

**ASSESSMENT OF FACTORS INFLUENCING ADHERENCE TO
ANTIRETROVIRAL THERAPY AT NYERI PROVINCIAL HOSPITAL
IN CENTRAL KENYA**

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DECLARATION

This thesis is my original work and has not been presented for a degree or other award in any other university

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DEDICATION

I dedicate this research thesis to my parents and my loving wife for the support and encouragement they have accorded me especially during my postgraduate studies.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti Retroviral Therapy
ARV	Anti Retro Viral
CCC	Comprehensive Care Clinic
CI	Confidence Interval
DOT	Directly Observed Therapy
FDC	Fixed Dose Combination
HAART	Highly Active Anti Retroviral Therapy
HIV	Human Immunodeficiency Virus
Ksh	Kenya Shilling
MEMS	Medication Events Monitoring System
NACC	National AIDS Control Council
NASCOP	National AIDS/STD Control Program
NNRTI	Non Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
OR	Odds Ratio
PGH	Provincial General Hospital
PI	Protease Inhibitor
PLWHA	People Living With HIV and AIDS
PMCT	Prevention of Mother to Child Transmission
STD/ STI	Sexually Transmitted Disease/ Infection
UN	United Nations
UNAIDS	United Nations Program on HIV and AIDS

UNDP	United Nations Development Program
USAID	United States Agency for International Development
VL	Viral Load
WHO	World Health Organization

DEFINITION OF TERMS

Active patient	A patient who has been registered and receives regular ART at a given facility
Adherence	For the purposes of this study, this refers to the extent to which patients follow the instructions of their health care providers with regard to taking their medicines
Adherence to ART: (Optimal)	Taking more than 95% of the prescribed pills in a given time
Adherence to ART: (Non-adherence or sub-optimal adherence)	Taking less than 95% of the prescribed pills in a given time
ART Acceptability	A measure of the patients' views on the professionalism, competence and attitude of healthcare providers, the quality of health education at the ART clinic and the benefits or adverse effects of ART
ART Accessibility	A measure of the patient's views on the appropriateness of physical location of the ART clinic, waiting time, ease of access to healthcare workers and convenience of the facility to the patient
ART Affordability	A measure of the ability of patients to pay for ART related services that they utilize at the facility
ART Availability	A measure of the patients' views on the availability of all the range of medical services that a HIV-infected patient may require including outpatient and inpatient services

ART regimen: First Line	The initial combination of antiretroviral drugs prescribed for an eligible HIV-infected patient who has not taken any ARV drugs before
ART regimen: Second line	The combination of antiretroviral drugs prescribed for a patient after the 1 st line regimen fails to suppress HIV replication
Lost to follow up patient	A patient who has not attended the ART clinic or pharmacy for more than 90 days since the last scheduled appointment and whose whereabouts are unknown to the clinic staff
GAPS Model of Services Quality	An important customer-satisfaction framework that seeks to identify major gaps that face organizations seeking to meet customers' expectations of the customer experience.
MEMS	A special pill bottle with a microchip that records each time a patient removes a pill. The data can then be retrieved into a computer and used to calculate adherence to medication
Meta-analysis	A statistical procedure that integrates the results of several independent studies considered to be combinable
Opportunistic Infections	Infections in an immuno-compromised individual caused by pathogens that usually do not cause disease in a healthy immune system
Pill counts	Method of measuring a patient's adherence to a prescribed regimen that involves counting the remaining doses of medication at the end of a given period and assuming that remaining pills in excess of what is expected represent missed doses
Pill dumping	Occurs when patients remove pills from their containers without taking them to avoid them being counted by the health care provider

Self-report	Method of measuring adherence where the patient voluntarily reports to the healthcare provider the number of doses of ARVs missed over a given period. The period may be 4 days, 7 days or one month.
Transferred out patient	A patient who is registered in the ART program at a facility and is later formally sent to another facility accompanied by a transfer letter signed by a medical officer or nurse at the original facility
Treatment supporter	A relative, friend or acquaintance to a patient on ART who is supposed to assist the patient to improve adherence to ART, attendance of ART clinic appointments as well as offer other support
Virologic failure	Viral load above 400 copies/ml after 24 weeks of treatment, above 50 copies/ml after 48 weeks, or repeated viral loads above 400 copies/ml after prior viral suppression

ABSTRACT

The Nyeri Provincial General Hospital (PGH) was one of the five pilot sites at which the Government of Kenya started providing antiretroviral therapy (ART) to HIV-infected patients in 2003. At this hospital, as in the other pilot sites, there was an increasing number of patients requiring a switch from first line to second line ART drug regimens due to treatment failure. There was little information available on levels of adherence to ART as well as the factors that influence adherence among patients to guide adherence promotion strategies and thus reduce the incidence of virologic and treatment failure. The objective of this study was to assess factors that influence adherence to ART at Nyeri PGH. The study was retrospective and cross-sectional. Two hundred and twenty nine patients were selected from a total of 705 patients who had been active on ART for at least one year and who were on solid drug dosage forms. Stratified random sampling was used to obtain the same relative proportions of adults, paediatrics, male and female respondents in the sample population as in the study population. Semi-structured interview schedules were used to obtain demographic information and patients' views on various dimensions of ART services at the hospital. Pill count data of patients collected over a period covering 3 clinic appointments was used to determine the percentage adherence levels of the patients to ART. For 13% of the patients for whom pill count data was not available, pharmacy refill dates were used to estimate adherence levels. Univariate analysis of various factors was undertaken to examine the odds of adherence and non-adherence to ART with respect to the various factors. Response values and categories were assigned to questions. Patient responses on ART services at the hospital were grouped into four categories: ART Acceptability, ART Accessibility, ART Affordability and ART Availability. The response scores were aggregated per statement and averaged to get mean scores for each category. The mean scores for each category of questions were subjected to correlation analysis to check for the influence of patients' views on their adherence level to ART. The mean adherence rate for all the patients was $92.7\% \pm 8.5\%$. The number of patients exhibiting optimal adherence (greater than 95%) to ART was 125, representing 55% of the total patients interviewed. 197 (86%) of the patients exhibited greater than 85% adherence to ART. Only 11 (5%) of the patients sampled had less than 75% adherence to ART. Being busy with household chores and job-related tasks (39%) as well as travelling (21%) were cited by the respondents as the most important factors affecting adherence. Occupation of patient was found to influence adherence with employed patients exhibiting a higher rate of non-optimal adherence (Odds Ratio of non-optimal adherence: 2.64, 95% CI, 1.3863 to 4.8708, $P < 0.005$). Age, gender, level of education, marital status and knowledge of HIV disease were not found to significantly affect adherence. On correlation analysis, patients' views on ART availability and ART acceptability were significantly correlated with percentage adherence to ART (Spearman's $r = -0.157$, $P < 0.05$ and Spearman's $r = 0.255$, $P < 0.01$ respectively). Based on the adherence levels established in this study showing that about 14% of the study population was at an elevated risk of virologic failure, there is urgent need to institute measures to identify those patients with non-optimal adherence to ART and work out strategies to improve their adherence. Particular effort should be made to prepare practical medication taking plans for employed patients initiating ART therapy.

CHAPTER 1: INTRODUCTION

1.1 Background

The HIV and AIDS epidemic continues to expand globally; an estimated 40 million people are now infected with HIV, and projections suggest that an additional 45 million people will become infected in developing countries between 2002 and 2010 (UN/WHO, 2002). Access to treatment, care, and support for people living with HIV and AIDS remains grossly inadequate. At the end of 2001, fewer than 4% of people in need of antiretroviral treatment (ART) in low and middle-income countries were receiving ART, and fewer than 10% of people living with HIV and AIDS had access to palliative care or treatment for opportunistic infections (UN/WHO, 2002). Unaffordable prices have in the past been one of the most commonly cited reasons for limited access to antiretroviral drugs. However, insufficient capacity of the health sector, including infrastructure limitations and shortage of trained personnel is also a major obstacle to ART delivery in many developing countries.

Antiretroviral drugs delay progression of HIV infection and improve the quality of life in HIV infected persons. The "3 by 5" motto of the World Health Organization (WHO) - treating 3 million by 2005- has provided impetus for greater use of antiretroviral therapy in developing and resource limited countries (WHO, 2003). The advent of combination ART has transformed this disease into a chronic treatable condition for a significant proportion of people living with HIV and AIDS (PLWHA) with access to this treatment. However, the need to maintain patients on treatment for decades rather than years, calls for a long-term perspective of antiretroviral therapy.

Due to the devastating nature of the HIV pandemic in developing countries, there has been a rapid scale up of provision of anti-retroviral medicines to those infected who are eligible to

receive these life-prolonging agents. In addition to poor coverage of key interventions like ART, there are simply not enough resources to do everything everywhere; choices must be made and priorities set to achieve desired cost-effectiveness during interventions (Feachem, 2004).

After about four years of provision of ART at the Nyeri PGH, it is useful to evaluate and analyze the data available for relationships and trends in order to make informed and useful policy and operational decisions to improve and strengthen existing ART systems. Of potential importance may be the factors that influence the outcome of therapy in patients on ART. It would be useful to conduct studies in health facilities offering ART services to investigate these factors.

The nature of adherence to ART is best envisioned by understanding the two dynamic circumstances around adherence (Paterson *et al.*, 2000): Firstly, achieving adherence is an interactive process; While the ultimate responsibility for adherence to treatment rests with the patient, it is a complex process influenced by factors both internal and external to the patient, and a process in which the patient must confront and come to terms with those influences in a manner that is conducive to adherence. Secondly, achieving adherence is not a one-time-only event; it is a dynamic and ongoing process that the patient negotiates each time a dose of medication must be taken. Every day with every dose, clients must navigate those influences, many of them negative and outside their sphere of influence.

Therein lies the difficulty in achieving adherence: negotiating the interplay of influences that come to bear upon the simple act of taking a medication and the fact that, in the case of the HIV-infected person, this negotiation must take place day after day, dose after dose and for as long as the patient is on medication. The WHO characterizes these factors as “interacting

dimensions” that exert negative or positive influences on treatment adherence (Gale and Paul, 2003). Knowledge of the behavioural factors that determine positive treatment outcomes in HIV-infected individuals on antiretroviral therapy would be useful to providers on the most effective mechanisms to employ to enhance and sustain ART uptake.

1.2 Problem Statement

According to the Ministry of Health, Kenya, about two percent of the estimated 160,000 people on free ARVs had developed resistance to the 1st line regimen in 2007 and although these numbers are relatively low, the threat of large-scale drug resistance is real and the consequences are dire (Kenya: Treatment literacy lagging behind ARV rollout, 2007). The Nyeri PGH was one of the five pilot sites chosen by the government of Kenya when the government-supported ART was started in the country in August 2003 (NAS COP, 2008). The other sites were; New Nyanza PGH, Rift Valley PGH, Coast PGH and Kenyatta National Referral Hospital.

In the past five years (from 2003 to 2008), Kenya has made tremendous strides in scaling up ART provision. Patient numbers have risen from barely 3,000 patients in 2002, when the public sector provision of ARVs commenced in Kenya, to 60,400 in 2005 and 172,000 in 2007 (NACC, Office of the President, Kenya, 2008). It is forecast that an increasing number of patients will require to be switched from the 1st line to the 2nd line ART regimens from 2008 to 2010 due to treatment failure (Figure 1.1).

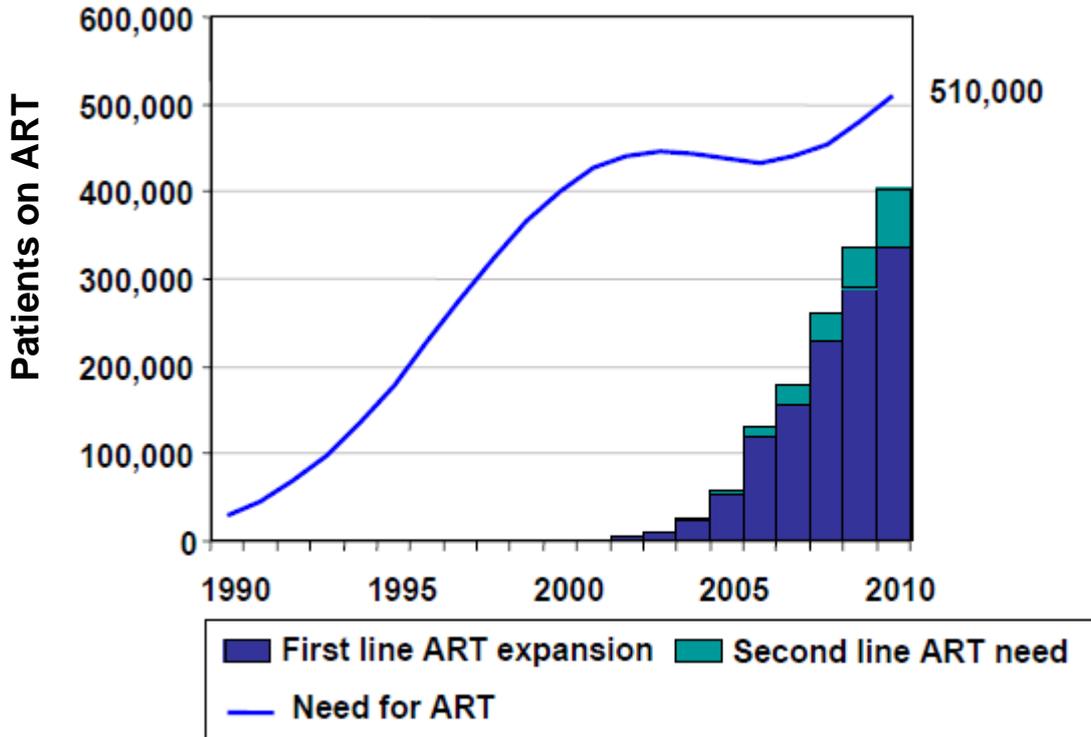


Figure 1.1: Estimated needs for first and second-line ART and its expansion in Kenya
(Source: NACC, 2008)

Nyeri PGH was selected for this study since it was one of the pilot sites for the ART program and therefore had a relatively large number of patients on ART compared to newer sites. In addition, the pharmacy at this hospital had collected pill count data for patients coming for their medication refills for several months hence facilitating calculation of adherence levels to ART. At the time of data collection, none of the four other pilot sites had patients' pill count data in their records. At the Nyeri PGH, as in the other pilot sites, there was an increasing number of patients requiring a switch from the 1st line treatment regimen to the more expensive 2nd line regimen which also has a higher pill burden.

