Prevalence and Predictors of Non-adherence, and Incidence of Treatment Failure among Patients on Free Highly Active Antiretroviral Therapy in Nairobi, Kenya

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DECLARATION

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

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DEDICATION

This thesis is dedicated to my mother, E. Wairimu and father, B. Wakibi for the firm foundation they laid in my life. To my wife, J. Wairimu and children, E. Wambui, J. Wangui and B. Mohe for their encouragement, support and understanding throughout this programme.

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LIST OF ABBREVIATIONS AND ACRONYMNS

AACTG	Adult AIDS Clinical Trials Group
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CASE	Center for Adherence Support Evaluation
CBS	Central Bureau of Statistics
CCC	Comprehensive Care Center
CPCRA	Community Programs for Clinical Research on AIDS
CMR	Centre for Microbiology Research
DAART	Directly Administered Antiretroviral Therapy
DOT	Directly Observed Therapy
HAART	Highly Active Antiretroviral Therapy
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
IDU	Injection Drug Use
IRIN	Integrated Regional Information Networks
ITAC	International HIV Treatment Access Coalition
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KAIS	Kenya AIDS Indicator Survey
KDHS	Kenya Demographic Health Survey
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KIPPRA	Kenya Institute of Public Policy Research and Analysis

KNH	Kenyatta National Hospital
MEMS	Medication Event Monitoring System
MOH	Ministry of Health, Kenya
MTCTP	Mother-To-Child Transmission Prevention
NACC	National AIDS Control Council
NARTI	Nucleoside Analogue Reverse Transcriptase Inhibitors
NASCOP	National AIDS and STD Control Programme
NERC	National Ethical Review Committee
NNRTI	Non-Nucleoside Analogue Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
PAGAA	Panel on Antiretroviral Guidelines for Adults and Adolescents
PI	Protease Inhibitors
PLWHA	People Living With HIV/AIDS
TB	Tuberculosis
UNAIDS	United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USD	United State of America Dollar
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

ABSTRACT

Management of HIV infection consists of Highly Active Antiretroviral Therapy (HAART) which suppresses viral replication and controls opportunistic infections. HAART regimen requires near perfect adherence (≥95%); suboptimal adherence to therapy can lead to incomplete suppression of viral replication, resulting in the emergence of drug-resistant HIV virus. Knowledge about non-adherence to HAART, treatment failure and associated factors in Kenya is limited. The objective of this study was therefore to determine prevalence and factors associated with non-adherence, and incidence of ARV treatment failure among HIV+ patients receiving free HAART in Nairobi. This was a facility-based cross-sectional study undertaken in purposively selected Comprehensive Care Centers at Kenyatta National Hospital, Kenya Medical Research Institute and Riruta Health Centre. Four hundred and three HIV/AIDS outpatients aged 18 or more years on free HAART for three or more months were recruited and analysed. Using a structured questionnaire, patients were interviewed about their health beliefs, health system interaction, ARV therapy uptake and reasons for non-adherence to regimen when they attended clinic for ART or routine checkup. Additional demographic data and treatment history was extracted from patients' files. The data were analyzed for frequencies, cross-tabulations, chi-square test and significance set at $p<0.05$. Multivariate logistic regression model was used to determine independently significant factors. Overall, 18% of respondents were non-adherent to therapy by self report – CASE adherence method, 99% had belief in benefits of HAART and 83% were knowledgeable about ART. Prevalence of HIV treatment failure

determined using immunological and clinical assessment was 4.7% and incidence rate, 1.45 per 100 person-years. Young age (<39.7 years), having difficulty with dosing schedule, perceived lack of social support, less than six months on ART, stating reason for missing therapy, accessing ART in a clinic within a walking distance from home and spending more than half day in clinic to refill were found to be associated with non-adherence to HAART. However, only accessing ART in a clinic within a walking distance from home (OR=2.387, $CI._{95}$=1.155-4.931; p=0.019), difficulty with dosing schedule (OR=2.310, $CI._{95}$=1.211-4.408, p=0.011) and giving reason for missing doses (OR=2.264, $CI._{95}$=1.261-4.064; p=0.006) predicted non-adherence to treatment by multivariate regression model. Forgetfulness was the most common reason given for missing medication. Time period on ART confounded the association between respondent's age and non-adherence to therapy, while social support and waiting time at clinic modified the effect of the variable giving reason for missing doses on non-adherence. The study found improved prevalence of adherence to HAART in Nairobi compared to previous studies and estimates in Kenya, and was comparable to rates in other developing countries. The improvement in adherence indicated that direct cost of ARV therapy together with knowledge of HAART and belief in benefits of therapy have positive impact on compliance to therapy and therefore free HAART should be made increasingly available for all eligible patients. However, further gains in adherence can be achieved through interventions employing behavioral educational strategies to increase knowledge about ART and ability to fit therapy in own lifestyle; cue-dose training to impact forgetfulness; influence

social groups to optimize social and emotional support and implement strategies to reduce time taken at clinics to refill. The interventions should target patients accessing therapy from ARV clinics within walking distance from their homes and those with short experience taking HAART. Health care provider should seek to know reasons why a patient is missing therapy and address them in a sociable manner. The study recommends research to determine whether indirect costs of ARV therapy impacts non-adherence among patients of low socioeconomic status. Further research is recommended to explain the high non-adherence rates among patients accessing therapy in clinics within walking distance to their homes. The study also recommends that treatment failure be confirmed using viral load test to avoid misdiagnosis.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Combating Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV/AIDS) is one of the eight Millennium Development Goals and a top priority in bilateral and multilateral development aid. However, over 25 years since the infection was first recognized in early 1980s, there is still no cure for HIV/AIDS. Available management of HIV infection consists of highly active antiretroviral therapy (HAART) which stabilizes patient's symptoms and viremia (Panel on Antiretroviral Guidelines for Adults and Adolescents (PAGAA), 2005). It is credited with transforming HIV/AIDS from a fatal condition to a manageable illness (Wood *et al.,* 2003). HAART has been reported to slow the rate of progression from HIV to AIDS by up to 86% when compared with no treatment.

Many people living with HIV/AIDS (PLWHA) from developed countries where therapy is accessible have benefitted from HAART. In order to address poor access especially in the developing world, HIV/AIDS experts hosted by the World Bank's Global HIV/AIDS Programme, the World Health Organization (WHO), and the International HIV Treatment Access Coalition (ITAC) recommended that HIV therapy be provided at no cost to the poor in developing countries (Lange *et al.,* 2004).

