUALITATIVE DATA COLLECTION TOOL- (KEY INFORMATION INTERVIEW GUIDE).

HEALTH CARE PROVIDER

Are you readily available at the CCC?.....

What is your own view on ARVs?.....

What are the constrains you encounter while administering ARV drugs for CCC patients?.....

What do you think hinder patients from adhering to ARV treatment?.....

What would you like improved in the CCC programme?.....

APPENDIX V

OBSERVATION GUIDE

What is the facility profile?.....

Is PLWHA's privacy respected?.....

What information is given to PLWHAs?.....

What is the waiting time at the CCC clinic?.....

APPENDIX VI

CHECKLIST MATERIALS

Name of health care facility.....

Date of interview.....

(The investigator should see the materials)

Record cards	1) available	2) not available	[]	[]
Record dairy	1) available	2) not Available	[]	[]
Counseling room	1) available	2) not Available	[]	[]
Have testing kits	1) available	2) not Available	[]	[]
Examination gloves	1) available	2) not Available	[]	[]
Spirit and alcohol swabs	1) available	2) not Available	[]	[]
Literature on CCC at the (HCF)				
Leaflets	1) available	2) not Available	[]	[]
Booklets	1) available	2) not Available	[]	[]
Posters	1) available	2) not Available	[]	[]
Most flowcharts	1) available	2) not Available	[]	[]
Flip charts	1) available	2) not Available	[]	[]
Newsletter for clinic provider	1) available	[]	2) not Available	[]

Available drugs

How are drugs stored?

Are they kept cool No, [] Yes, []

Are they kept in dark No, [] Yes, []

If no drugs are available, what are the reasons?.....

Which ART combination are the patients currently taking? (Review the patient's records)

Drug	How often do they take them?		
1)	[] Once	[] Twice	[] Thrice
2)	[] Once	[] Twice	[] Thrice
3)	[] Once	[] Twice	[] Thrice
4)	[] Once	[] Twice	[] Thrice



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email: kutbps@yahoo.com

Our Ref: I57/12666/05
Your Ref:

Date: 21st November, 2007

The Permanent Secretary,
Ministry of Education, Science & Technology,
P.O. Box 30040,
NAIROBI

Dear Sir/Madam,

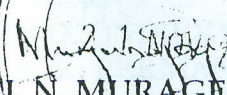
RE: RESEARCH AUTHORIZATION:
NYAMBURA ANTHONY WANJOHI - REG. NO.
I57/12666/05

I write to introduce Mr. Nyambura Anthony Wanjohi who is a Postgraduate Student of this University. He is registered for a M.P.H. degree programme in the Department of Public Health.

Mr. Wanjohi intends to conduct research for a project entitled: "Factors that Influence Non-Adherence to Treatment Among HIV and AIDS Patients in Central Province Kenya."

Any assistance given to him will be highly appreciated.

Yours faithfully,


J. N. MURAGE

FOR: DEAN, GRADUATE SCHOOL

C.C. Registrar (Academic)
Dean, Graduate School - to note on file
Dean, School of Health Sciences
Chairman, Department of Public Health

JNM/cww

REPUBLIC OF KENYA



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REF: MOST13/001/37C798/2

29th November 2007

NYAMBURA ANTHONY WANJOHI
KENYATTA UNIVERSITY
P O BOX 43844
NAIROBI

Dear Sir

RE: RESEARCH AUTHORIZATION

Following your application for authority to conduct research on "Factors that influence non-adherence to treatment among HIV and Aids patients in Central Province, Kenya". This is to inform you that you have been authorized to carry out research in Central Province for a period ending 30th January 2008. You are advised to report to the Provincial Commissioner Central Province, and the Provincial Medical Officer Central Province before commencing your research..

On completion of your research, you are expected to submit two copies of your research report to this office

Yours faithfully

A handwritten signature in black ink, appearing to read 'M.O. Ondieki'.

**M.O. ONDIEKI
FOR: PERMANENT SECRETARY**

CC:

THE PROVINCIAL COMMISSIONER
CENTRAL PROVINCE

THE PROVINCIAL MEDICAL OFFICER OF HEALTH
CENTRAL PROVINCE

**For PERMANENT SECRETARY
MINISTRY OF EDUCATION
SCIENCE AND TECHNOLOGY**

OFFICE OF THE PRESIDENT



PROVINCIAL COMMISSIONER
CENTRAL PROVINCE
P.O. Box 33-10100

11th December 07
..... 20.....

Telegrams:
Telephone: Nyeri 30619
When replying please quote
Ref. No. ADM 1/57/161
.....
and date

The Provincial Medical Officer
CENTRAL PROVINCE

RE: RESEARCH AUTHORIZATION: NYAMBURA ANTHONY
WANJOHI

The above named is a student from Kenyatta University pursuing a masters degree. He is hereby authorized to conduct research on "Factors that influence non-adherence to treatment among HIV and Aids patients in Central province".

This is therefore to request you to allow him access the following facilities PGH Nyeri, Karatina and Thika District Hospitals.

Original Signed by

Wenstas S. A Ong'ayo

W. S. A. ONG'AYO OGW
FOR: PROVINCIAL COMMISSIONER
CENTRAL PROVINCE

Appendix X: MAP OF THE STUDY AREA



MAP OF CENTRAL PROVINCE