The main reason for switching to the 2nd line regimens is treatment failure secondary to incomplete adherence. High rates of resistance correlate to low adherence to Non Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-based regimens (Bangsberg *et al.*, 2004). Others

include adverse drug reactions and interactions with other drugs like anti-tuberculosis drugs (NASCOP, 2005).

A review of records for a 20-month period by NASCOP concluded that adherence to ART is high based on the fact that only 3% patients stopped ART voluntarily and about 13% of patients were lost to follow up (NACC, Office of the President, Kenya, 2007). However, the review examines only adherence of patients to clinic appointments and not to actual taking of medication. While patients on ART may get clinical care and refills of their antiretroviral and other medication at each clinic visit, it is not known whether they actually adhere to their treatment regimen. It is critical to establish adherence levels among patients on ART in order to detect possible sub-optimal adherence, the factors contributing to this and to correct sub-optimal adherence to avert the looming threat of widespread treatment resistant strains of HIV.

Whereas a number of studies on adherence to ART have been undertaken in the developed countries, few such studies have been conducted in Africa: in Kenya particularly few such studies have been documented. In Kenya, just like Uganda, there is growing concern about loss to follow-up and sub-optimal adherence to ART which have been shown to be significant barriers to care (Kityo, 2002). It is against this background that this study sought to explore various factors influencing ART adherence by patients at this provincial hospital in Kenya.

1.3 Research Questions

- (a) What are the characteristics of patients on long-term antiretroviral therapy?
- (b) What are the proportions of patients exhibiting optimal, high but sub-optimal and low and sub-optimal adherence levels?
- (c) What factors influence ART adherence among these patients?

- (d) How do patients view the availability, accessibility, affordability and acceptability of ART services at the Nyeri PGH?

1.4 Study Hypothesis

There exist no factors that significantly contribute to ART adherence at the Nyeri PGH.

1.5 Study Objectives

1.5.1 General Objective

The general objective of the study was to assess factors that influence adherence to ART at Nyeri Provincial General Hospital.

1.5.2 Specific Objectives

- (a) To establish the characteristics of patients on long-term antiretroviral therapy.
- (b) To establish the proportion of patients exhibiting optimal, high but sub-optimal and low and sub-optimal adherence levels.
- (c) To identify factors influencing ART adherence among these patients.
- (d) To evaluate the views of the patients on accessibility, availability, affordability and acceptability of ART services at the Nyeri PGH.

1.6 Significance of Study

The study was suitably designed to achieve the outlined study objectives. Demographic data of the patients and other information such as socio-economic status and disclosure status of HIV were collected. These data were compared to the adherence to ART medication by the study patients to establish which factors influenced adherence to ART medication.

Other groups of factors that influence adherence are: Healthcare team & health system related factors, characteristics of therapies and condition-related factors (WHO, 2003). Healthcare team & system related factors were not investigated since, for reasons explained in section 1.2, this was a single-centre study. Since all the patients in this study had HIV infection and were all under the care of the same healthcare team, condition-related factors and healthcare team and health system related factors were not expected to account for any observed differences in adherence. The treatment regimens taken by the patients were very similar and thus characteristics of therapy would not be expected to contribute to differences observed in adherence.

Four dimensions of ART service quality as perceived and received by the patients were identified: availability, accessibility, affordability and acceptability of ART medication. These were translated into questions addressing specific issues believed to represent and highlight the four dimensions. They were measured and correlated to other relevant studies and variables for further analysis to establish their relative importance.

The study sought to identify specific issues requiring attention from the service providers while providing scientific foundation for practical patient-friendly recommendations. The study intended to provide a viable platform for informed and useful policy and operational decisions to improve and strengthen existing ART systems as well as to identify areas requiring further research with regard to adherence to ART.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Although global commitment to control the HIV and AIDS pandemic has increased significantly in recent years, the virus continues to spread with alarming and increasing speed. By the end of 2005, an estimated 40 million people worldwide were living with HIV infection or disease, a notable rise from the 35 million infected with HIV in 2001 (UNAIDS, 2005). In 2005, close to 5 million new HIV infections and 3 million AIDS-related deaths occurred. Sub-Saharan Africa remains the region most affected by HIV and AIDS. Despite the rapid spread of HIV, several countries have achieved important success in curbing its transmission.

The extraordinary potential of HIV prevention is exemplified by such diverse efforts as Thailand's 100 percent condom program (UNAIDS/UNDP, 2005), Uganda's remarkable decrease in HIV prevalence (USAID, 2005) and the community-based syndromic management of sexually transmitted infections (STIs) in Mwanza in Tanzania (UNAIDS/UNDP, 2005). Successes also include the development and effective use of highly sensitive and specific HIV screening tests, which have virtually eliminated infection from the blood supply in the developed world and in most parts of the developing world (WHO, 2003). In addition, the administration of a short course of Nevirapine to mothers during labour and to newborns postpartum reduces the risk of mother-to-child transmission (MTCT) by as much as 47 percent (Guay *et al.*, 1999). However, recent data suggest that such short-term successes may be at the expense of resistance and viral failure once treatment is introduced after delivery (Eshlemam *et al.*, 2001).

2.2 Adherence to ART

Adherence to an ARV treatment regimen involves several components: Taking all the medicines which make up the ARV combination in the correct quantities, taking the pills at the right times (taking the medication at the wrong time can cause a rise in viral load and this may lead to the development of drug resistance) as well as ensuring that the medication is taken with or without food, according to the instructions (Carter, 2005). Some medicines need to be taken with food to ensure that the body absorbs them properly while others need to be taken on an empty stomach, a certain amount of time before or after eating. It is also important that the patient eats the right kind of food; for example, the amount of fat eaten can make a difference as to how well some drugs are absorbed. Checking for interactions with any other medication or drugs is critical. This includes medicines that have been prescribed for the patient, or bought at a pharmacy, supermarket or health store, including complementary or alternative therapies. Some recreational and illegal drugs can have potentially dangerous interactions with ARVs (World Health Organization, 2006).

The best response to ART is seen when adherence is 100%. Levels of adherence below 95% have been associated with poor suppression of HIV viral load and a lower increase in CD4 count. When a patient is taking once-daily treatment, 95% adherence means missing no more than one dose a month. If a patient is taking treatment twice a day, 95% adherence means missing no more than three doses a month. If a patient is taking treatment three times a day, 95% adherence means missing no more than four doses a month (Carter, 2005).

The efficacy of combination of antiretroviral therapies (ART) medication for the management of HIV is now well documented. Combination therapies can inhibit viral replication and reduce viral load to a point where viral particles are undetectable in the blood of infected individuals. Significant and sustained suppression of HIV replication is

associated with improved clinical outcomes (Bruno *et al.*, 1999). Adherence to antiretroviral therapy is a powerful predictor of survival for individuals living with HIV and AIDS (Darder *et al.*, 2004).

These benefits are only tenable when adherence to precise dosing schedules is rigorous and other treatment requirements are closely followed. Antiretroviral therapy (ART) has transformed HIV infection into a manageable, chronic condition. The need to continue therapy for decades rather than years, calls for sustained patient adherence to ART. Adherence to the regimen is essential for successful therapy and sustained viral suppression. Studies have indicated that at least 95% adherence to ART regimens is the optimal; moreover a 10% increase in the level of adherence results in a 21% reduction in disease progression (Nischal *et al.*, 2005).

Partial or poor adherence can lead to the resumption of rapid viral replication, poorer survival rates, and the mutation to treatment-resistant strains of HIV (Ajay *et al.*, 2003). Studies have shown that behaviourally based interventions will continue to be integral to the success of any medication advances and their health outcomes. Therefore, understanding and enhancement of ART treatment adherence remains a critical goal for the individuals receiving treatment, for those providing treatment, for public and private health officials who are responsible for making treatment available, and for the public health at large (Bruno *et al.*, 1999).

In response to this pressing need, scientists and practitioners have made significant gains in ART adherence research. For example, progress has been made to simplify dosing regimens, to ameliorate aversive medication side effects, to improve access to health care and to facilitate behaviour changes to avoid re-infection with HIV or other STDs. Efforts have also

been made to intervene with consumer and provider characteristics (such as increase self-efficacy, remove barriers to adherence, treat psychosocial factors that can impair adherence), in order to advance treatment adherence to an acceptable level. However, as the HIV pandemic and treatment rapidly evolves, the goals of ART adherence research must also evolve to build on scientific advances and the changing needs of those affected by HIV (Mannheimer *et al.*, 2005).

Since 1996, an overwhelming amount of evidence from clinical trials has been published validating the use of ART for the management of HIV/AIDS. The biological and clinical goals of ART have been defined as the suppression of viral replication, restoration of the immune response, a halt in the progression of disease, increased survival rates, reduced morbidity and a better quality of life (Pallela and Paterson., 1998). In countries where access to this level of care is available, AIDS-related mortality and morbidity have significantly declined (Sethi, 2003). Consistent and nearly perfect adherence is considered an essential requirement for HIV-positive patients on antiretroviral therapy (ART) to fully realize its life-extending benefits (Fabrizio *et al.*, 2006). However, many factors have been identified as barriers to adherence including unstable residential housing, current active substance use of time-distorting binge drugs, depression, severe side effects, and a past history of non adherence to an antiretroviral drug regimen (Schackman *et al.*, 2005).

In recent years, much effort has been devoted to the assessment of medication adherence in HIV-seropositive persons. Empirical data collected so far to assess sub-optimal adherence to ART medications essentially support what is commonly found in other areas of medicine e.g. hypertension and diabetes management (Amico *et al.*, 2005). Maximum and sustainable suppression of HIV viral replication to below the level of detection is necessary to achieve

these biological and clinical goals. To achieve success requires near-perfect adherence to combination ARV regimens.

2.3 Effects of non-adherence to ART

Many HIV-infected people do not manage to achieve optimal levels of adherence. Failure to suppress viral replication completely inevitably leads to the selection of drug-resistant strains, limiting the effectiveness of therapy. Sub-optimal adherence to ART is the strongest predictor of failure to achieve viral suppression below the level of detection and most often underlies treatment failure. Evidence suggests that greater than 95% adherence may be necessary to adequately suppress viral replication, produce a durable response and halt disease progression (Paterson *et al.*, 1999). This means that missing more than one dose of a regimen per week may be enough to cause treatment failure. In addition to leading to disease progression this may result in the development and transmission of drug-resistant viruses which cannot be treated with first-line (lower cost) medicines. This will require treatment with second- and/or third-line medicines, which are more expensive, associated with many side-effects and are complex to manage.

The challenge of adherence in the face of potential viral resistance, treatment failure, disease progression and the spread of drug-resistant virus to sexual partners is of great concern. Patients on long-term ART with undetectable plasma levels of HIV still harbour replication-competent virus (Furtado *et al.*, 1999). For this reason, with current medications, ART is a life-long process. While conscientious treatment adherence is difficult under any circumstances, the unforgiving nature of HIV replication, the complexity of the ART regimens, and the associated short and long-term toxicity of the medicines all pose difficult challenges for patients (Paterson *et al.*, 1999).

It should be recognized that adherence to ART is a critical issue, and it is clear from previous studies that the factors that influence a patient's ability to adhere are multiple and complex. A multitude of variables such as income, education and marital status have all been shown to affect adherence to ART, to differing degrees. In addition, some studies of ART in developing countries show that resistance is already circulating among patients starting their first "official" course of therapy. The official course therapy is described as that used by a patient when he/she acknowledges his/her HIV status, is willing to speak about it freely and is seeking treatment from an accredited site for proper monitoring and follow-up (Oyugi *et al.*, 2007).

2.4 Enhancing adherence to ART

The goals of antiretroviral therapy (ART) are 5-fold: The clinical goal is prolongation of life and improvement of quality of life. The virologic goal of ART is to achieve the greatest reduction in viral load for as long as possible to halt or delay disease progression. The immunologic goal is immune reconstitution that is both quantitative (CD4 cell count in normal range) and qualitative (pathogen specific immune response). The therapeutic goal is to achieve a rational sequencing of drug regimens in a manner that achieves the immunologic, virologic and clinical goals while preserving future treatment options, limiting toxicity and facilitating adherence and finally, the epidemiologic goal is to limit rate of HIV transmission (Sabin *et al.*, 2005).

Early favourable response of viral load (VL), as soon as six days after ART initiation, can signify that the patient is initially adherent to treatment, which is necessary in the long term for a successful regimen. Early favourable response is also an indicator of adequate pharmacokinetic profile and potent antiviral activity of the drug regimen. It also can indicate that the predominant HIV strain infecting the patient is sensitive to the treatment regimen. It

is worth noting that adherence support is complicated by the fact that tools for measuring adherence which include self-reporting, pill counts, blood tests for viral load and ARV plasma levels, and Medication Event Monitoring Systems (MEMS) caps (which detect and store the times a patient removes pills from the medicine bottle) are only blunt instruments at best. For instance if a patient's blood test doesn't show HIV viral load reduction, it does not necessarily mean the patient hasn't been adhering, since non-adherence is just one of several possible causes for virologic failure (Amir, 2007).

Previous studies that sought to investigate the evaluation of 'adherence initiative' interventions indicate that several techniques and tools can have some positive effect on adherence include: Pharmacist-or nurse-provided education and counselling; Peer counselling and support; Reminder devices (such as beepers and phone calls). Others are: Medication pickup (in which the patient comes to the clinical setting to get his or her medications); Readiness training (educating the patient about the ART regimen, purpose, and side effects and perhaps doing a "dry run" with placebos) (Hsu and Hopkins, 2005; Mannheimer, 2006).

Other studies have also shown that other interventions can be somewhat helpful (Mannheimer, 2006; Simoni *et al.*, 2006; Poppa *et al.*, 2004). These include: Directly Observed Therapy (DOT), in which a health care worker watches the patient take the medications, cued-dose timing (in which the patient learns to take his or her doses around daily events, such as meal times), Electronic reminders, including Internet pagers and programmed wrist watches, cash incentives, timelines (which involve a nurse or other health care employee sitting down with the patient and creating a daily timeline on which dosing times are marked) and pillboxes set up by a clinician.

Each of the adherence strategies listed above has specific limitations. For instance, timed reminders are helpful only if the patient misses doses because s/he is actually forgetting them- but if harsh side effects are the real reason for non-adherence, a patient shies away from taking medications; no system centred on reminders is going to succeed. DOT also works well in controlled settings such as drug rehabilitation facilities or prisons, but its effectiveness immediately ceases once the observation ends. Furthermore DOT is labour intensive, especially when health care professionals must go out into the field to perform it.