Kenya started implementing free HAART rollout programmes to improve treatment access in 2003. By 2007, a total of 288 Comprehensive Care Centers (CCC) had been opened in Kenya, and were providing free HAART to 160,000 HIV+ patients in need of treatment (Integrated Regional Information Networks (IRIN**)**, 2007). Of the 288 CCCs, 167 were in government facilities, including all provincial hospitals, all district hospitals, most sub-district hospitals and some health centers (IRIN, 2007). This has lead to a decline in AIDS-related morbidity and mortality rates, and improved quality of life (IRIN, 2007). ART reduced annual number of adult deaths in Kenya from 120,000 in 2003 to 85,000 in 2006 (National AIDS and STD Control Programme (NASCOP) and National AIDS Control Council (NACC), 2007). Kenya aims to achieve universal access to ART and to reduce HIV related mortality by 50% by 2010 (NASCOP, 2009).

Unfortunately, not all PLWHA can benefit from ARV treatment. A significant number cannot tolerate ARVs because of drug toxicity or due to drug resistance (Lange *et al*., 2004). A major challenge, however is to ensure near perfect adherence to therapy for life. Management of HIV entails taking HAART, maintaining special dietary practices and lifestyle.

Non-adherence to therapy is defined as failure to take correct dose of medication, at the right time and lack of observing dietary restrictions prescribed (Silverman S, 2006). This may vary from missing one dose of one or all drugs; missing multiple

dosages or not observing time intervals and/or diet restriction. Studies have used varying levels as thresholds for adherence to ARV therapy. However, adherence of at least 95% is required to fully attain the benefits of HAART (Paterson *et al*., 1999; Munyao *et al*., 2005).

Ninety five percent adherence is the recommended threshold for first-line treatment of HIV and AIDS in Kenya (NASCOP, 2005). In this study, a composite score (The Center for Adherence Support Evaluation (CASE) adherence index) in a CASE adherence questionnaire (Appendix 5) was used to determine non-adherence (Mannheimer *et al*., 2006). The tool has high degree of sensitivity and specificity with the Adult AIDS Clinical Trials Group (AACTG) 3-day self-report (concurrent validity) and is a better predictor of HIV RNA changes over time than 3-day self-report (Mannheimer *et al*., 2006).

Suboptimal adherence to HAART regimen can lead to incomplete suppression of viral replication (Byakika *et al*., 2005), resulting in the emergence of drug-resistant virus (Bangsberg *et al*., 1999; 2003). The consequences of drug resistance include treatment failure, increased direct and indirect costs associated with the need to start more costly second-line treatment, spread of resistant strains of HIV and the need to develop new anti-HIV drugs (Ferrantelli *et al*., 2004; Little *et al*., 1999; Harrigan, 2005).

Treatment failure occurs when HIV medications do not adequately control the infection. In developed countries, success has been defined using viral load tests which are often difficult to provide in developing countries. Alternatives such as CD4 T-cell counts and experiences of HIV-related conditions or decline in physical health despite at least 3 months of HIV treatment are therefore used (Bisson *et al.,* 2008).

The major concern over the rapid scaling up of ART in developing countries is the emergence and transmission of HIV drug resistant strains at the population level. This could lead to failure of basic ART programmes as well as strategies to prevent HIV transmission through pre-exposure prophylaxis or the use of topical microbicides. In large scale, it can lead to drug resistance pandemics.

To minimize the risk of such pandemics, it is recommended that scale-up ART programmes include support structures to help patients adhere, HIV prevention activities to minimize spread of drug resistant HIV virus strains, and HIV therapy be provided at no cost to all needy cases (Lange *et al*., 2004). Risk of non-adherence in health conditions requiring long-time treatment is high; Lafeuillade (2001) and Cheever and Wu (1999) reported a non-adherence prevalence of 50% on average across a range of chronic conditions.

In Kenya, there is no reported empirical data to demonstrate effectiveness of adherence to HAART. Studies in Kibera (N=357) and Mombasa (N=116) reported 52% (Ellis *et al.,* 2006) and 36% (Munyao *et al*., 2005) adherence respectively. It was also estimated that by 2007, 2% of the 160,000 PLWA on free HAART in Kenya were drug resistant (IRIN, 2007). This was likely to increase as more people accessed ARV therapy and as they remained on therapy for a life time (Byakika *et al*., 2005).

Researchers have found reasons for poor adherence to HAART to be varied and overlapping. Major psychosocial issues, such as poor access to medical care, inadequate social support, psychiatric diseases, drugs abuse and health beliefs (Cheever and Wu, 1999) have been reported in various countries. The complexity of the HAART regimens, whether due to the number of pills, dosing frequency, meal restrictions or side effects also contribute to poor adherence (Nieuwkerk *et al*., 2001; WHO, 2006)

Loss of earning associated with clinic attendance and indirect costs such as transport, medical consultation fees and routine tests required to put patients on treatment and subsequent medical monitoring where initial costs have been paid for, have been reported to influence adherence to treatment (Aspeling and Van Wyk*,* 2008; Munro *et al.,* 2007; WHO, 2003).

The pharmaceutical industry is making strenuous efforts to address regimen characteristics that are amenable to change including pill burden, dosage frequency, administration in relation to food intake, and the presence of irritating daily toxicities (WHO, 2006).

Thorough knowledge of non regimen factors:- psychosocial issues; access to medical care, social support, psychiatric disease, drug abuse and health beliefs is required by health workers to make better predictions of patients' adherence tendency and to inform decisions about treatment.

1.2 Problem Statement

Adherence to long term therapy has been found to be multicausal. However, most drugs taken for chronic health conditions demonstrate acceptable efficacy even when a considerable number of doses are missed, making occasional lapses harmless. Unfortunately, HIV treatment is less flexible. In order to attain the full benefits of HAART, at least 95% adherence is required (Paterson *et al*., 1999; Munyao *et al*., 2005).

To attain the near perfect adherence, the required adherence interventions are to be designed and nested in treatment programmes. To design and appropriately "nest" effective adherence interventions in HAART programmes, information about barriers and facilitators for adherence are required. In Kenya, the level of non-

adherence, effectiveness of adherence programmes being implemented alongside HIV treatment, prevalence of treatment failure and factors associated with non-adherence is not well known. This formed the basis of this study.

1.2.1 Justification

Kenya is implementing a free HAART programme to expand access to benefit majority of HIV+ patients in need but cannot afford the cost of treatment. By year 2007, 172,000 adults were benefiting from the free ARV therapy and the number is expected to increase to 400,000 by end of 2010 (NACC/OP, 2008). However data on non-adherence to HAART and factors influencing adherence in Kenya is limited.