It is therefore critical to have intrinsic patient motivation to achieve successful results in ART adherence. Enhanced patient involvement can improve adherence in other illness and motivational interviewing can promote self-efficacy and health behaviour change in ART patients. Golin *et al.* (2002) and Kennedy *et al.* (2004) emphasize the need for self determination as a success platform to achieve consistent adherence to ART medications. They point out that ultimately, patients have the ultimate say on whether they shall take the medication prescribed and any interventions to improve adherence should take cognizance of this fact.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Research Design

A retrospective and cross-sectional analytic approach was adopted for the study. Information was systematically gathered on the largely unexplored and complex interplay of forces contributing to patients' adherence to ART medication at Nyeri PGH. The study used both qualitative and quantitative data to explore patient adherence to ART. Quantitative research was employed to describe the demographic profile of respondents and to gain insight into ART adherence levels. Qualitative research was utilized to understand patient attitudes/perceptions of ART and how they in-turn affected treatment outcomes. In-depth interviews provided a flexible tool to collect narrative data describing interviewees' perspectives. This type of data can be difficult to assess using quantitative methods, particularly in the exploratory stage of research, before the hypotheses can be clearly articulated. The value of qualitative perspectives in social and behavioural health research have gained favour amongst researchers, and in HIV and AIDS research in particular, where many of the social phenomena being studied are personal, intensely private, and sometimes illicit (Rhodes *et al.*, 2003).

3.2 Conceptual Framework

Four interacting elements may cause non-adherence (WHO, 2003): Health care team and system-related factors; Condition-related factors; Characteristics of therapies; and Patient-related factors (Figure 3.1). This study set out to investigate patient-related characteristics that enhance or hinder ART adherence at the Nyeri PGH.

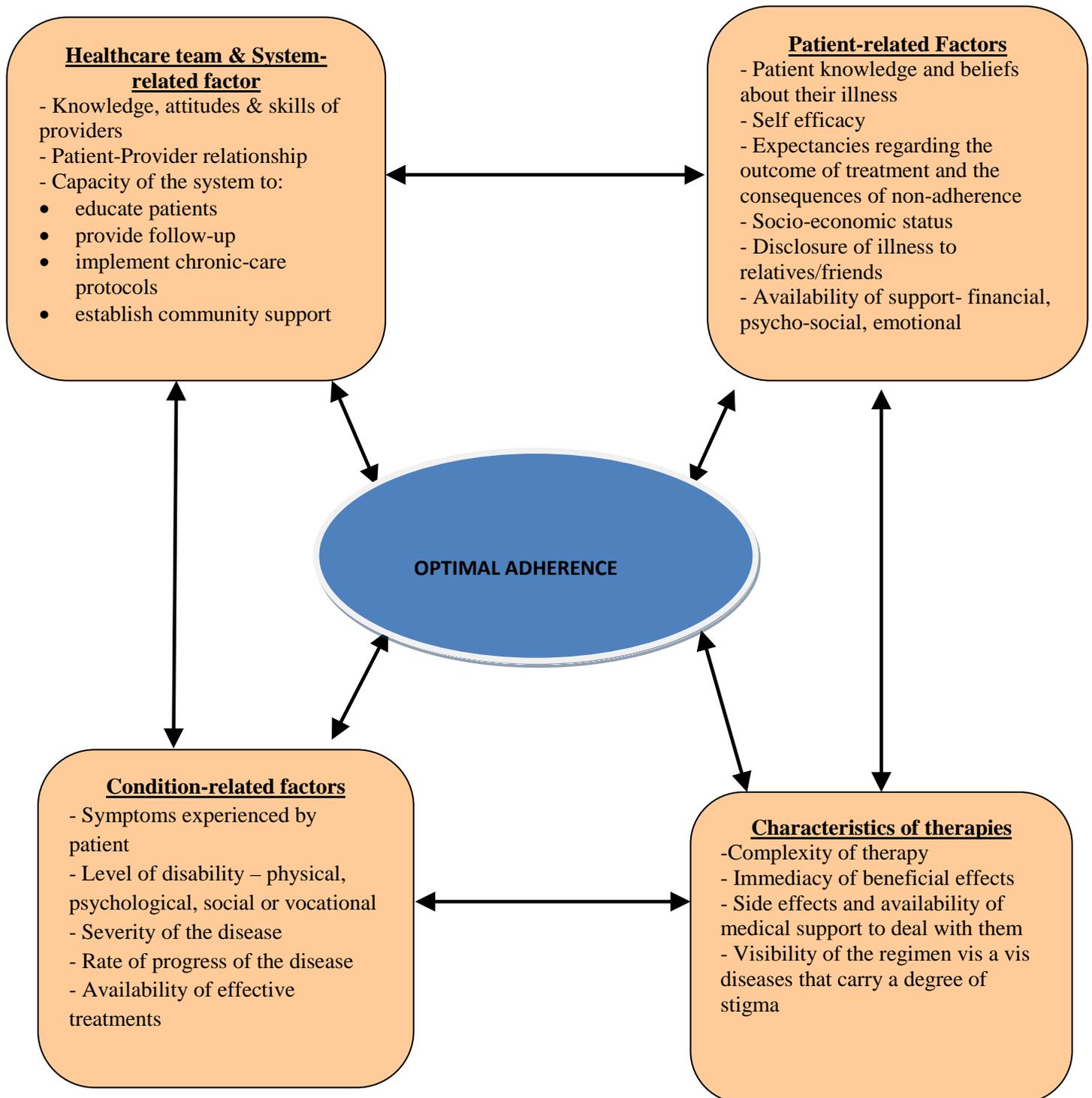


Figure 3.1: Factors affecting adherence to ART (Adopted and modified from WHO, 2003)

3.3 Variables considered in the study

3.3.1 Independent variables

The independent variables investigated in the study were; patient age, patients sex, marital status, disclosure of HIV status, socio-economic status and patients' views on Accessibility, Affordability, Acceptability and Availability of ART services.

3.3.2 Dependent variable

The dependent variable assessed in the study was adherence level to ART.

3.4 Study Duration

The data collection using interview schedules was undertaken from October to December 2007.

3.5 Study Location

The study was conducted at the Comprehensive Care Centre (CCC) for HIV-infected patients in Nyeri Provincial General Hospital. The hospital is in Nyeri District in Central Province of Kenya. Nyeri PGH was selected for this study since it was one of the five pilot sites for the ART program and therefore had a relatively large number of patients on ART compared to newer sites. Whilst the initial intention was to have a multi-centre study of 3 of the pilot sites, this was not possible as, at the time the study was conducted, the 4 other pilot sites did not have documented pill count data required to establish adherence levels.

3.6 Study Population

The study population comprised all adult and paediatric patients on ART for more than one year as at 1st October 2007. The exclusion criterion was patients who did not give informed

consent for the interview and those who had been on ART for less than one year as at 1st October 2007. Nyeri PGH had a total of 1,797 patients on ART between 2003 and September 2007. Of these, 1249 (accounting for 69.5%) were still active on ART. However, only 705 out of 1082 who were started on ART before October 1st 2006 had remained active on ART. These formed the study population.

3.7 Sampling

The formula for determining sample size by Kothari (2005) was used:

$$n = \frac{Z^2 pqD}{d^2}$$

Where:

n = desired sample size if target population > 10,000

Z = standard normal deviate at the required confidence level

P = proportion in the target population estimated to have the characteristics being measured

q = 1 – p

D = design effect- usually 1 where there are no replications

d = the level of statistical significance set

$$n = \frac{1.96^2 \times 0.7 \times 0.3 \times 1}{0.05^2} = 322$$

If the target population is less than 10,000 then the final estimate is calculated using the formula:

$$n_f = \frac{n}{1 + n/N}$$

where n_f = desired sample size where population < 10,000

n = desired sample size where population > 10,000

N = total study population

$$n_f = \frac{322}{1 + 322/705} = 221 \text{ patients}$$

In the treatment of HIV and AIDS, adherence to antiretroviral agents has been observed to vary between 37%-83% depending on the drug under study (Markowitz, 2000; Stein *et al.*, 2000) and demographic characteristics of patient populations (Laine *et al.*, 2000). However, adherence to ART has been shown to be higher in African cohorts than in North American cohorts. A meta-analysis to evaluate estimates of antiretroviral therapy adherence in sub-Saharan Africa and North America by Mills *et al.* (2006) found that, in the pooled analysis of African studies (12,116 patients total), more than 70% exhibited optimal adherence while, in the North American studies, the figure was 55%.

For this study, an adherence figure of 70% was taken given that almost all the patients in the population were on fixed dose combination pills containing Stavudine, Lamivudine and Nevirapine or Efavirenz where they needed to take a maximum of 3 pills daily. Fixed dose combination pills have been shown to enhance adherence by reducing the pill burden to the patient (WHO, 2003).

3.8 Data Collection

The data was collected through semi-structured face-to-face interview schedules and secondary data on adherence based on pill counts and ARV drug refill dates from the patient pharmacy database over the period April to November 2007- which is the period for which pill count data was available.

Sampled patients were interviewed to gather the necessary information. Eight eligible patients who were not in the original sample requested to be allowed to present their views in the study increasing the total number of patients in the study to 229. For 19 paediatric

patients (those below 14 years), administration of the interview schedules posed a challenge because a big proportion of these patients had not been disclosed to their HIV status. Moreover, it is the guardians of these patients who were taken through pre-ART patient education and who were therefore primarily responsible for medication taking by the paediatric patients under their care. Since adherence by paediatric patients is hugely dependent on the guardians' knowledge, attitude and behaviour with regard to ART, a decision was made to interview the guardians in cases where the patient was <14 years.

The interview technique was selected because it is the most suitable for descriptive or explanatory research such as attitude studies or opinion research (Anderson, 1961). In closed questions the respondents chose the relatively best answer from a set of given options. In open questions they were free to express their views unrestricted. The interview schedule for this study was designed to include both types of questions to capture both descriptive and enumerative issues and effectively examine, describe and explain concepts of cause-effect relationship best illustrated by ART adherence. As described in Section 3.6, in the case of paediatric patients (less than 14 years) included in the sample, the interview schedule was administered to the guardian accompanying the patient.

In-depth interviews were factored in the interview schedule. The interviewees had the opportunity to talk freely about perceptions, experiences, events, behaviour and beliefs related to ART. Such informant interviews were used to explore in-depth patients' points of view on ART and how the same affected adherence. This multi-method approach was employed to help capture the core of qualitative attributes of patient-related factors in ART as well as to add check and balance to the whole data collection process. It ensured that triangulation-data was observed from different points of view through collection of high quality data hence cancelling out potential "method effects" (Duffy, 2007). Secondary data

formed a vital base and background from which the study was conducted by providing reference and comparison for contextual discussion during the data analysis process (Anderson, 1961).

The pharmacy ART database was also used to establish the retention rate of patients on ART since the program began. This entailed establishing what proportion of patients who had been initiated on ART at Nyeri PGH before 1st October 2006 were still active on ART at the facility as at 1st October 2007.

3.9 Pilot Study

The interview schedule was pretested at Nyeri PGH on five patients on ART but who were not included in the sample to assess the suitability of the questions in the schedule. This enabled the researcher to obtain some assessment of question validity and data reliability. However, cost and time constraints prohibited comprehensive pilot testing. The initial interview schedule was administered to five patients on ART who were not eligible for inclusion in the study by virtue of having been on ART for less than one year. The interview schedule was repeated with the same five patients after two weeks to test for the reliability of the instrument and consistency of responses.

The pre-testing sought to establish how long it would take to administer the interview schedule (and hence the cost of hiring data collection assistants), which questions were ambivalent, the right use of language and the relevance of questions and coding. The data collection team interviewed each of the five patients together in order to standardize the way the interview schedule would be administered in the actual study. The joint interviews were aimed at establishing a standard way of asking the interview questions by the different interviewers in order to minimize interviewer bias during the actual data collection exercise.

3.10 Data Analysis

Data was analyzed using the Statistical Program for Social Scientist (SPSS) version 12.0 as an appropriate statistical tool for the largely descriptive nature of the study. The patients sampled were stratified into four groups; those exhibiting adherence levels of greater than 95%, those exhibiting adherence levels of 86% - 95%, those with 76-85% adherence and those exhibiting <75% adherence. These adherence levels were selected as they have been associated with different treatment outcomes in various studies (Maggiolo *et al.*, 2005).

In the current study, percentage adherence was determined in 2 ways as described by Liu *et al.* 2001:

Method 1: Where at least 2 pill count measurements were available:

$$\% \text{ adherence} = \frac{(PC_1 + Q) - PC_2}{N_d \times P_d} \times 100\%$$

PC₁ = First Pill Count

N_d = no. of days between visits

PC₂ = Second Pill Count

P_d = no. of pills taken per day

Q = Quantity of ARVs dispensed

Method 2: Where pill count data were not available, the patients refill history in the previous 2 visits was assessed. If the patient was late for the ARV drug refill by *y* days, that patient was assumed to have missed (*y* × P_d) tablets where P_d = no. of pills taken per day.

$$\% \text{ adherence} = \frac{(N_d \times P_d) - (y \times P_d)}{N_d \times P_d} \times 100\%$$

N_d = no. of days between scheduled visits.

Univariate analysis of various factors was undertaken to examine the odds of adherence and non-adherence to ART with respect to the factors. Response values and categories were assigned to questions. Patient responses on ART services at the hospital were grouped into four categories: ART Availability, ART Accessibility, ART Affordability and ART

Acceptability. The response scores were aggregated per statement and averaged to get mean scores for each category. The mean scores for each category of questions were subjected to correlation analysis to check for the influence of patient views on their adherence level to ART.

Patient expectations of ART were reference points for performance against which treatment outcome experiences were compared. The GAPS model of service quality was used to explore patients' satisfaction by identifying disparities between their expectations and perceptions of ART treatment outcomes (Catz *et al.*, 1999). The model assisted in identifying gaps and issues in dimensions of availability, accessibility, affordability and acceptability (Zeithaml and Bitner, 2003) of ART to the HIV infected patients.

3.11 Credibility of Findings and Study Limitations

Reliability refers to the extent to which the same or similar results can be obtained under different circumstances, at different times and using different respondents or interviewers. Validity is the extent to which the research design measures what it purports to measure and therefore meeting the study objectives (Anastas, 1999). For qualitative studies, reliability and validity are more difficult to address adequately than in quantitative studies (Taylor and Crinin, 1994). However, this was addressed by the multi-method approach of data collection, backed by reliable conventional research and statistical analytical techniques. To further enhance interpretive validity the following approaches were observed consistently throughout the study: contextual completeness, awareness of the researcher's influence, and reliability in reporting from transcripts (Leedy, 1997).

Data collection was done at Nyeri PGH. While the selected provider was considered largely comparable to the four other ART pilot sites countrywide, there may have been specific

issues in the catchment area for this facility that would make it different from other regions in the country. These could be different socio-cultural profiles of the population, different economic activities and levels of income as well as different levels of infrastructure development.

Due to limited time, it was possible to get a maximum of only 3 pill count measurements for any patient and only one was available for several patients. Therefore, adherence levels obtained were only for the 2 to 3 months preceding data collection. It would have been preferable to obtain the mean adherence levels over a period of at least 6 months to take care of potential spikes in adherence due to various patient-specific factors e.g. travelling, pill holidays or even transient depression (Monica *et al.*, 2005).

3.12 Ethical Considerations

All medical standards (Kenya Medical Practitioners and Dentists' Board, 2003) and research related ethical standards were observed at all times. Informed consent was obtained from each participant prior to filling the interview schedule and before starting the interview. For participants less than 18 years, consent was sought from parents or guardians. Clearance to conduct the study was obtained from the Medical Superintendent on behalf of the hospital's medical board (Appendix 1).

Participants were informed that they were free to decline or discontinue the data collection process at any given time. No financial rewards or inducements were offered or given to the participants. All interview notes were recorded in a masked way and data obtained were treated confidentially at all times.

CHAPTER 4: RESULTS

4.1 Retention rate of patients on ART for more than one year

From an analysis of the pharmacy ART patient database, the relative proportions of patient population active on ART for more than one year did not differ markedly from those of all the patients ever started on ART at the hospital. The patient statistics for all patients ever put on antiretroviral therapy at the hospital before October 1st, 2006 and those still active on therapy by September 30th, 2007 were strikingly similar (Table 4.1).

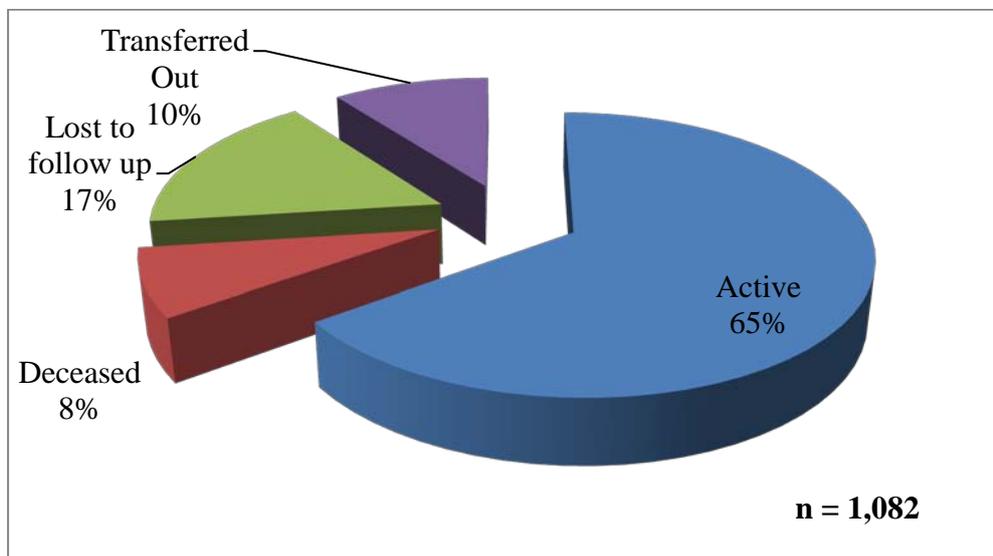


Figure 4.1: Status of patients initiated on ART at Nyeri PGH before Oct 01, 2006 (Source: ART Patient database at Nyeri PGH)

The retention rate (patients known to be alive and receiving ART at the end of a follow up period) for the ART program as at September 30th 2007 was 65% (Figure 4.1). This was the retention rate for patients who had been on ART for one year or longer. Of the 1,082 patients who had been on ART for more than one year, 65% (705) were still active on ART, 8% (85) were confirmed deceased, 10% (111) had been officially transferred out to other health facilities while 17% (181) were lost to follow up (Figure 4.1).

A breakdown of the patient statistics for Nyeri PGH is shown in Table 4.1. The ratio of male: female adult patients started on ART as well as those still active on ART was approximately 1:2. The numbers of patients confirmed deceased was similar for males (40) and females (45). A larger proportion of the patients lost to follow up was female (62%) compared to male patients who constituted 38% of those lost to follow up. Of the patients transferred out, 25 (23%) were male while 86 (77%) were female.

Table 4.1: ART Patient statistics for Nyeri Provincial General Hospital

Patients' Description	All Patients	Gender	
		Male	Female
All patients ever started on ART before Oct 01, 2006 (T)	1,082	375 (35%)	707 (65%)
Adult	965 (89%)	322 (30%)	643 (59%)
Paediatric	117 (11%)	53 (5%)	64 (6%)
Patients started before Oct 01, 2006 still ACTIVE on ART as at Sep 30, 2007 (T₁)	705 (65% of T)	241 (34%)	464 (66%)
Adult	631 (89%)	208 (29%)	423 (60%)
Paediatric	74 (11%)	33 (5%)	41 (6%)
T deceased as at September 30, 2007	85 (8% of T)	40 (47%)	45 (53%)
Adult	78 (92%)	35 (41%)	43 (51%)
Paediatric	7 (8%)	5 (6%)	2 (2%)
T lost to follow up as at September 30, 2007	181 (17% of T)	69 (38%)	112 (62%)
Adult	156 (86%)	57 (31%)	99 (55%)
Paediatric	25 (14%)	12 (7%)	13 (7%)
T Transferred Out as at September 30, 2007	111 (10% of T)	25 (23%)	86 (77%)
Adult	100 (90%)	22 (20%)	78 (70%)
Paediatric	11 (10%)	3 (3%)	8 (7%)
Patients interviewed	229	70 (35%)	149 (65%)
Adult	210 (92%)	67 (29%)	143 (63%)
Paediatric	19 (8%)	13 (5%)	6 (3%)

T: All patients ever started on ART before October 1st, 2006

T₁: Patients started on ART before October 1st, 2006 still active on ART as at September 30th, 2007

4.2 Demographic and other characteristics of respondents

4.2.1 Age of respondents

The mean age of the respondents included in the sample was 37.5 years \pm 12.3. The youngest

patient included in the sample was 4 years old while the oldest was 65 years. The median and modal ages of the respondents were 39.0 and 35.0 years respectively.

Table 4.2: Age distribution of correspondents

Sex	Age Group (years)					Total
	< 14	14 – 17	18 – 34	35 – 50	> 50	
Male	13	3	10	39	15	80
Female	6	3	33	96	11	149
Total	19	6	43	135	26	229

4.2.2 Level of education

Respondents less than 18 years were excluded from this analysis as they were still in school and therefore had not yet achieved their highest level of education. Slightly less than half of the respondents had achieved only primary school level of education. Only 7% had attained education level above secondary school. The difference in the levels of education between males and females among the sampled patients was not statistically significant (Table 4.3, $P > 0.1$, $\chi^2 = 1.94$). This may imply that there were equal opportunities for education in the communities from which the patients came.

4.2.3 Marital status

Respondents less than 18 years were excluded from this analysis as the minimum legal age of marriage in Kenya is 18 years. The number of women widowed, separated or divorced was much higher than that for men. The difference was statistically significant (Table 4.3, $P < 0.001$, $\chi^2 = 22.63$). The study did not investigate possible causes for this difference between the two sexes. Further research in this area could possibly provide some useful insights into this observation.

4.2.4 Occupation of respondents

All the paediatric patients in the sample were school-going and these were included in the analysis and their occupation was considered to be student/pupil. Majority of the respondents- 120 (52%) were self employed. Female and male respondents differed in their reported occupation with a big proportion of the women self-employed (87) 58% vs. male 33 (41%). A bigger proportion of the female respondents were also unemployed- 25 (17%) vs. male 9 (11%). The differences in occupation between the sexes were statistically significant (Table 4.3, $P < 0.05$, $\chi^2 = 15.09$). Investigation of the possible reasons for these differences was beyond the scope of this study. It could be speculated that men, being the traditional breadwinners in many African societies, are more likely to seek formal employment while the women stay at home and take care of the family.

4.2.5 Average income of respondents

Respondents less than 18 years were excluded from this analysis. Poverty levels were higher among female patients than male patients with more of the females reportedly living on the equivalent of less than one US dollar per day compared with the males (43% vs. 23%). The average income for men was Ksh 7,207 (median salary ksh 4,000) while that for women was Ksh 3,909 (median salary Ksh 2,000). The lowest and highest monthly incomes reported among men were Ksh 100 and Ksh 35,000 respectively while for women the corresponding figures were Ksh 100 and Ksh 40,000 respectively. The difference in income between males and females was statistically significant (Table 4.3, $P < 0.01$, $\chi^2 = 12.51$). The income differences were related to the occupation of the respondents. Since a bigger proportion of women were unemployed or self employed, their mean monthly income was also lower. Employed respondents generally reported higher monthly incomes than the self-employed respondents.

4.2.6 Disclosure status of respondents

Majority of both male and female respondents (95%) had disclosed their HIV status to family, friends or relatives. There was no statistically significant difference in the disclosure status of between the sexes (Table 4.3, $P > 0.1$, $\chi^2 = 0.97$). The number of patients who had not disclosed their HIV status was very low (12) and if any gender differences existed with regard to disclosure status, these would probably not have been captured given the small number of patients who had not disclosed their status.

Table 4.3: Demographic and other characteristics of male and female respondents

Variable	All Patients	Gender		Significance
		Male	Female	
Highest level of education (n = 204)				
Primary	92 (45%)	26 (41%)	66 (47%)	$\chi^2 = 1.94$ $P > 0.1$ not significant
Secondary	93 (46%)	34 (53%)	59 (42%)	
Mid-level college	10 (5%)	3 (5%)	7 (5%)	
University	5 (2%)	1 (1%)	4 (3%)	
No response	4 (2%)	0 (0%)	4 (3%)	
Marital Status (n = 204)				
Never Married	18 (9%)	4 (6%)	14 (10%)	$\chi^2 = 22.63$ $P < 0.001$ significant
Married not living together*	06 (3%)	4 (6%)	2 (1%)	
Partner cohabiting	64 (31%)	33 (52%)	31 (23%)	
Married living together	11 (6%)	5 (8%)	6 (4%)	
Widowed	52 (25%)	9 (14%)	43 (31%)	
Separated/divorced	53 (26%)	9 (14%)	44 (31%)	
Occupation of respondents (n = 229)				
School going (student/pupil)	25 (11%)	16 (20%)	9 (6%)	$\chi^2 = 15.09$ $P < 0.01$ significant
Unemployed	34 (15%)	9 (11%)	25 (17%)	
Employed	50 (22%)	22 (28%)	28 (19%)	
Self-employed	120 (52%)	33 (41%)	87 (58%)	
Monthly income (Ksh) [n = 204]				
< 2,000	75 (37%)	15 (23%)	60 (43%)	$\chi^2 = 12.51$ $P < 0.01$ significant
2,000 – 10,000	73 (35%)	27 (42%)	46 (33%)	
10,000 – 40,000	28 (14%)	15 (23%)	13 (9%)	
No response	28 (14%)	7 (11%)	21 (15%)	
HIV status disclosed (n = 229)				
Yes	217 (95%)	76 (95%)	141 (95%)	$\chi^2 = 0.97$ $P > 0.1$ not significant
No	12 (5%)	4 (5%)	8 (5%)	

* Married not living together refers to a situation where the 2 spouses live in different towns mainly for work-related reasons

4.3 Factors Affecting Adherence to ART

4.3.1 Factors affecting adherence to ART as reported by the patients

Patients were asked to state the main factor that affects adherence to their medication. The answer “being busy” was given by 89 (39%) of the patients while “travelling” was cited by 48 (21%) of the patients as the main factors affecting adherence to their medication. “Side effects”, and “forgetfulness” were cited by 18 (8%) and 20 (9%) of the patients respectively. Twenty six (12%) of the patients cited a variety of other reasons (events, stress, meals and stigma) as the main factor. Twenty eight (12%) stated no reason for missing doses (Figure 4.2).

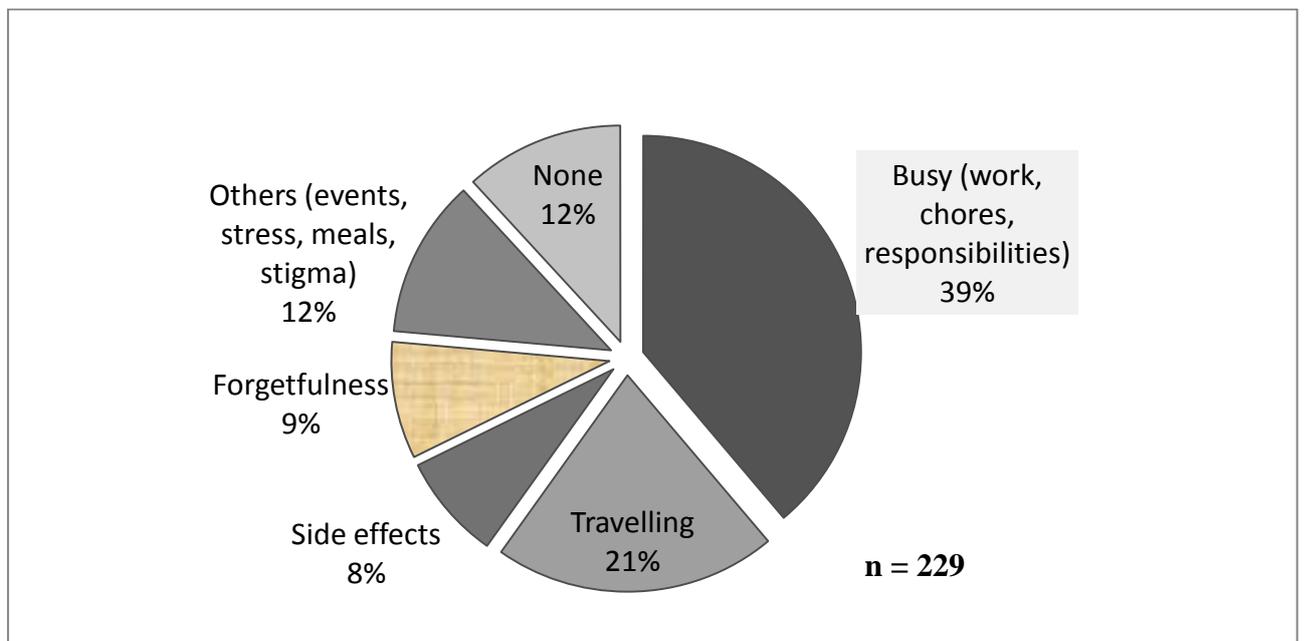


Figure 4.2: Reasons for missing doses as reported by respondents

4.3.2 Analysis of factors affecting adherence to ART

Adherence to ART was calculated based on pill count data for 203 (87%) of the 229 study patients. For the remaining 26 patients, pharmacy appointment keeping was used to calculate adherence to ART. Apart from the routine medication use counselling offered by the pharmacy staff and the rest of the ART care team, no targeted interventions to improve

adherence were implemented during the entire study duration. Patients were neither made aware of the purpose of the pill counts nor admonished for missing doses. This was meant to reduce the possibility of “pill dumping” where patients remove the pills they have missed and only present the expected number of pills to the health worker (Rudd *et al.*, 1989).