It is estimated that 2% (3200 cases) of the 160,000 PLWHA on free HAART in Kenya are drug resistant (IRIN, 2007) and the number is likely to increase as more PLWHA access free ARV therapy. Zeh *et al.* (2008) in a study among breastfeeding mothers in Kisumu, Kenya, found 6% drug-naïve breastfeeding babies whose mothers were on HIV treatment. It is known that 18-28% of women and 31-49% of men in Kenya engage in high risk sexual behaviours (CBS, 2004). If hypothetically the estimated 3200 drug resistant patients engaged in risky sexual behaviours, the increased infection rate with HAART resistant HIV virus may result in drug resistant pandemic.

The purpose of this study was therefore to determine prevalence of non-adherence to HAART, associated factors, and prevalence and incidence of treatment failure among patients receiving free ARV in Nairobi, Kenya.

This knowledge generated will inform and contribute to design of adherence to therapy interventions for health conditions requiring long-term treatment and ensure adherence is “nested” in therapy. In the short term, the findings will help free HAART programme implementers to predict non-adherence and enrich HAART by introducing an evidence based adherence track. The findings will also inform health policy and resource allocation by government in expanding access to therapy.

1.3 Hypothesis

H_0: There is no association between putative factors and non-adherence to HAART among HIV patients in Nairobi, Kenya

H_1: There is an association between putative factors and non-adherence to HAART among HIV patients in Nairobi, Kenya

1.4 Objectives

1.4.1 General objective

To determine prevalence and predictors of non-adherence, and incidence of treatment failure among patients on free HAART in Nairobi, Kenya.

1.4.2 Specific objectives

1. To determine prevalence of non-adherence to ARV therapy among HIV+ patients on free HAART in Nairobi, Kenya.
2. To determine factors associated with non-adherence to ARV therapy among HIV+ patients on free HAART in Nairobi, Kenya.
3. To estimate the incidence of treatment failure among HIV+ patients on free HAART in Nairobi, Kenya.

CHAPTER TWO

LITERATURE REVIEW

2.1 History and Epidemiology of HIV

Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS); a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections (Coffin *et al*., 1986). The virus infects vital cells in the human system; CD4+ T cells, macrophages and dendritic cells.

The infection was first recognized in 1981 and by 2006, UNAIDS/WHO estimated that AIDS had killed more than 25 million people and about 0.6% of the world's population was infected with HIV (UNAIDS, 2006). By the end of 2004, 2.1 million people were living with HIV/AIDS in Europe with the majority coming from Eastern Europe. In 2005 alone it was estimated that between 2.4 and 3.3 million people died from AIDS worldwide with a third of the deaths occurring in sub-Saharan Africa, especially in countries in the Eastern, Central and Southern Africa (UNAIDS, 2006). Currently, more than 6800 people are becoming infected with HIV and more than 5700 are dying every day worldwide (WHO, 2009).

The first case of HIV/AIDS in Kenya was reported in 1984. The cases rapidly grew from 5% in 1990 to 14% by the end of 1998. In November 1999, HIV/AIDS was declared a national emergency in Kenya and NACC; a multi-sectoral body was

created to coordinate and develop an action plan to effectively combat the menace (Kenya Institute of Public Policy Research and Analysis (KIPPRA), 2004).

The Kenya Demographic and Health Survey (KDHS) of 2003 reported a decline in HIV prevalence to 6.7% among adults aged 15-49 years. The results of Kenya AIDS Indicator Survey (KAIS) in 2007 revealed a statistically insignificant increase in HIV prevalence to 7.1% among adults age 15-64 years; 5.4% in men and 8.4% in women. Regional differentials were reported and varied from 14.9% in Nyanza province, 8.8% in Nairobi to a low 0.8% in North Eastern province. Gender differences were found in all regions with women consistently recording higher prevalence (NASCOP and Ministry of Health, Kenya (MoH), 2008). Kenya's target is to reduce HIV prevalence in adults to less than 5% by 2010 (NASCOP, 2005).

Known exposure routes for HIV infection in the world vary from blood transfusion with 9000 infections per 10000 exposures; childbirth, 2500; Needle-sharing injection drug use (IDU), 67; receptive anal intercourse with no condom, 50; receptive penile-vaginal intercourse with no condom, 10; insertive anal intercourse with no condom, 6.7; and insertive penile-vaginal intercourse, 5 (Smith *et al*., 2005).

The importance of the mode of HIV transmission varies by region and community depending on the social and cultural context; especially cultural factors that govern

community's sexual practices and beliefs. In Europe and America, the primary modes of transmission are IDU, and homo and heterosexual contact (WHO, 2006). In Asia, the primary modes of transmission are mainly heterosexual contact and to a lesser extent IDU.

In Kenya, the most important routes of HIV transmission are heterosexual contact and mother to child transmission (MTCT); in uterus, during child birth and breastfeeding (CBS, 2004). Heterosexual transmission accounts for 75% of all transmissions while approximately 30 to 40% of babies born to HIV+ positive mothers in Kenya end up being infected (CBS, 2004).

Injecting drug use as a mode of HIV transmission in Kenya has not been extensively studied. However, Ndetei (2004) found 68% to 88% of IDUs in Mombasa to be HIV positive. A seroprevalence study among IDUs in Mombasa reported 50% prevalence while six out of seven women in the sample tested positive for HIV (NASCOP, 2005).

Use of antiretroviral therapy during pregnancy and postpartum, judicious use of caesarean sections and avoidance of breastfeeding have been found to reduce mother to child HIV transmission considerably. A reduction of MTCT from 30-40% to approximately 2% has been reported in Europe. However, such achievements are unlikely in the general population in developing countries where breastfeeding

is a deep rooted practice. In Kenya, only 0.8% of mothers are reported not to breastfeed in the first two months of life (CBS, 2004).

Reduction of risk of heterosexual HIV transmission is mainly by condom use and avoidance of high risk sexual behaviour. However, prevalence of condom use among high risk groups (multiple, concurrent and a high frequency of changing partners) in Kenya is about 28%, 19% and 18% among women who have never married, married and divorced/widowed respectively; and 49%, 45% and 31% among men who have never married, married and divorced/widowed respectively (CBS, 2004). This uptake is low considering the high HIV prevalence rates reported in some regions such as Nyanza province.

2.2 HIV Therapy

Acquired immunodeficiency Syndrome (HIV/AIDS) has no cure. The only known method of prevention is avoiding exposure to the virus. Basic prevention measures for HIV include condom use, harm-reduction services such as distribution of disinfectants and clean syringes for injection drug use, antiretroviral prophylaxis, sex education and avoiding breastfeeding. Antiretroviral post-exposure prophylaxis is believed to reduce the risk of infection if initiated immediately after exposure (Fan *et al*., 2005).