4.3.3 Overall adherence rates

The mean adherence rate for all the patients was $92.7\% \pm 8.5\%$. Though this figure may appear high, a closer evaluation of the data reveals that the number of patients exhibiting optimal adherence (greater than 95%) to ART was only 125, representing 55% of the total patients interviewed. One hundred and ninety seven (86%) of the patients exhibited greater than 85% adherence to ART. Only 11 (5%) of the patients sampled exhibited less than 75% adherence to ART.

4.3.4 Influence of occupation on adherence to ART

There was a statistically significant difference in adherence when the respondents were categorized by occupation (Table 4.4, $P < 0.05$, $\chi^2 = 16.96$). Employed patients seemed to exhibit comparatively lower levels of adherence with only 36% in this group having $>95\%$ adherence. This group also had the largest percentage (10%) exhibiting $<75\%$ adherence to ART. The odds ratio of an employed person exhibiting non-optimal adherence compared to all the other categories was 2.64 (95% CI, 1.3863 to 4.8708, $P < 0.005$). The paediatric patients in the sample were all in school (from pre-school to secondary school) and their occupation was listed as student/pupil.

4.3.5 Influence of age and gender on adherence to ART

There was no difference in adherence levels among patients of different age groups and between male and female patients on ART (Table 4.4, $P > 0.1$, $\chi^2 = 5.05$ and $P > 0.1$, $\chi^2 = 1.01$

respectively). The mean adherence rate for younger patients (less than 50 years) was not significantly different from that for older patients- 50 years or older (92.6% versus 93.2%). The odds ratio (OR) of optimal adherence for patients 50 years or older compared to those less than 50 years was 1.15 (95% confidence interval (CI) 0.51 – 2.61) while the relative risk of older patients being optimal adherers compared to younger patients was 1.08. This means that, although older patients were more likely to be optimal adherers, the odds ratio and relative risk values were low. The higher the values of these two parameters are, the greater is the difference between the groups being compared.

4.3.6 Influence of level of education on Adherence to ART

There was no difference in adherence levels among the various categories of education ($P > 0.1$, $\chi^2 = 7.22$). The odds ratio (OR) for optimal adherence comparing those with low levels of education versus those with secondary school education and above was 1.05 (95% CI, 0.619 to 1.769, $P > 0.10$); indicating that there was no significant difference in adherence between the two groups. The Nyeri PGH patients were on NNRTI-based regimens for which fixed dose combinations (FDCs) are available. In clinical practice, FDCs enable simplification of ART regimens and the patients require to take only 1 or 2 pills in a day.

4.3.7 Adherence levels for respondents of different marital status

There was no difference in adherence levels among categories of different marital status (Table 4.4, $P > 0.1$, $\chi^2 = 1.90$). The OR that a patient who was married or living with a partner would be non adherent compared to a patient who was single, separated or divorced was 0.919 (95% CI, 0.6259 to 1.8919) indicating that adherence levels were similar for patients of different marital status.

4.3.8 Adherence levels and disclosure of HIV status

This study showed no relationship between adherence to ART and disclosure of HIV status by the patient to others (Table 4.4, $P > 0.1$, $\chi^2 = 0.36$). Most of the respondents (217 (95%)) had disclosed their status to at least one person.

4.3.9 Knowledge of basic ART facts and adherence to ART

Questions regarding factors that can cause non-adherence to ART and patients' knowledge of their last CD4 count as well as the normal range of CD4 count were intended to check the patients' basic knowledge of ART and evaluate a possible relationship of this knowledge with ART adherence.

At Nyeri Provincial General Hospital, most of the respondents (70%) knew of substances that when consumed could lead to non-adherence to ART. Knowledge of this did not however affect the adherence level to ART as there were almost identical proportions of those who knew and those who did not know of these substances in each adherence category (Table 4.4, $P > 0.1$, $\chi^2 = 0.009$). A majority of the respondents (75%) also knew their latest CD4 count while a majority did not know the normal range of CD4 cell count. However, knowledge of the two parameters did not seem to significantly affect adherence to ART (Table 4.4, $P > 0.1$, $\chi^2 = 2.6$ and $P > 0.1$, $\chi^2 = 1.3$ respectively).

Table 4.4: Factors affecting adherence to ART

Variable	All Patients (n=229)	Adherence Level to ART				Significance
		> 95% (n = 125)	86%-95% (n = 72)	75%-85% (n = 21)	<75% (n = 11)	
Percentage of total respondents	100	55	31	9	5	-
Age						
< 14 years	19 (100)	12 (63)	4 (21)	3 (16)	0 (0)	$\chi^2 = 5.05$
14-17 years	6 (100)	3 (50)	3 (50)	0 (0)	0 (0)	$P > 0.1$

Variable	All Patients (n=229)	Adherence Level to ART				Significance
		> 95% (n = 125)	86%-95% (n = 72)	75%-85% (n = 21)	<75% (n = 11)	
18-34 years	43 (100)	22 (51)	12 (28)	4 (9)	5 (12)	not significant
35-50 years	135 (100)	73 (54)	45 (33)	11 (8)	6 (5)	
> 50 years	26 (100)	15 (58)	8 (31)	3 (11)	0 (0)	
Sex						$\chi^2 = 1.01$
Male	80 (100)	42 (53)	26 (32)	9 (11)	3 (4)	P > 0.1
Female	149 (100)	83 (56)	46 (31)	12 (8)	8 (5)	not significant
Highest level of education*						$\chi^2 = 7.22$
Primary school	97 (100)	51 (53)	36 (36)	8 (9)	2 (2)	P > 0.1 not significant
Secondary school	94 (100)	53 (56)	27 (29)	8 (9)	6 (6)	
Mid-level college	10 (100)	4 (40)	3 (30)	1 (10)	2 (20)	
University	5 (100)	3 (60)	1 (20)	0 (0)	1 (20)	
No response	4 (100)	2 (50)	1 (25)	1 (25)	0 (0)	
Marital Status*						$\chi^2 = 1.90$
Never married	18 (100)	9 (50)	7 (39)	2 (11)	0 (0)	P > 0.1 not significant
Married not living together	6 (100)	2 (33)	3 (50)	0 (0)	1 (17)	
Partners cohabiting	64 (100)	34 (53)	21 (33)	5 (8)	4 (6)	
Married living together	11 (100)	8 (73)	3 (27)	0 (0)	0 (0)	
Widowed	52 (100)	28 (54)	15 (29)	5 (10)	4 (7)	
Separated/Divorced	53 (100)	29 (55)	16 (30)	6 (11)	2 (4)	
Occupation						$\chi^2 = 16.96$
Student/pupil	25 (100)	15 (60)	7 (28)	3 (12)	0 (0)	P < 0.05 significant
Unemployed	34 (100)	15 (44)	15 (44)	1 (1)	3 (9)	
Paid employee	50 (100)	18 (36)	23 (46)	4 (8)	5 (10)	
Self-employed	120 (100)	77 (64)	27 (22)	13 (11)	3 (3)	
Know their last CD4 count**						$\chi^2 = 2.6$
Yes	171 (100)	93 (54)	57 (33)	13 (8)	8 (5)	P > 0.1
No	58 (100)	32 (55)	15 (26)	8 (14)	3 (5)	not significant
Know normal CD4 count**						$\chi^2 = 1.3$
Yes	41 (100)	19 (46)	16 (39)	3 (7)	3 (7)	P > 0.1
No	158 (100)	106 (56)	56 (30)	18 (10)	8 (4)	not significant
Know substances that can lead to non-adherence**						$\chi^2 = 0.009$
Yes	160 (100)	87 (54)	50 (31)	17 (11)	6 (4)	P > 0.1
No	69 (100)	38 (55)	22 (32)	4 (6)	5 (7)	not significant
Disclosed HIV status						$\chi^2 = 0.36$
Yes	217 (100)	118 (54)	67 (31)	21 (10)	11 (5)	P > 0.1
No	12 (100)	7 (58)	5 (42)	0 (0)	0 (0)	not significant

NOTE: Data are no. (%) of patients on the respective row, unless otherwise indicated

Married not living together: refers to a situation where one partner works and lives in different town

*Chi square computation for marital status vs. adherence and highest level of education vs. adherence excludes paediatric patients

** Knowledge of guardian was evaluated for these categories

4.4 Analysis of patients' views on ART availability, accessibility, affordability and acceptability at the hospital

4.4.1 Introduction

In addition to obtaining patients' demographic characteristics, basic knowledge on ART and disclosure status, the study also sought to obtain patients views and perceptions on various dimensions of ART services offered at the hospital. For this purpose ART services were categorized into four groups. ART availability; covering the patients perceptions on the various medical services in the hospital that they may have required partly due to their HIV infection, for instance, counselling on ART adherence, inpatient care for HIV-infected patients, Prevention of Mother to Child Transmission (PMCT) of HIV, psychiatric services and Ear Nose Throat (ENT) services; ART Accessibility- dealing with appropriateness of physical location, waiting time, accessibility to healthcare workers and convenience of the facility to the patient. ART affordability covered the patients' perceptions of the cost of ART services and other related medical services at the hospital and ART acceptability dealt with the patients' views on the professionalism competence and attitude of healthcare workers, quality of health education provided at the ART clinic and the benefits or adverse effects of the patients' ART regimen.

For each category, the scores for each patient were aggregated to obtain a mean score. Correlation analysis was done for each category to evaluate its influence on adherence. For the questions that could not be graded, for example, the average time taken to get to the facility from one's home, or how long a patient would be willing to wait for a doctor, a separate analysis was done to check for any effect on adherence to ART. Patients' views on the various dimensions of ART services as well as their recommendations on possible improvements in various areas were summarized.

4.4.2 ART Availability

Patients' perceptions on ART availability was negatively correlated with percentage adherence to ART and the correlation was statistically significant (Table 4.5, Spearman's $r = -0.157$, $P = 0.017$).

Table 4.5: Correlation between patients' views on ART services and percentage adherence to ART

ART Services Category	Percentage Adherence		N
	Spearman's Correlation Coefficient (ρ)	Significance (2-tailed)	
Availability	-0.157	0.017*	229
Accessibility	0.068	0.308	229
Affordability	0.016	0.811	229
Acceptability	0.255	0.000**	229

* Correlation is significant at the 0.05 level; ** Correlation is significant at the 0.01 level

When asked what suggestions they had for improving ART services at the hospital, 41% of the patients interviewed wanted the administration to improve the waiting area by installing a television set or radio system, 24% wanted delays at the pay points to be reduced, 9% wanted to have a comprehensive care centre in which all ART related services were provided (including laboratory and pharmacy services) and 5% wanted all service charges to be waived for HIV-infected patients (Table 4.6).

Table 4.6: Patients' suggestions for improving ART services at the hospital

Patients' suggestions for improving provision of ART Services at the hospital	Number (%) of patients (n = 229)
Improve auxiliary services (TV/radio at waiting area, refreshments)	94 (41%)
Faster processing at pay points	55 (24%)

Patients' suggestions for improving provision of ART Services at the hospital	Number (%) of patients (n = 229)
All ART-related services should be offered at the ART Clinic	21 (9%)
Waive all service charges for HIV-infected patients	11 (5%)
Have more doctors at the CCC	7 (3%)
Others (buy viral load machine, offer nutritional support to patients, expand waiting bay)	18 (8%)
No changes proposed	23 (10%)

4.4.3 ART Accessibility

This dimension of ART service provision evaluated the patients' views on the location of the HIV care clinic, the waiting time at the hospital as well as the convenience of the facility to the patients. It also sought to establish the time taken for patients to travel from their places of residence to the hospital for treatment.

It took 69% of the respondents less than 1 hour to reach the CCC. Only 10% respondents took more than two hours indicating an overall high rating of accessibility to the CCC (Figure 4.3). Patients' perceptions on ART accessibility were positively correlated with the percentage adherence. However, the correlation was not statistically significant (Table 4.5, Spearman's $r = 0.068$, $P = 0.308$). This absence of a correlation between the two factors at Nyeri PGH was probably because the catchment area of the hospital has a well developed transport system with several affordable means of getting to the hospital.

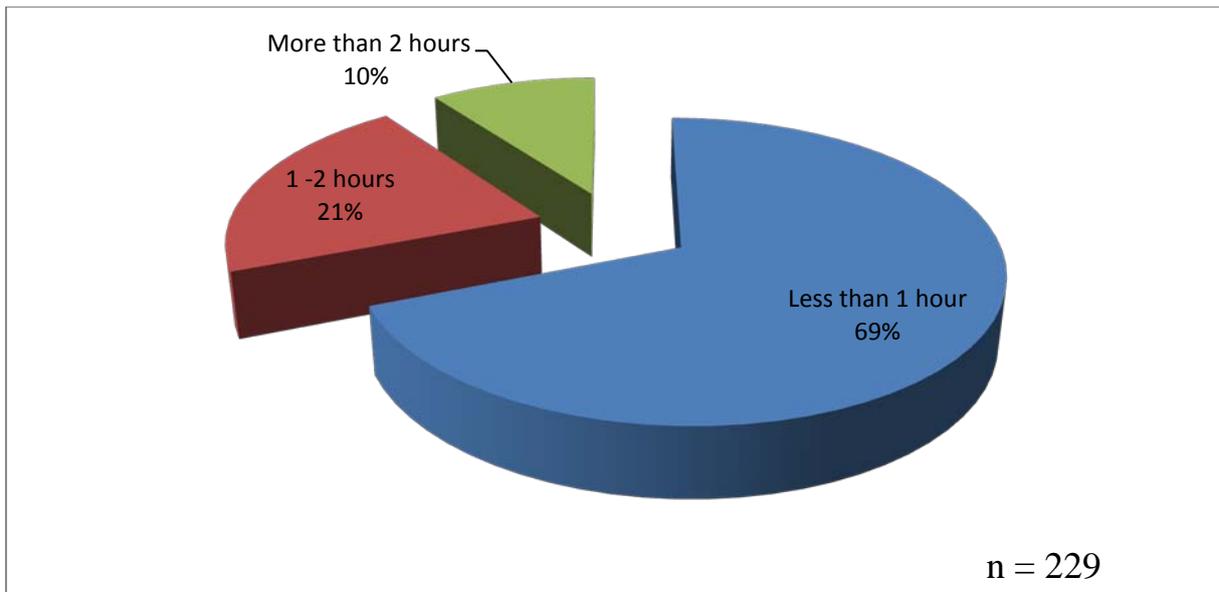


Figure 4.3 Time taken by patients to travel from home to the hospital

Patients were asked to state how long they would be willing to wait to be seen by a doctor at the ART clinic. The average time stated was 39 minutes while the median was 30 minutes. At the two extremes, one patient was willing to wait for up to 8 hours to be seen by a doctor while two patients did not wish to wait at all and wanted to be seen immediately they arrived at the clinic (Figure 4.4). Areas within the hospital mentioned by the patients as having the longest waiting times were the CCC (52%) and the Pharmacy (26%). The study did not however investigate the actual waiting time experienced by the patients to compare with the desired waiting time stated by the patients.

4.4.4 ART Affordability

Patients' perceptions on ART affordability were weakly correlated with the percentage adherence to ART and this correlation was not statistically significant (Table 4.5, Spearman's $r = 0.016$, $P = 0.811$). When asked whether they would refer other patients to seek ART services at Nyeri PGH based on the costs and charges at the hospital, 99% of the patients

answered in the affirmative. This is an encouraging response indicating that the hospital has largely succeeded in offering affordable ART services to its patients.

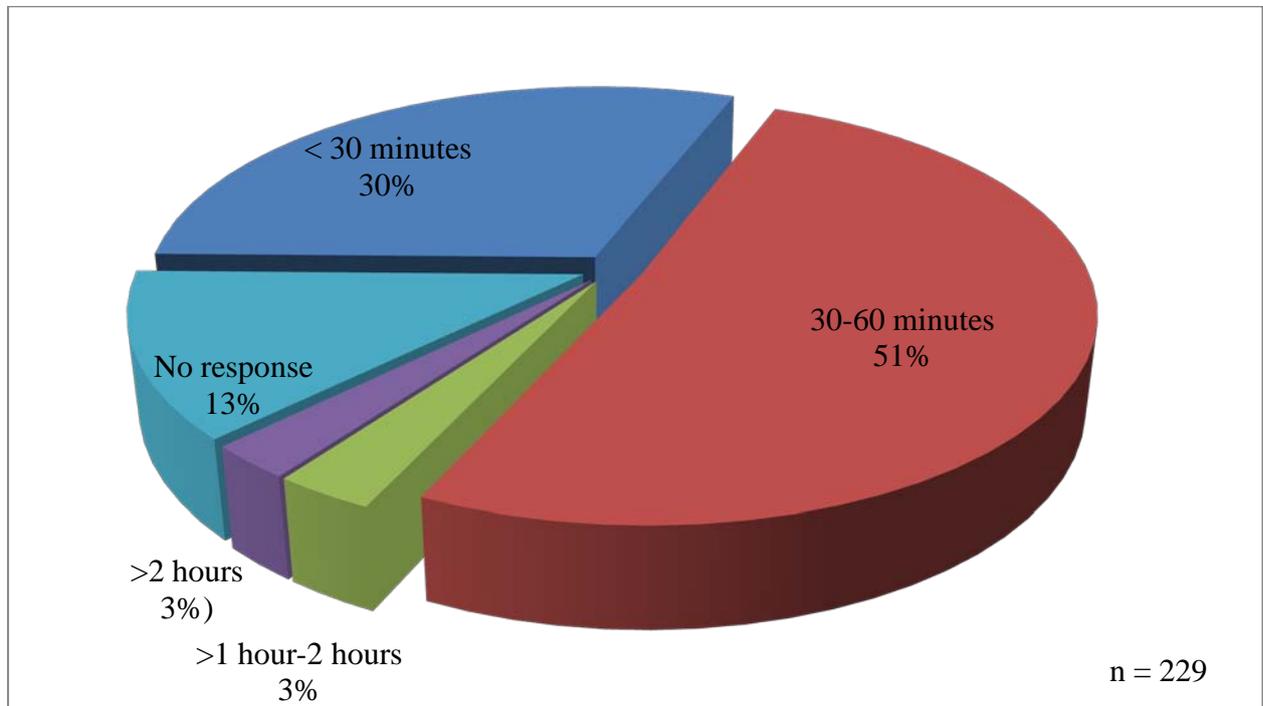


Figure 4.4: Time patients would be willing to wait before being seen by a doctor

4.4.5 ART Acceptability

This dimension of ART services sought to capture patients' views on the quality of service provision at the hospital as well as their confidence in the healthcare system and in antiretroviral therapy as a whole. The patients' mean scores were positively correlated with percentage adherence to ART and the correlation was highly significant (Table 4.5, Spearman's $r = 0.255$, $P < 0.01$). Patients with a high level of trust in the health care workers' competence and the quality of services at the hospital were found to generally exhibit higher adherence levels to ART. Almost all the patients, 224 (98%) rated the professional competence of the doctors at the ART clinic as good or excellent and the same proportion was satisfied with the consultation time with the doctor at the clinic.

Privacy during consultation was a concern for 18 (8%) of the patients due to the practice of two doctors sharing consultation rooms and seeing two patients at the same time. However, most of the patients, 209 (91%) did not think that this practice invaded their privacy. The rating of the nurses by the patients was lower than that of the doctors with about a quarter of the patients ranking the nurses behaviour as average or poor (Table 4.7).

Other parameters of ART acceptability were generally ranked highly by the respondents. These included the quality of health education provided at the clinic which was ranked as good or excellent by 77% of the respondents. Eighty nine percent rated the communication and information received at the clinic as good or excellent. The quality of consultation time with doctors was similarly highly rated, with 97% of the respondents rating it as good or excellent (Table 4.7). All these high ratings are an indicator of the patients' confidence and trust in the healthcare professionals providing ART services at the clinic.

Table 4.7: Patients' rating of various parameters of ART Acceptability

Parameter	Rating: Number of patients (%)				
	Excellent	Good	Average	Poor	None
Professional competence of doctors	197 (86%)	22 (10%)	9 (4%)	0 (0%)	1 (0%)
Doctors' interaction with patients	177 (77%)	43 (19%)	8 (3%)	1 (0%)	0 (0%)
Quality of consultation time	192 (84%)	30 (13%)	7 (3%)	0 (0%)	0 (0%)
Privacy during consultation with doctor	177 (77%)	30 (13%)	12 (5%)	9 (4%)	1 (0%)
Nurses' interaction with patients	58 (25%)	119 (52%)	33 (14%)	18 (8%)	1 (0%)
Nursing care	65 (28%)	114 (50%)	28 (12%)	18 (8%)	4 (2%)
Provision of health education	114 (50%)	62 (27%)	39 (17%)	7 (3%)	7 (3%)
Communication and information	124 (54%)	81 (35%)	12 (5%)	4 (2%)	8 (3%)

CHAPTER 5: DISCUSSION

5.1 Retention rate of patients on ART for more than one year

The retention rate for patients on ART for more than one year at Nyeri PGH was 65%. The data for Nyeri PGH included all patients who had been on ART for at least one year. Thus the study population at Nyeri PGH included some patients who had been on treatment for up to four years. A longer period of follow up would be associated with lower retention rates as patients will invariably be transferred out of the facility while others will die.

A systematic review of patient retention rates in antiretroviral therapy programs in Sub-Saharan Africa by Rosen *et al.* (2007) found that the reported mean retention rates of patients by ART programs in Africa at the end of 12 months was 75%. This is 10% higher than the figure observed for Nyeri PGH in this study. The systematic review by Rosen *et al.* (2007) included 32 studies in 13 countries that reported the proportion of adult HIV-1 patients retained in ART programs implemented in service delivery (non research) settings in sub-Saharan Africa between 2000 and 2007. The total number of patients on ART covered in the 32 studies was 74,289.

5.2 Proportions of patients deceased, lost to follow up and transferred out

The proportions of patients deceased, lost to follow up and transferred out were relatively high at Nyeri PGH compared with findings from other studies. The slightly higher proportion of lost to follow up patients observed at Nyeri PGH might be due to the fact that the study population comprised all patients who had been started on ART more than one year prior to the study period. Since the ART program at Nyeri PGH commenced in 2003, the study population included patients who had been on ART for up to 4 years.

With regard to the proportion of patients transferred out to other facilities, in a situation like Kenya's where ART services were first introduced in several pilot sites and later decentralized to lower-level facilities, it is expected that a considerable proportion of patients would seek to be transferred to facilities that are more convenient or accessible to them. Rosen *et al.* (2007) found that the mean proportion of patients known to be transferred out to other facilities after 10 months follow up in the studies included varied from 0.7% to 12.1% of the total number of patients who were started on ART.

In the systematic review by Rosen *et al.* (2007), the mean proportion of patients known to be deceased after 10 months follow up in the studies included was 8.8% of the total number of patients who were started on ART. The actual figure of patients deceased in the current study could be much higher than the one quoted as there is a possibility that some patients died away from the hospital and the hospital staff were not yet aware of this. Such patients would end up marked as lost to follow up until news of their death reaches the hospital staff.

In the same review by Rosen *et al.* (2007), the mean proportion of patients lost to follow up after 10 months in the studies included was 12.32% of the total number of patients who were started on ART. In another study, the ART-LINC Collaboration, which analyzed data from 18 cohorts across the developing world, reported loss to follow up rates among the 13 sub-Saharan African cohorts averaging 15% in the first year after ART initiation (Braitstein *et al.*, 2006).

5.3 Factors Affecting Adherence to ART

5.3.1 Factors affecting adherence to ART as reported by the patients

The reasons stated by patients at Nyeri PGH for missing their medication included being busy, travelling, forgetfulness and stigma. These reasons have been reported in other studies

on adherence to ART. Pierre *et al.* (2006) compared adherence to antiretroviral therapy between patients in France and in sub-Saharan Africa. Adherence was measured using patients' self assessment of their pill taking. Sixty one percent of the patients in France and 31% of those in Africa stated "being busy" as the main reason for missing doses. In the same study, 18% of patients in France and 21% of patients in Africa reported "forgetfulness" as the main reason for missing doses. The proportion of patients reporting "side affects" as the cause of missed doses was 5% for the patients in France and 8% for the patients in Africa.

In an assessment of adherence to ART medication by patients living in an impoverished community in South Bronx New York, Weidle *et al.* (1999) conducted confidential interviews with patients who were on ART to assess their adherence to the ART medication. Additionally, each respondent was requested to voluntarily fill out an anonymous self-administered questionnaire further assessing their adherence to ART medication in the previous month. Not all patients interviewed agreed to fill out the anonymous questionnaire.

The answers obtained were assigned to response category in a list of responses. For the response categories that were similar for Nyeri PGH and the study by Weidle *et al.* (1999), the proportions of patients in each category were markedly different: "forgotten", 8% for Nyeri PGH and 39% for the New York (NY) population; "side effects", 8% for Nyeri PGH and 14% for the NY population (Table 5.1). The differences in the responses could be because of differences in the way data was obtained in the 2 studies. In addition, the socio-demographic characteristics of the two study populations were different, with the NY study focusing on an impoverished community while the Nyeri PGH study included a heterogeneous group of patients with varying socio-economic profiles.

Table 5.1: Reported reasons for missing a dose of ART medication

Reported most common reason for missing a dose of ARVs	No. (%) of patients				
	Nyeri PGH (n=229)	Pierre <i>et al.</i> (2006)		Weidle <i>et al.</i> (1999)	
		In Africa (n=38)	In France (n=38)	Confidential Interview (n=57)	Anonymous questionnaire (n=74)
Busy	89 (39%)	12 (31)	23 (61%)	-	-
Travelling	48 (21%)	-	-	-	-
Forgotten	20 (8%)	8 (21%)	7 (18%)	22 (39%)	15 (20%)
Side effects	18 (8%)	3 (8%)	2 (5%)	8 (14%)	21 (28%)
Others (stigma, stress, special occasions)	27 (12%)	-	-	6 (11%)	6 (8%)
Stigma	-	8 (21%)	2 (5%)	-	-
Out of stock	-	1 (3%)	2 (5%)	-	-
Feeling well	-	0 (0%)	1 (3%)	-	-
Feeling bad	-	3 (8%)	1 (3%)	-	-
Inconvenient storage	-	3 (8%)	0 (0%)	-	-
Instructed by health	-	-	-	3 (5%)	1 (1%)
Lack of effect	-	-	-	0 (0%)	6 (8%)
ARVs inaccessible	-	-	-	15 (26%)	20 (27%)

In Table 5.1, a dash (-) indicates that the corresponding response category was not listed in the study represented by the respective column.

5.3.2 Adherence levels and age

In the sample of patients interviewed at Nyeri PGH, older patients (50 years or more) constituted only 11% of the patients interviewed. Most of the patients- 178 (78%) - were between the 18 and 49 years old. The fact that there were relatively fewer patients outside this age group may have masked differences in adherence levels between younger and older patients as the latter sample was too small.

Studies in other countries have shown an influence of age on adherence to ART. Hinkin *et al.*, (2004) used MEMS to study the effect of patient age on medication adherence in 148

HIV-infected patients in the United States. The mean adherence rate for the entire cohort was 80.7%, with older patients (≥ 50 years) demonstrating significantly better medication adherence than younger patients (87.5 versus 78.3%). Logistic regression analyses found that older patients were three times more likely to be classified as good adherers (defined as $\geq 95\%$ adherent). Golin *et al.* (2002) found that younger patients were less likely to be adherent than older patients ($P = 0.4$).

5.3.3 Adherence levels and gender

At Nyeri PGH, gender was not found to be a predictor of adherence level to ART as there was no difference in adherence levels among male and female patients. Many studies have demonstrated that gender is not a predictor of adherence levels to ART. The Adherence and Efficacy to Protease Inhibitor Therapy (ADEPT) study was a prospective observational investigation of medication adherence in HIV (Golin *et al.*, 2002) that involved 140 patients in a public hospital-affiliated HIV care clinic in the United States. Adherence to ART in this study was measured using a combination of MEMS, pill count and self reported adherence. The authors found that gender was not associated with adherence ($P = 0.61$). Orrell *et al.* (2003) in a study that used pill counts to measure adherence to ART also found that gender was not a predictor of adherence to ART ($P = 0.7$). The study involved an African HIV-infected cohort in South Africa.