Management of HIV infection consists of highly active antiretroviral therapy (HAART) which stabilises patient's symptoms and viremia (PAGAA, 2005). This has been highly beneficial to many PLWHAs since its introduction in 1996, when the protease inhibitor (PI) -based HAART became available (Palella *et al*., 1998).

Current HAART options are combinations (or "cocktails") consisting of at least three drugs belonging to at least two types, or "classes," of anti-retroviral agents. Typically, these classes are two nucleoside analogue reverse transcriptase inhibitors (NARTIs or NRTIs) plus either a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor (NNRTI) (PAGAA, 2005). The standard first-line regimen for adults in Kenya is a combination of three antiretroviral drugs; stavudine (d4T), lamivudine (3TC), nevirapine (NVP) or efavirenz (EPZ) (NASCOP, 2005).

Data indicates that achieving complete adherence to treatment for chronic conditions is problematic and should be expected in most settings. Long-term drug regimens involve further challenges and complications to adherence (Jefferds *et al*., 2001). The average prevalence of non-adherence is 50% (Lafeuillade, 2001; Cheever and Wu, 1999) across a range of chronic conditions.

Most drugs taken for chronic conditions demonstrate acceptable efficacy even when a considerable number of doses are missed making occasional lapses

harmless (Harrigan, 2005). Antiretroviral regimens, however, requires an unprecedentedly high level of adherence over an indefinite time period to give best results (Simoni *et al*., 2003). Ninety five percent is the recommended threshold for adherence to first-line treatment of HIV and AIDS in Kenya (NASCOP, 2005).

Various studies have found adherence to HAART a major predictor of viral suppression of HIV replication, emergence of drug resistance, disease progression and death (Nachega *et al*., 2006; Byakika *et al*., 2005; Bangsberg *et al*., 2003; Paterson *et al*., 1999; Cheever and Wu, 1999; Mills *et al*., 2006).

2.3 Adherence to HAART

Adherence is defined as the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider (WHO, 2003). It is a behavioral process, strongly influenced by multiple factors.

Prevalence of non-adherence to long-term therapy of 50% has been reported in various studies (Lafeuillade, 2001 and Cheever and Wu, 1999). Jefferds *et al.* (2001) reported a 40% full adherence to antimicrobial inhalational anthrax therapy in a 60 days adherence study. Munro *et al.* (2007) found 50% of all TB patients did not complete treatment. Silverman (2006) reported 26% non-adherence to osteoporosis therapy in women while WHO (2003) reported 51%, 43%, 27% and

26% adherence to antihypertensive medication regimen in United States, China, the Gambia and the Seychelles, respectively.

Adherence to ARV therapy is the ability of the person living with HIV/AIDS to be involved in choosing, starting, managing, and maintaining a given therapeutic combination of medication regimen to control viral replication and improve immune function (Simoni *et al*., 2003). Adherence to HAART has been measured using a variety of methods. These include pill count, pharmacy records, and self-report (Watson *et al*., 1998). Other methods are drug plasma concentration (Murri *et al*., 1999), plasma HIV-1 RNA and CD4 cell count (Haubrich *et al*., 1999); medical appointment keeping, electronic medication monitoring/medication event monitoring system (MEMS) (Bangsberg *et al*., 1999), and clinician/provider estimate of adherence (Miller *et al*., 1999). Of these, self-report is the most practical and widely used tool (Atreja *et al*., 2005). It is easy to administer, inexpensive and may reveal reasons for missed doses. Self-report of non-adherence is reliable and adherence measured by self-report correlates with HIV laboratory and clinical outcomes (Mannheimer *et al*., 2006).

Self-report method varies from use of a tool developed by AACTG where 3 or 4-days self-report is used; patients are made to recall day-by-day, dose-by-dose ART medication uptake over 3 or 4 days to other simpler formats such as Community Programs for Clinical Research on AIDS (CPCRA) 7-day self-report,

Visual Analog Scale and the Center for Adherence Support Evaluation (CASE) Adherence Index.

Studies to investigate adherence to ARV therapy have used 100% (Iliyasu *et al*., 2005), >95% (Byakika *et al*., 2005), >90% (Orrell *et al*., 2003) and >80% (Mills *et al*., 2006) as threshold for adherence and found adherence of at least 95% to stabilize patient's symptoms and viremia. For patients to achieve 95% adherence, all barriers must be addressed; patients, the regimen, providers and HIV care sites must work in harmony (Stone, 2001).

Laws *et al.* (2000) and Atreja *et al*. (2005) described adherence to ART as complex, while Aspeling and Van Wyk (2008) and Remien *et al.* (2003) found non-adherence multi-causal in studies on factors associated to ART in developed countries. Cheever and Wu (1999) found approximately 40% of patients receiving antiretroviral therapy to have significant problems with adherence. In a meta-analysis study of prospective studies assessing adherence, Mills *et al.* (2006) found a combined continental adherence to AR therapy of 64% with 55% adherence in North America and 77% in Africa.

In a HIV Cost and Utilization Study in the United States in a national representative probability sample of 1910 persons taking ARTs, it was found that 57% of the subjects were 100% adherent over the seven days prior to interview (Wenger *et*

al., 1999). In Netherlands, in a study to investigate adherence to HAART among patients in a clinical cohort study, Nieuwkerk *et al.* (2001) found 47% of the patients took all antiretroviral medication in accordance with time and dietary instructions.

Byakika *et al.* (2005) found 68% adherence to HIV treatment in Uganda, 54% in Nigeria (Iliyasu *et al*., 2005) and 63% in South Africa (Orrell *et al*., 2003) with sample sizes >260 using patient self-report and pharmacy records. Adherence to ARV therapy of 95% has been reported in Rwanda (Omes *et al*., 2004) and Malawi (Hosseinipour *et al*., 2004) at 100% and 95% threshold; Traore *et al.* (2004) found 30% adherence at 100% threshold using self-report in Burkina Faso. Boileu *et al.* (2005) found 51% adherence in Burkina Faso and Mali while Eholie *et al*. (2004) found 49% in Cote D'Ivoire at 90% threshold. Ferris *et al.* (2004) reported 77% optimal adherence (≥95%) in South Africa.

In a study to compare three methods of evaluating adherence to ART in patients receiving free treatment in Blantyre, Malawi, Bell *et al.* (2007) reported 57.5% and 97.5% adherence by MEMS and pill count methods respectively. A cross-sectional survey to determine adherence to ART in Dakar, Senegal reported 58% adherence (Sow *et al*., 2007).

Ellis *et al.* (2006) in a cross-sectional study of adherence to short-term drug regimens in Kibera slums in Nairobi, Kenya, reported 52% adherence. An interventional study to evaluate strategy to improve adherence to ARV therapy in Mombasa, found 59% and 36% patients on treatment (DAART) and control groups respectively had attained near perfect adherence using refilling method (Munyao *et al*., 2005).

Non-adherence to ART medication has attracted increasing attention due to the seriousness and urgency of the problem. Effective adherence interventions in Europe offered patient support and education, and incorporated strategies that were cognitive to teach, clarify or instruct patients on ART use; behavioral to shape, reinforce and influence behaviour and affective to optimize social and emotional support. Other strategies include cue-dose training and directly observed therapy (DOT) whereby, a health care provider observes a patient taking medications in a clinic or community setting (Simoni *et al*., 2003).

2.4 Reasons and factors associated with non-adherence to ARV therapy

Many studies have found health system, drug characteristics and individual factors important in adherence to long-term disease therapies. For example, Munro *et al.* (2007) found structural factors, social context factors, health service factors, and personal factors (including attitudes towards treatment and illness) were associated with adherence in a tuberculosis treatment study in South Africa.

The reasons for non-adherence to HAART are varied (Remien *et al.,* 2003) and overlapping. Major psychosocial issues, such as poor access to medical care, inadequate social support, psychiatric disease and drug abuse have been reported. Social and economic factors, health care team/system, characteristics of the disease, disease therapies and patient-related factors (WHO, 2003) have also be associated with non-adherence.

In Europe factors associated with non-adherence to ARV therapy vary from those related to the patient, the treatment regimen, the doctor-patient relationship, and the system of medical care. Depression, active alcohol/substance abuse, self-efficacy, belief that medications can fit into one's day schedule, understanding the relationship of viral resistance and adherence, and history of adherence have been found to be strongly associated. Sex, race, age, stage of disease (Wenger *et al*., 1999) are inconsistently associated. Education, income, employment, HIV risk factors and belief that medications will improve health have not been found to be always associated.

Studies in Spain, Italy and France; countries with highest epidemic in Western Europe, showed that even where therapy is accessible, injection drug users, immigrants or people with low income and education levels are still less likely to adhere to treatment (Carballo *et al*., 2004). This may be due to poor understanding

of treatment regimen, failure in communication with clinicians or poor social support (Murri *et al*., 2004).

Studies in US have associated heavy alcohol and drug use with non-adherence. Wenger *et al*. (1999) found sex and age; male and being older to predict good adherence. Where drug regimens fitted well into patient's daily schedules or patients perceived ARTs as effective and understood that non-adherence to therapy leads to viral resistance, adherence was good. Low income and education levels; complexity of HAART regimens due to pill number, dosing frequency, meal restrictions or side effects were associated with non-adherence (Nieuwkerk *et al*., 2001; Murri *et al*., 2004). Depression, alcohol and illicit drug use, poor self-efficacy, and certain health beliefs were associated with non-adherence (Cheever and Wu, 1999).

Patients have given varying reasons for missing drugs. These include not having medication at the time of the dose, simply "forgot" to take it, asleep at time of dose, too busy at the time, off usual daily schedule/routine, using drugs/alcohol, pills too difficult to take (too many, too big, schedule too complicated), didn't want to be reminded of HIV/AIDS and stigma associated with ART uptake. Nieuwkerk *et al.* (2001) found forgetting, activities of the moment, feeling sick or ill, change of daily routine, and not having the medications at the requested time important factors in adherence.

In sub-Saharan Africa, Iliyasu *et al.* (2005) found that educated patients were four times ($CI._{95}$ = 1.75-9.24) more likely to adhere to ARV therapy in Nigeria. Age and sex had no significant influence on compliance. Main reasons for non-adherence to medication were non-availability of drugs, forgetfulness and lack of funds.

Byakika *et al*. (2005) in a study to assess level of adherence and associated factors in Uganda found lack of money, forgetfulness, drug inaccessibility, adverse effects of the drug, traveling away from home, unclear instructions by the health provider, being too busy, regimen too complex, fear of wasting drug and presence of other disease conditions as reasons for non-adherence. Income and being single were independent predictors of adherence. Age, gender, education, religion, treatment duration, dosing interval, pill burden, drug and alcohol consumption, confidence in ART, distance from treatment centre, cost of medications, depression, social support and number of concurrent conditions did not predict adherence.

Other researchers have reported nausea, forgetting to take dose, and drug (including IDU) and alcohol use to be related to poor adherence. In a study of 505 HIV+ patients receiving therapy for 4 months in a London hospital, 35% discontinued treatment. 32% of those who discontinued treatment did so because of nausea to ritonavir (Youle, 1998). In a diverse sample of AR recipients in the

United States of America, 29 poorly adherent patients listed a total of 50 reasons for not adhering to their therapy. Over half were related to side effects/toxicity and forgetfulness; 28% and 24% respectively (Weidle *et al*., 1998).

In Kenya, reasons and factors associated with non-adherence are not well understood and documented. ActionAid Kenya attributed non-adherence to treatment in Western Kenya to poor nutrition and poor access to correct information; treatment literacy is not only low among patients, but also among health workers (IRIN, 2007). Hawkins *et al.* (2007) reported more than half (54%) of patients switched at least one drug. 41% of those who switched, was because of clinical toxicity (Lange *et al*., 2004). Ellis *et al* (2006) reported lack of food and clean water, stress, and financial problems to be barriers to adherence in Kibera slums.

Barriers to HAART seem to vary from region to region depending on socioeconomic development, and accessibility to therapy. Thus for an effective adherence programme, knowledge about factors associated with non-adherence among the inhabitants is required.

2.5 HIV Drugs resistance and treatment failure

Interruption of ARV therapy risks patients developing resistance. The consequences of drug resistance include treatment failure, increased direct and

indirect health costs associated with the need to start more costly second-line treatment for patients, severely limit patients' future treatment options, spread of resistant strains of HIV and the need to develop new anti-HIV drugs (Ferrantelli *et al*., 2004; Little *et al*., 1999; Harrigan, 2005).

Studies have reported 5–15% infections with resistant virus among newly infected patients in North America and Europe (Lange *et al*., 2004). The prevalence of drug resistance in drug-naive HIV-infected patients in the UK is among the highest in the world (Booth *et al*. 2007). Booth *et al*. (2007) reported a prevalence of 7.1% among HIV patients diagnosed between 2004 and 2006, 6% among those diagnosed between 1999 and 2001, and 7% for patients diagnosed between 1996 and 2000.