5.3.4 Adherence to ART and level of education

Eighty five percent of the patients interviewed at Nyeri PGH patients were on NNRTI-based regimens for which fixed dose combinations (FDCs) were available. In clinical practice, FDCs enable simplification of ART regimens and the patients require to take only 2 pills in a day. This fact might have reduced the importance of level of education as a factor in understanding one's treatment regimen and hence being able to adhere to it correctly.

Various studies have yielded conflicting findings on the relationship between adherence and level of education. In a cross-sectional study of 366 patients in Spain, subjects with a low level of education had the worst adherence while those with a university degree had the best (Gordillo *et al.*, 1999). A notable fact in this study was the complexity of regimens. The patients were on protease inhibitor-based ART which requires more pills to be taken per day often with dietary restrictions. It is conceivable that a higher level of education would make it easier to understand complex regimens hence increasing adherence levels in this sub-group of patients.

In a study in an African cohort in Botswana by Weiser *et al.* (2003), the odds ratio of adherence for patients who did not complete secondary school as compared with those with higher levels of education was 3.87 ($P = 0.02$) showing that lower levels of education were actually associated with higher adherence.

5.3.5 Adherence to ART and marital status

The study at Nyeri PGH did not find marital status to be a factor in adherence to ART. A study by Byakika-Tusiime *et al.* (2005) at three treatment centres in Kampala Uganda found that marital status was associated with non-adherence (OR = 2.93, 95% CI 1.32–6.50) with married people more likely to adhere to ART. The study involved 304 patients and adherence information was based on patient self reports from structured interviews as well as unstructured qualitative interviews.

Further research is probably needed to gain more insight into the influence of marital status on ART adherence. A possible explanation for the findings of the Uganda study would be that married people living together who are both on ART would provide each other with adherence support hence enhance medication taking. However, it is not known whether there

exist important differences in the relationship dynamics between married couples in Uganda and in Nyeri district in Kenya. Thus being married may be a positive predictor of adherence to ART in some communities but not a factor at all in other communities.

5.3.6 Adherence to ART and occupation

Occupation was found to be a significant factor at Nyeri PGH with employed patients as a group exhibiting poorer adherence levels than the self-employed and unemployed groups. A possible explanation for the results observed at Nyeri PGH is that the employed patients interviewed generally had relatively busier schedules than the other groups and their lifestyles usually involved travelling, sometimes quite early, from their residences in order to arrive at their workplaces on time and getting home from work late in the evening. On the other hand, given that farming is one of the main occupations for self-employed individuals in Nyeri district, this group usually worked within their homesteads and it would probably be easier for this group to develop and follow a regular medication taking schedule compared to the patients who were employed.

A few studies have explored the relationship between adherence to ART and occupation of patients. A multicentre cohort study by Kleeberger et al. (2001) in the US involving 5,622 patients found no relationship between adherence and employment status ($P = 0.96$). However, the study populations comprised only homosexual and bisexual men.

5.3.7 Adherence to ART and disclosure of HIV status

This study at Nyeri PGH showed no relationship between adherence to ART and disclosure of HIV status by the patient to others (Table 4.5, $P > 0.1$, $\chi^2 = 0.36$). Other studies conducted elsewhere have yielded different results. A study by Stirratt *et al.* (2006) examined the relationship between HIV serostatus disclosure and adherence to antiretroviral therapy

(ART). The study was conducted with 215 HIV-seropositive patients who demonstrated poor adherence (<80%). Participants who reported greater serostatus disclosure to others demonstrated higher rates of adherence. In Tanzania, Ramadhani *et al.* (2005) concluded that disclosure of HIV serostatus to persons other than health care workers at the Infectious Diseases Clinic was protective against non-optimal adherence to ART (P = 0.048). The study was conducted in Northern Tanzania and included 185 patients.

A possible reason for the observation at Nyeri PGH that disclosure had no effect on adherence levels is the small number of patients who had not disclosed their status to their relatives or friends. These were only 12, representing 5% of the patients interviewed. This might have reduced the statistical power of the study to detect any differences in adherence between the two groups.

5.3.8 Knowledge of basic ART facts and adherence to ART

The study at Nyeri PGH found that knowledge of basic facts about ART was not correlated to the patients' adherence levels. It appears from findings of various studies that patients in general may still adhere to ART medication even without solid knowledge of their treatment. It could perhaps suffice for patients to be aware of the importance of strict adherence to their ARV medication for them to exhibit high levels of adherence.

Knowledge of basic facts of ART has not been shown to be correlated with adherence levels. Golin *et al.* (2002) found that knowledge of some basic facts about ART was not correlated to the patient's adherence level. The questions used to evaluate knowledge of ART and the P values for statistical test evaluating the responses and patient adherence to ART were as follows; Do you agree that resistance to ART may develop if drugs are not taken as directed (P = 0.54), and do you agree that one can fight HIV without ART (P = 0.11)?

5.4 Effect on adherence to ART of patients' views on ART Services

The four dimensions of ART services are ART availability, accessibility, ART affordability and ART acceptability. These dimensions have been evaluated in an attempt to find a connection between patients' views on these and adherence to therapy. A patient's perception on accessibility of services is an important factor for optimal adherence to ART. One of the factors grouped under ART accessibility is 'distance of a patient's residence from the clinic'.

At Nyeri PGH there was no correlation between the patients' views on ART accessibility and adherence to ART. Under ART accessibility factors such as distance from the clinic, waiting time and convenience of the ART clinic's location were explored. The absence of a correlation between the distance to the hospital and adherence to ART at Nyeri PGH was probably because the catchment area of the hospital has a well developed transport system with several affordable means of getting to the hospital.

Some studies have shown a link between this distance and adherence to ART. Ramadhani *et al.* (2007) studied predictors of incomplete adherence, virologic failure, and antiviral drug resistance among HIV-infected adults receiving antiretroviral therapy in Tanzania. They found that an increase in the walking distance from home to the hospital was associated with increased odds ratio of non-adherence (OR per 10 minute increment= 1.2 P = 0.05).

Since ARVs have been delivered free since early 2005, the cost of basic ART care at the HIV clinic and ARV medications themselves were not barriers to adherence at this hospital. However the user bears the cost of medical support services in other hospital departments as well as transport to and from the hospital. These additional costs are often an unbearable financial burden, which cause patients to default on their treatment (NACC, 2008). Many

studies have also established that cost of ARV medicines is a major barrier to adherence, especially in resource poor developing countries.

Hardon *et al.* (2007) used rapid appraisals (involving mainly qualitative methods) to find out why and when people do not adhere to ART in Uganda, Tanzania and Botswana. Though ARVs were free of charge at the facilities assessed, long waiting time at the clinics, leading to loss of wages, was cited as one of the main obstacles to optimal adherence. Rita *et al.* (2000) in a study at a HIV outpatient clinic of the Catholic University of Rome in Italy found that the odds ratio for non-adherence for patients reporting long waiting times was 4.7; 95% CI, 1.0-21.7. Thus patients who reported long waiting times at the ART clinic were also more likely to be non-adherent to ART.

Lanièce *et al.* (2003) found that financial difficulties were the leading cause of treatment interruption among patients in an ARV program in Senegal. The study, which was conducted over a period of three years, also showed that there was a significant increase in adherence when the cost of ARV medicines was reduced. In another study evaluating barriers to antiretroviral adherence for patients living with HIV infection and AIDS in Botswana, Weiser *et al.* (2003) found that one of the principal barriers to adherence was financial constraints. On the basis of logistic regression, if cost were removed as a barrier, adherence was predicted to increase from 54% to 74%.

The importance of patients' trust in the healthcare system on adherence to ART was evaluated in this study. The findings at Nyeri PGH were that the patients' views on the quality of services provided were positively correlated with percentage adherence to ART and the correlation was highly significant. Patients with a high level of trust in the health care

workers' competence and the quality of services at the hospital were found to generally exhibit higher adherence levels to ART.

The lower rating of nurses compared to that of doctors at Nyeri PGH is probably related to the fact that the patients usually spend most of the time with the nurses and the nurses are responsible for implementing many of the decisions agreed upon by the ART multidisciplinary team. Some of these decisions may be unpopular with patients, for example, ensuring that patients arrive before a certain time for their appointments and turning away those who do not, ensuring that paediatric patients only come on a designated day of the week and that patients starting antiretroviral treatment have a treatment supporter.

Shaahu *et al.* (2006) in a study on the role of healthcare workers in adherence to ART in Makurdi, Nigeria concluded that perceived non-judgmental attitude and support given by the health workers was significantly associated with adherence to ART ($\chi^2 = 9.47$, $P = 0.002$). Another study in the United States to establish whether the quality of the patient-provider relationship was associated with better adherence and health outcomes for patients with HIV found that patients who reported a good relationship with their health provider were more likely to be adherent to ART than those who did not (76% versus 67%, $P = 0.007$), and missed fewer clinic appointments (Beach *et al.*, 2006).

CHAPTER 6: SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 Summary

In this study, factors influencing adherence to antiretroviral therapy at the Nyeri provincial general hospital are presented. Various socio-demographic differences were observed between the male and female patients on ART but the adherence levels between the sexes were essentially the same.

Female patients were more likely to be widowed, separated or divorced while male patients were more likely to be in a steady relationship or married. Females were also worse off than men when it came to occupation with a greater proportion being unemployed and a bigger proportion of men being employed. Consequently, the average income of men was significantly higher than that of women. However there was no difference in the levels of education between the two groups. The mean adherence rate for all the patients was $92.7\% \pm 8.5\%$. The number of patients exhibiting optimal adherence (greater than 95%) to ART was 125, representing 55% of the total patients interviewed. 197 (86%) of the patients exhibited greater than 85% adherence to ART. Only 11 (5%) of the patients sampled had less than 75% adherence to ART.

Being busy with household chores and job-related tasks as well as travelling were cited by the respondents as the most important factors affecting adherence. Occupation was the only factor found to influence adherence among the respondents with the employed patients exhibiting relatively lower adherence levels. Age, gender, level of education, marital status and knowledge of HIV disease were found not to significantly affect adherence.

Among the four factors of ART service provision, patients' views on ART availability and ART acceptability were found to be correlated with percentage adherence to ART. Patients'

views on ART accessibility and ART affordability were not significantly related to percentage adherence. The main areas for improvement identified by patients were improvement of the waiting bay (41% of the patients) and reduction of delays at the pay points (24% of the patients). Almost all the patients (98%) had a positive view of the competence of doctors and the quality of professional consultation at the ART clinic.

6.1.1 Implications of the findings

In order to examine the implications of the findings at Nyeri PGH, it is useful to evaluate outcomes observed at various adherence levels in other published studies.

Maggiolo *et al.* (2005) in a prospective study of 543 patients on ART, investigated the effect of adherence on the risk of virologic failure. All patients completed a self-reported questionnaire derived from the Adult AIDS Clinical Trials Group adherence follow-up questionnaire. Patients were followed up for the subsequent 6 months to document virologic failure, which was defined as 2 consecutive viral load measurements of 1500 HIV RNA copies/mL. Among patients who reported an adherence rate of less than 75%, the rate of virologic failure was 17.4%; this rate decreased to 12.2% for patients whose adherence rate was 76%–85%, to 4.3% for patients whose adherence rate was 86%–95%, and to 2.4% for patients whose adherence rate was greater than 95% (Table 6.1). The mean adherence rate for the patients in the study by Maggiolo *et al.* (2005) was $92.3 \pm 12.5\%$. This is close to the mean adherence rate for Nyeri PGH patients of $92.7\% \pm 8.5\%$ reported in this study.

If the results of the quoted study are extrapolated to the Nyeri PGH adherence results, and assuming that the adherence levels observed among the sampled patients are generalizable to the whole study population of 705 patients on ART for more than one year, then a significant number of patients at Nyeri PGH face the possibility of virologic failure. Approximately 35

patients (5%) face an elevated risk of virologic failure while another 63 patients (9%) have a 12.2% risk of virologic failure (Table 6.1). Thus a total of 98 patients are at a high risk of experiencing treatment failure secondary to virologic failure.

Table 6.1: Risk of virologic failure rate for patients on ART

Adherence level	Virologic failure rate Maggiolo <i>et al.</i> (2005)	Nyeri PGH Patients	
		Sampled patients	All patients on ART for > 1 year
< 75%	17.4%	11 (5%)	35 (5%)
75% - 85%	12.2%	21 (9%)	63 (9%)
86% - 95%	4.3%	72 (31%)	219 (31%)
> 95%	2.4%	125 (55%)	388 (55%)
Total		229 (100%)	705 (100%)

The cost of 2nd line ART regimens is considerably higher than that of 1st line regimens. A typical adult 1st line regimen in the Kenyan ART Guidelines comprising Stavudine 30mg, Lamivudine 150mg and Nevirapine 200mg tablets cost US\$10.80 per patient per month in May 2007. In comparison, the recommended adult 2nd line regimen comprising Abacavir 300mg, Tenofovir 300mg and Lopinavir/ritonavir combination cost US\$97.92 per patient per month (Clinton Foundation HIV/AIDS Initiative, 2007). To treat an adult patient on a 2nd line regimen therefore costs almost 10 times more than it costs to treat the same adult on a 1st line regimen.

In addition to the huge increase in cost, in the regimen examples given above, the pill burden for the 2nd line regimen is 7 tablets per day while that for the 1st line regimen is only 2 tablets per day. Thus if a patient has failed on the 1st line regimen due to poor adherence, the increased pill burden on the 2nd line regimen will probably not help to improve the patient's adherence to ART. Maggiolo *et al.* (2005) observed that a lower number of pills in a prescribed ART regimen and a lower number of required daily doses were both independent

predictors of increased adherence. Thus every effort should be made to ensure that patients stay on the 1st line regimen as long as possible through optimal adherence and thus a lower risk of virologic and treatment failure. The importance of this is even greater in developing countries where resources may not be adequate to cater for the increased cost of ART due to large numbers of patients being switched to the 2nd line regimens.

6.2 Conclusion

- i) Characteristics of patients on long-term antiretroviral therapy: 65% of the patients were female and 92% had either primary or secondary education. One third of the respondents had a steady partner with whom they were living and 22% were widowed. Women were more likely to be widowed, separated or divorced than men. The respondents had an average monthly income of Ksh. 4,977 with women reporting a significantly lower average monthly income (Ksh. 3,909) compared to men (Ksh. 7,207).
- ii) Proportions of patients exhibiting various adherence levels: The mean adherence level for all the patients sampled was $92.7\% \pm 8.5\%$. More than half (55%) of the respondents had optimal adherence to ART based on pill count and pharmacy refill data. 31% had adherence levels of 86%-95% while 9% had adherence levels of 75%-85%. Only 11 (5%) of the patients exhibited adherence levels less than 75%.
- iii) Factors influencing ART adherence among the study population: Patients reported being busy (39%), travelling (21%), forgetfulness (9%) and side effects (8%) as the most common factors affecting their taking of ARV medicines as prescribed. Occupation of respondents was found to significantly affect adherence with employed patients exhibiting a higher odds ratio for non-optimal adherence to ART. Gender,

level of education, marital status, knowledge of normal CD4 count range and patient's last CD4 count as well as disclosure of HIV status were not found to significantly influence adherence to ART.