Drug resistance is the latest challenge in HIV therapy. Resistance to one or more of the drugs used in the three-drug cocktail is an increasingly common problem. Consistent yet imperfect use of HAART, has been reported to increase by more than four times the risk of developing resistance to one or more of the three drugs in the first-line treatment (Paterson *et al*., 1999). Imperfect use of therapy has been reported in 50% of HIV patients in the U.S. (Lange *et al*., 2004; Harrigan, 2005). There is also an increasing trend in both developing and developed countries to shift to second-line treatments. In Romania, a third of HAART patients had shifted to second-line treatment because of perceived resistance by 2003 (WHO, 2006).

Cases of drug resistance are still low in Africa (Byakika *et al*., 2005) but it is expected to increase with the free HAART rollout. Drug Access Initiative projects reported that in Cóte d'Ivoire 97 out of 241 patients on HAART experienced a rebound in viral load while Uganda reported 50% rebound (Watson *et al*., 1998). In Kenya, it is estimated that two percent of 160,000 HIV+ patients on free ARVs by 2007 had developed resistance ((IRIN, 2007). Zeh *et al.* (2008) in a HAART study among breastfeeding mothers on treatment in Kisumu, Kenya, found 6% drug-naïve breastfeeding babies were drug resistant.

Drug resistance leads to treatment failure which presents as virologic failure (HIV is detectable after 48 weeks on treatment), immunologic failure (CD4 cell count decline), clinical progression (patient on ART experiences an HIV-related condition despite at least 3 months of HIV treatment).

Virological failure is the most common regimen failure. Failure to switch to a more effective treatment regimen, virological failure progresses to immunologic failure within about 3 years. Immunologic failure may be followed by clinical progression (PAGAA, 2008).

Testing for treatment failure is expensive and beyond reach of many in developing countries. In Kenya, for example cost of drug resistance testing ranges between US$500 and $600 per test (IRIN, 2007) which is prohibitive for ordinary Kenyans.

2.6 Expanding Access to ARV therapy

Due to high cost of anti-retroviral drugs, majority of the world's infected individuals especially in sub-Saharan Africa did not have access to medications and treatments for HIV and AIDS before 2002 (Ferrantelli *et al*., 2004).

By 2002, 381000 people in Europe were in need of ARV therapy and up to 277100 were accessing therapy. Those who were not, were either defaulters, individuals who had developed drug resistance or special cases, such as migrants who were not in contact with the public health care system (WHO, 2006). In Sub-Saharan Africa by 2005, 4,700,000 people were in need of ARV therapy but only 500,000 (11%) had access and, with regional differentials. To improve access, the WHO/UNAIDS 3 by 5 initiative (3 million more people to access HAART by 2005) was established. Many countries are now implementing free HAART rollout programmes.

The impact of increased ART coverage is enormous. USA has decreased AIDS-related morbidity and mortality by up to 90% (Boulle and Ford, 2007). In Brazil, following presidential decree to provide antiretroviral agents through the country's

public health system, HIV-related mortality declined by between 40 and 70%, and HIV morbidity fell by 60–80% between 1996 and 2002. Brazil also experienced a sevenfold reduction in rates of HIV-related hospitalization. It is estimated that nationwide antiretroviral access in Brazil enabled the country to avert 58,000 new AIDS cases and 90,000 HIV-related deaths (Galvao, 2002).

The first public-sector ART treatment programmes in developing countries (with the exception of Brazil) date back to 2000 in Central Haiti (Farmer *et al*., 2001). Since 2002, developing countries have increasingly implemented ART rollout programmes to benefit from HAART's improved survival and quality of life for HIV patients (WHO, 2002).

In February 2003, Biryogo Medical and Social Center in Kigali, Rwanda became the first developing-country health facility to provide ART with USAID funding. The Ghana ART programme, was launched in May 2003 at Atua and St. Martins hospitals. Kenya programme, was initiated in June 2003 at Coast Provincial General hospital in Mombasa (Family Health International, 2005).

Estimates from WHO indicate that as of June 2005, the proportion of patients requiring urgent access to ART and receiving therapy was 56% in Botswana, 10% in Burkina Faso, 15.8% in Cameroon, 5.4% in Cote d'Ivoire, 3.2% in the

Democratic Republic of Congo, 13.6% in Malawi, 8% in Nigeria, 26.5% in Rwanda, 12.5% in South Africa, 3.2% in Tanzania and 56% in Uganda (Mills *et al*., 2006).

In the report by WHO, UNAIDS and UNICEF (2007), many countries are still far from achieving universal access. The report stated that developing countries, had 7 million people in need of ARV therapy and only 2 million had access. In sub-Saharan Africa by December 2006, ART coverage was 28% and 45% in Kenya.

Even with improved access, patients starting ART in developing countries are at up to 4 times greater risk of dying in the first few months on ART compared to those in Europe and North America. The high risk of death has been attributed to burden of co-morbidity and late initiation of therapy (Boulle and Ford, 2007).

Universal access to comprehensive health services is needed to reduce HIV related morbidity and mortality worldwide. However, to fully attain the benefits of HAART, there is a strong need for effective adherence interventions in the care of HIV-infected patients. The HAART rollout should be a patient-tailored intervention and is only attainable when the problem of non adherence is known from the patient's perspective. Limited studies had been conducted in Kenya to understand the problem of non-adherence to ARV therapy from patient's perspective.

Scaling up HAART and improving adherence remains a challenge in both developing and developed countries (WHO, 2006). Studies elsewhere have found that approximately 50% of patients prescribed ARVs take less than 80% of medicine (Lafeuillade, 2001; Cheever and Wu, 1999). Some individuals and groups were not only less likely to start ARV treatment (Witteveen and van Ameijden, 2002), but those who did, had problems with adherence and consequently had worse health outcomes than other PLWHA on HAART (Van Asten *et al*. 2003).

Kenya is implementing a free HAART programme to increase access through CCC. By 2007, 288 comprehensive care centers had been opened in government health facilities and were providing therapy to 160000 adult HIV +ve patients (IRIN, 2007). The target for free HAART rollout is to reach 209,000 adults and 20,000 children by 2008, and with 180,000 actively adhering to treatment by 2010.

Considering the importance of adherence in minimizing the occurrence of ARV drug resistance, practical measurements and close monitoring of adherence to therapy are required. There is no evidence that adherence is in tandem with HAART rollout. There is need to understand the factors that influence adherence to HAART. The knowledge generated would be used to develop promotional strategies to improve adherence.

2.7 The CASE Adherence Index

The CASE Adherence Index is an easy to administer instrument for assessing adherence to HAART. The tool was developed by the New York Academy of Medicine's (NYAM) Center for Adherence Support Evaluation (CASE) during a large Health Resources and Services Administration (HRSA)-funded evaluation study (1999-2003) of 12 US adherence support programs. The interventions primarily targeted under-served populations with high rates of comorbidities and barriers to ART adherence.

The interventions employed included, readiness training, modified directly observed therapy, stages of change interventions, professional case management, peer counseling and pharmacist monitoring.

The CASE Adherence Index questionnaire (Appendix 5) consists of three unique adherence questions measured on a Likert scale. Composite score obtained by adding responses, is the Index score and range from 3 to 16 points. Higher scores indicate better adherence. An Index Score > 10 denotes adherence and $\leq$ 10 non adherence.

To validate, the CASE Adherence Index was compared to a standard three-day self-reported adherence measure among participants in a longitudinal, prospective cross-site evaluation of 12 adherence programs in the United States. The CASE

adherence tool and three self-report were administered by interviews every three months over a one-year period. Data from the CASE adherence index questions were compared to three-day self-report data and HIV RNA and CD4 outcomes in cross-sectional analyses. The CASE Adherence Index correlated strongly with the AACTG three-day self-reported adherence data ($p < 0.001$), was more strongly associated with HIV outcomes and performed as well as the three-day self-report when predicting CD4 cell count status. Participants with a CASE Index score >10 achieved a 98 cell mean increase in CD4 count over 12 months, compared to a 41 cell increase for those with scores ≤10 ($p < 0.05$) (Mannheimer *et al*., 2006).

2.8 Health belief model

In interventions that are complex and require lifestyle modifications, it is worthwhile to address patients' beliefs, intentions, and self-efficacy (perceived ability to perform action). This is because knowledge alone is not sufficient to enhance adherence in recommendations involving complex behavior change (Atreja *et al*., 2005). Management of HIV entails taking HAART, maintaining special dietary practices and lifestyle. Successful management would therefore require attention not just to observable behaviour but to the underlying attitudes and belief systems which drive that behaviour.

The Health Belief Model (HBM) (Rosenstock, 1974) has been used widely to explore a variety of long and short-term health behaviors, including sexual risk

behaviors and the transmission of HIV/AIDS. The HBM is derived from a well-established body of psychosocial and behavioral theory and hypotheses that health behaviors depend mainly on the desire to avoid illness and the belief that certain actions will prevent or alleviate disease. The model originally consisted of four constructs; perceived susceptibility, perceived severity, perceived benefits, perceived barriers. Self-efficacy was added in 1988.

In this study, Beliefs about Medicines Questionnaire (BMQ) developed by Horne *et al.* (1999) was employed to collect data for the Health Belief Model to understand beliefs about HIV medications among participants by examining self-efficacy, perceived non-adherence severity, perceived benefits of HAART and perceived barriers to adherence to therapy. By knowing which beliefs are below a level presumed necessary for good adherence, a provider may tailor interventions and "nest" to suit the unique needs of patients.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Area

This study was carried out in three Comprehensive Care Centres (CCC) in Nairobi, Kenya: Kenyatta National Hospital, KEMRI and Riruta Health centre. Nairobi covers an area of 684 square kilometers, has a population of 3 million people (KEBS, 2009) and is the smallest, but most densely populated of the 8 provinces in Kenya. It is situated at an altitude of just over 1660m and lies at $1^{0}17^{'}$ S and 36^{0} $49^{'}$ E (Appendix 1) and is Kenya's principal economic hub and the seat of government. Nairobi has a large population living in large urban low-income informal settlements and high unemployment and underemployment rates. According to NACC and NASCOP (2007) HIV prevalence in Nairobi was 10.1% in 2006 with 196,917 people (15-49 years old) living with HIV. Notable differentials in HIV prevalence exist in Nairobi with Kibera slum; largest informal settlement in Kenya leading with 15%. Twenty two thousand and ninety five HIV related deaths were reported in the province in 2006. By 2005, 50,665 adults and 7,595 children were in need of ART in Nairobi (NACC and NASCOP, 2006). Nairobi has both a National referral hospital, Kenyatta National hospital (KNH) and a district hospital, Mbagathi District Hospital which mainly cater for cases of infectious diseases including TB and HIV. It has three main CCC, KNH, KEMRI and Mbagathi District Hospital and numerous health centres that provide HIV/ AIDS counseling and treatment. Riruta health center is one of the many government health centers in

Nairobi. Beside the general health services, it is also a CCC and provides VCT services and free HAART to mainly residents of Kawangware slum and the neighbouring urban and peri-urban population. Mbagathi district hospital did not give consent as there were similar studies going on and, Riruta health centre was selected to replace it. It was chosen KNH and KEMRI CCC provide HIV related services only and caters for patients from all over Nairobi and the neighbouring districts. A HIV patient attending KNH CCC pays Kshs. 100 (USD 1.4) per visit but is free at KEMRI and Riruta Health Center.

3.2 Study Design

This was a facility-based cross-sectional study where HIV+ patients receiving free HAART were recruited proportionately (Table 3.1) from three purposively selected CCC in Nairobi. Data was collected between November, 2008 and April, 2009.

Table 3.1: Distribution of respondents by study site

Comprehensive Care Centre	Total population of active ART patients	Number of Respondents	Percentage (%)	Percentage in the study sample
Riruta	1000	84	8.4	20
KNH hospital	2000	167	8.4	40
KEMRI	1900	165	8.6	40
Total	4900	416	8.5	100

Patients were systematically selected and approached upon receipt of ART. A structured interview questionnaire (Appendix 5) was administered on 416 qualifying HIV+ patients returning for monthly ARV follow-up and routine check-ups at the three participating sites.

3.3 Study Population

The study population were HIV+ patients accessing free HAART at Kenyatta National Hospital, Riruta Health Centre and KEMRI CCC in Nairobi and were on follow-up and present during the data collection period.

3.3.1 Inclusion criteria

1. Adult patients, 18 or more years old and on HAART for at least three months at the selected Comprehensive Care Centers
2. Patient mentally competent to give consent
3. Consent given by the comprehensive care centers and patients

3.3.2 Exclusion Criteria

1. HAART defaulting HIV+ patient
2. Consent not given
3. Patient too ill to participate

3.3.3 Assumptions

1. There will be adequate cases of treatment failure
2. HIV+ patients not adhering will be available and willing to be interviewed
3. Informed consent will be given by participants approached

3.4 Sample Size Determination

The sample size was determined according to the formula of Lemeshow *et al.* (1996) for prevalence studies. Based on a required precision of ±5% around the 95% confidence interval of adherence rate, and a 10% estimate of non responses, and estimated adherence rate to HAART of 44% derived from 52% (Ellis *et al*., 2006) and 36% (Munyao *et al*., 2005) prevalence rates reported in two studies conducted at a clinic in Kibera slums, Nairobi and Mombasa respectively.