- iv) Patients' ranking of ART availability was negatively correlated with adherence to ART while that of ART acceptability was positively and highly correlated with adherence to ART. Patients' views on ART affordability and ART accessibility were not found to be correlated with their adherence levels to ART.

6.3 Recommendations

6.3.1 Application of the findings

- i) Patients exhibiting sub-optimal adherence should be identified promptly by pharmacy staff in the ART team pharmacy from ARV drug refill records and performing pill counts before dispensing a new supply of ARV drugs. The ART doctors should assess these patients for signs of treatment failure for instance falling CD4 counts, recurrence of opportunistic infections and rising viral load.

Appropriate measures should be taken by the ART team to improve medication use by these patients; on their 1st line regimen if this is still working, or their 2nd line regimen if treatment failure has already occurred.

Unfortunately, the definitive intervention to promote adherence to antiretroviral therapy has yet to be developed. To date, interventions have either been ineffective or have produced only short-term benefits (British HIV Association, 2001). However, after a comprehensive evaluation of published and unpublished research articles, Stone (2001)

suggested, among others, the following strategies for improving adherence to ART that may also be utilized at the Nyeri PGH:

- (a) Developing a set of adherence-focused activities that are provided for each patient, including an assessment of readiness for HAART, education regarding importance of adherence and consequences of non adherence, an individualized dosing-instruction sheet with photographs of medications, structured follow-up assessment of adherence, and problem-solving for adherence-related difficulties that are identified.
- (b) Giving patients the time and opportunity to develop a warm, caring patient-provider relationship with the health care providers, even if they are not yet receiving ART or do not feel ready to begin receiving ART.
- (c) Making it easy for patients to call and obtain answers to their questions, for instance by giving them the cell phone numbers of the members of staff, and allowing the patients to come in at short notice if problems develop.
- (d) Utilize a multidisciplinary team approach so that the doctors, nurses, pharmacists and counsellors will be available to coordinate some of the adherence-related activities. This also increases the likelihood that patients will find someone on the care team to whom they can comfortably relate and from whom they can get needed information about their medications.
- (e) Scheduling intensive and frequent visits during the month after initiation of ART. These should focus on identifying and solving adherence problems and difficulties with medication tolerance. These visits can also be used to obtain early measures of adherence and to reinforce the correct dosing schedule.

- (f) Providing access to reminder devices, such as beepers, watches with alarms, or medication organizers (pill boxes) for patients who believe that they may benefit from their use.
- (g) Assessing adherence at each visit and using each visit as an opportunity to discuss adherence with every patient

All these proposals are feasible and inexpensive and may be attempted in the setting of a public hospital to improve adherence to ART.

- ii) The category of employed individuals among the patients on ART should be given particular attention by the healthcare team to assist them develop strategies of optimizing their adherence to ART to prevent early development of resistance and subsequent treatment failure.
- iii) Efforts should be made, in the short term, to make the clinic as user-friendly as possible by improving the waiting bay at the CCC through provision of magazines, educational or entertaining videos and, if resources are available, refreshments for the patients as they wait to be attended to. This can be undertaken by the ART committee in close liaison with the hospital management team as well as other partners who support ART programs.

In the long term, strategies should be put in place by the hospital management team to reduce waiting time by increasing the number of health care workers attending to the patients. The ART team can also space out appointments for stable patients so that they attend the clinic once every few months instead of once a month.

- iv) Although the relatively lower rating of nursing care might not be an indicator of low quality of service provision, efforts should be made by the nursing team, with support

from the ART clinic doctors, to explain to the patients the reasons for making some potentially unpopular decisions or policies affecting the patients.

- v) Given the highly significant correlation between patients' ranking of ART acceptability and adherence levels to ART, potentially large increases in the number of patients exhibiting optimal adherence may be realized by improving the parameters included under ART acceptability. These include the quality of consultation time, privacy during consultation with the clinician, nursing care, provision of health education and communication and information received at the ART clinic. Such improvements are inexpensive and relatively easy for the ART team to implement.
- vi) At national level, the Ministry of Health and the National AIDS and STI Control Program should issue guidelines for adherence measurement and monitoring and conduct regular reviews of adherence data to identify facilities whose patients exhibit low adherence levels. Such facilities can then receive additional technical and/or financial support to address the causes of low adherence by their patients.

6.3.2 Suggestions for further Research

- i) A longitudinal study to evaluate patients' adherence over a period of time would provide additional insight on the adherence patterns of patients. It may also be necessary to incorporate multiple methods of measuring patients' adherence, for instance patient self reports and unannounced pill counts by telephone, to ART patients to increase the reliability of the adherence data obtained.

- ii) It would be useful to evaluate the influence of adherence levels of patients on their clinical outcomes for example patients' CD4 counts and viral loads as well as occurrence of opportunistic infections.

- iii) Further multi centre studies addressing healthcare team and health system-related factors affecting adherence among ART patients would also assist in creating a clearer picture of the multiple, and often complex, factors that influence adherence to therapy.

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APPENDICES

Appendix 1: Clearance Letter from Nyeri PGH Management

MINISTRY OF HEALTH

Telegrams: "MEDICAL", Nyeri
Telephone: Nyeri 061-30819
Fax No. 061-2185
When replying please quote
Ref No.



MEDICAL SUPERINTENDENT,
PROVINCIAL GENERAL HOSPITAL,
P.O. Box 27,
NYERI

Date: 04 October 2007

To:
Victor Sumbi Muthiani,
Pharmacy Department,
P.O. Box 27,
Nyeri

Dear Victor Sumbi,

**REF: ASSESSMENT OF PATIENT RELATED FACTORS INFLUENCING
ADHERENCE TO ANTIRETROVIRAL THERAPY AT NYERI PROVINCIAL
GENERAL HOSPITAL**

Reference is made to your application dated 02-October-2007 requesting permission to conduct the above-mentioned study at this hospital. The proposal has been evaluated and found to have merit. Kindly be informed that approval has been granted under the following conditions:

1. Informed consent shall be sought and obtained from all patients before the interview is conducted
2. Confidentiality of patient data will be ensured as stated in the research proposal

You are also requested to share the findings of your study with the relevant hospital department when you complete your thesis. I wish you success in your undertaking.

Sincerely,
 Dr. S. Ojiambo
For
Medical Superintendent

Appendix 2: Results of Pilot Study

1. Time taken to conduct the interview

The interview schedule took an average of 35 minutes to administer to the five patients with a maximum of 43 minutes and a minimum of 37 minutes. The time taken was rated as acceptable by all the five respondents

2. Reliability of the instrument

Four of the five respondents gave generally the same responses to the demographic questions and the closed ended questions for both occasions that the interview schedule was administered to them. The one respondent who gave markedly differing responses at the two interviews also gave some conflicting demographic information on the two occasions. It was therefore concluded that the instrument was reliable and could collect consistent data over time

3. Structure of the questionnaire

After the pilot testing, the interview schedule was subdivided into five sections mainly to improve its flow, make the interview better structured and also to facilitate data entry. Prior to the pilot test, the interview schedule was in two parts- the Background Information and the questions.

4. Clarity of interview questions

The data collection team clarified several ambivalent and unclear questions in the interview schedule and agreed on a standard way of administering the interview.

Appendix 3: Letter of Consent from Respondent

I _____ have out of my own will, without prejudice agreed to take part in the study **“Assessment of factors influencing adherence to antiretroviral therapy at Nyeri Provincial General Hospital”**.

I have read the purpose of the study and the requirements attached to it. I am also aware of my right to withdraw my consent and participation at any stage of the study should I desire to.

Signed:_____
Patient_____
Researcher_____
DATE

Appendix 4: Interview Schedule

Instructions:

- i) Answer the questions by circling the answers you feel most appropriate.
- ii) Where applicable, write your answers in the space provided.
- iii) If you would like to add any comments or suggestions, use the space at the end of the interview.

1. BACKGROUND INFORMATION

- 1.1 Date..... 1.2 **Interview No. Q-**
- 1.3 Age..... 1.4 Sex: Male/Female.....
- 1.5 What is your highest level of **education**?
1. Primary 2. Secondary 3. Mid-level college 4. University 6. No response
- 1.6 What is your occupation?
1. Student 2. Unemployed 3. Paid employee 4. Self employed
- 1.7 What is your marital status?
1.Never married 2.Steady Partner not living together 3.Steady partner living together 4.Married monogamous 5.Married polygamous 6.Widowed 7. Separated/Divorced
- 1.8 Have you disclosed your HIV status to any one?
1. Yes 2. No 3. No response 4. Don't remember
- 1.9 If Yes in 1.8 above, what was the relationship with the person/s you disclosed to?
1. Spouse/Sexual partner 2. Parents/Children 3. Relatives 4. Friends/Colleagues 5. Spiritual leader (You can tick more than one choice if applicable)
- 1.10 From the options in 1.9 above, what type of support did you receive?
Psychological/Emotional=1, Financial=2, Moral=3, Spiritual=4 N/A=5 (You can tick more than one choice if applicable)
- 1.11 How would you rate the overall support received from Spouse/Sexual partner, Parents/Children, Relatives, Friends/Colleagues etc listed above?
Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5 N/A=6
- 1.12 How would you rate your satisfaction with the support above?
Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5 N/A=6
- 1.13 What is your average monthly income? Ksh_____
- 1.14 What type of housing do you live in?
1. Permanent 2.Semi-permanent 3.Grass-thatched 4.Shanty None=0
- 1.15 Do you know your latest CD4 count?
1. Yes 2. No 3. No response 4. Don't know
- 1.16 Do you know the normal range of CD4 cell count?
1. Yes 2. No 3. No response 4. Don't remember

1.17 Do you know any substances that when consumed can lead to non adherence?

1. Yes 2. No 3. No response 4. Don't know

1.18 If Yes in 1.16 above, kindly list them in order of their contribution to non-adherence.....

.....

2. ART AVAILABILITY

2.1 How would you rate the overall (availability of) ART services at the hospital/CCC?

2.1.1) On-going counselling

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.2) TB

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.3) ARV

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.4) Wards

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.5) PTC

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.6) PMCT

Excellent=1 Good=2 Average=3 Poor=4 Don't Know=5

2.1.7) Any other (Specify).....

2.2 How would you rate the (availability of) **ART medical supporting facilities** at this hospital/CCC

2.2.1) Pharmacy

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

2.2.2) Laboratory

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

2.2.3) Any other (Specify).....

2.3 How would you rate the (availability of) **general auxiliary facilities** at this hospital/CCC (refreshments, TV, radio, flowers etc)?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

2.4 Which **important facilities/services** do you think the hospital/CCC should have, that are not currently available (list in order of priority)?

.....

.....

2.5 Any comments/suggestions/critique etc on/of (the availability of) ART services at the hospital/CCC

.....

.....

3. ART ACCESSIBILITY

- 3.1 How would you rate the appropriateness of **physical location / accessibility** of this hospital/CCC (ease of access)?
Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5
- 3.2 **How long** did it take you to reach this hospital/CCC from your home?
 Specify
- 3.3 How would you rate **waiting time** at this hospital/CCC?
Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5
- 3.4 List the areas where you experienced **long waiting times** (in order of duration):

- 3.5 How would you rate the **convenience of facilities** for people with **chronic ailments** at this hospital/CCC?
Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5
- 3.6 How would you rate the **convenience of facilities** for **children** and/or people with **children** at this hospital/CCC?
Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5
- 3.7 How would you rate the accessibility of **any doctor** in this hospital (clinical officers, ART specialists etc)?
Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5
- 3.8 How long would you be **willing to wait for a doctor** in this hospital/CCC? (Specify)

4. ART AFFORDABILITY

- 4.1 How would you rate the **overall** charges & costs of ART at the CCC?
High=4 Reasonable=3 Low=2 Don't Know=5 Free of Charge=1
- 4.2 How would you rate the charges & costs for any **specialized** treatment you receive resulting from ART medication at the CCC?
- 4.2.1 Psychiatry
High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5
- 4.2.2 Ophthalmology
High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5
- 4.2.3 Dental
High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5
- 4.2.4 E.N.T
High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5
- 4.2.5 Dermatological

High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5

4.2.6 Other (Specify): _____

High=1 Reasonable=2 Low=3 Don't Know=4 Free of Charge=5

4.3 Does the hospital/CCC waive fees for children **less than 5 years**?

No= 0 Yes=1 Don't Know=3

4.4 Given the charges & costs at this hospital/CCC, would you recommend other people for ART services here?

Totally agree=1 Agree=2 Disagree=3 Totally Disagree=4 Don't Know 5

5. ART ACCEPTABILITY

5.1 In your opinion, how would rate the **professional competence** of doctors handling your ART needs?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.2 In your opinion, how would rate the **doctor's behaviour** (friendly, caring, listening etc)?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.3 In your opinion, how would rate the **quality of time spent by the doctor** addressing your needs (explaining about health & treatments, patient & not in a hurry etc)?

Very adequate=1 Adequate=2 Inadequate=3 Very inadequate=4 Don't Know=5

5.4 In your opinion, how would you rate **privacy/confidentiality during examination** at this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.5 In your opinion, how would rate the **behaviour of nurses** (smiling faces, polite, caring attitude, supportive, time to talk, time to explain issues etc)?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.6 In your opinion, how would rate the **nursing care** (promptness in meeting needs, enquiries about discomfort etc)?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.7 How would you rate the provision of **health education** at this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.8 How would you rate the level of **communication and information** you received this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.9 How would you rate the **reliability of information** given to the actual experience(s) received?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.10 How would you rate the **general state of the facilities** at this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.11 How would you rate the **general cleanliness** at this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.12 How would you rate the accuracy of **record keeping** at this hospital/CCC?

Excellent = 1 Good = 2 Average = 3 Poor = 4 Don't Know = 5

5.13 Have you experienced any side effects as a result of using ART medication?

Yes=3 No=1 No response=4 Don't remember=2

5.14 If yes in 5.14, in your opinion, how would you rate the severity of the side effects?

Grade 4=5 Grade 3=4 Grade 2=3 Grade 1=2 Not Applicable=1

5.15 If yes in 5.14 above, how does this side effect affect your overall perception of ART?.....
.....

5.16 What other factor(s) other than those mentioned in this interview affect your adherence to ART medication?
.....
.....

5.17 What is your overall satisfaction with ART medication?
.....
.....