The Lemeshow *et al*. (1996) formula for prevalence studies is as follows.

$n = (z^2_{1-\alpha} X p(1-p)/m^2)$

where: n = sample size

$z_{1-\alpha}$ = standard normal deviate corresponding to α = 0.05

p = estimated prevalence of adherence to ARV therapy = 0.44

m = expected precision (0.05)

$n=(1.96^2 X 0.44 X 0.56/0.05^2)=378$ respondents

Refusals = 10% of n = 38 respondents

Sample size (adjusted n) = n+ refusals=378+38=416 respondents

A sample size of 416 HIV infected patients aged at least 18 years is sufficient to give estimates of the prevalence of ARV drug resistance with a 5% error at the 95% confidence level, considering 10% refusal.

3.5 Data Collection Tools

A structured questionnaire (Appendix 5) was developed in English, translated to Kiswahili and pre-tested. It consisted of both closed and open ended questions and was used in part to record demographic and treatment failure data from patient file. Face-to-face interviews were conducted to gather additional data relating to socio-demographic characteristics, socio-economic conditions, medication related factors, health care delivery systems and adherence to therapy. Beliefs about medication were measured using a set of 10 Likert scale questions addressing patients' concerns and necessity of HIV medicine. The patient's registration number was used as patient's identifier for cross referencing, data entry and analysis. To assess non-adherence, patients were questioned about missed doses and correct timing of dosing prior to the interview. HIV patients were interviewed in English or Kiswahili according to their preference. The independent variables were socio-demographic characteristics, clinical characteristics, socio-economic conditions, medication related factors and beliefs in medication. The dependent variable was a composite index; CASE adherence index.

3.6 Data Management and Statistical Analysis

Socio-demographic and clinical characteristics of patients were described and summarized using descriptive statistics.

Socioeconomic index for respondents was determined by adding classification score in education and income factor. The total scores ranged from 2 to 11 points. Respondents who scored between 2 – 4 points were classified as of low socioeconomic status, those who scored between 5-8 as middle, and 9 to 11 to upper stratum.

Respondents' belief about necessity of medication to control illness was determined using the Beliefs About Medicines Questionnaire (BMQ). Scores for benefits and risks on a likert scale, were summed separately. Total score for risks was subtracted from benefits to arrive at a summary score (Horne *et al.*,1999).

Self-reported adherence to therapy was determined using CASE adherence index. Patient's responses in the CASE adherence index questionnaire were added to obtain a composite score that ranged from 3 to 16 points. Lower scores indicated poor adherence. The index was used to dichotomize the study population sample into adherent and non-adherent. Patients with Index score $\leq$ 10 points were classified as non-adherent and those with Index score > 10 adherent (Mannheimer *et al.*, 2006).

Respondents' data about therapy change from first line to second line regimen in the last twelve months to the interview was abstracted from hospital records. To estimate treatment failure, HIV patients on second line regimen were identified and summarized as incidence and prevalence rate.

To investigate correlation between prognostic factors and adherence to therapy, odds ratio and chi-square test were carried out. P-value was set to $p < 0.1$ in order to account for potential confounding and effect modification. Qualifying factors were included in a multivariate logistic regression model to estimate adjusted odds ratios and to identify the persistent independent predictors of non-adherence (association) judged by significance of $p< 0.05$.

Throughout the study, the term significant indicates a chi-square p-value less than 0.05; marginally significant indicates a p-value between 0.05 and 0.10, inclusive; and not significant indicates a p-value greater than 0.10.

To determine confounders and effect modifiers, stratification analysis was performed on univariate variables. Confounders were analyzed by the Mantel-Haenszel method and effect modifiers by Breslow-Day test of homogeneity as follows:

2x2xK contingency tables

Notation: outcome=d; predictor=e; categorical covariate=k

Steps

1. Calculated crude $OR_{d\text{-}e}$ and stratum-specific OR's: $OR_{d\text{-}e/k=K}$ (stratification analysis)
2. If crude OR and stratum-specific OR's are all similar, *k* is not a confounder or an effect modifier.
3. If crude OR and stratum-specific OR's differed→proceeded to (a) or (b) below:

   a) If stratum-specific OR's are similar to each other, suspected confounding

      (i) Applied Cochran-Mantel-Haenszel test of conditional independence:

      - H_0: *e* and *d* are conditionally independent.

      (ii) Calculated Mantel-Haenszel summary OR/adjusted for confounding by *k*).

      - If P>0.05, *e* and *d* are conditionally independent, k is a confounder. Report MH summary OR

   b) If stratum-specific OR's differed from each other, suspected effect modification

      (i) Applied Breslow-Day test of homogeneity of the OR's:

- H_0: stratum-specific OR's are equal (homogenous)
    - If P<0.05, reject null hypothesis and conclude k is an effect modifier. Report stratum-specific OR's
    - Else, insufficient evidence of effect modification, calculated and reported Mantel-Haenszel summary OR.

3.7 Operational Definitions

Adherence – Three Likert Scale adherence questions were presented to respondents. A composite score; CASE Adherence Index was computed using the sum of the 3 questions. If respondents scored 10 or less, they were non-adherent. Adherence was considered as a score more than 10.

Treatment failure – reported change of regimen from 1st to second line drugs based on immunological tests and clinical assessment.

3.8 Potential Risks/Discomfort and Benefits

Participation in this study involved no physical risk. However, there was the possibility of psychological risk if the answers to interviews were made public or questions asked were emotive. The outcome of this study will be used to inform designing and implementation of interventions to help HIV+ patients adhere to treatment.

3.9 Ethical Considerations

The study was reviewed and cleared by the KEMRI/National Ethical Review Committee (NERC), Nairobi, Kenya (Appendix 3). Permission was sought in writing from the participating clinics to use their clients (Appendix 4). Written informed consent was obtained from the study participants after explaining to them the purpose of the study (Appendix 2). Interviews were conducted in private to create an atmosphere of empathy and confidence, and strict control maintained over data. Respondents' personal data was kept confidential. Where respondents were uncomfortable, they could refuse to answer any questions. Participation in the study was voluntary and there was no penalty for refusing to take part; patients could refuse to participate, refuse to answer any questions or withdraw from the interview at any point. Where a patient had no formal education, the study was orally explained to ensure informed consent. The procedures were in accordance with the ethical standards of the Kenyan Ministry of Health as well as the Helsinki Declaration of 1975.

CHAPTER FOUR

RESULTS

Out of 416 ART patients interviewed in this study, 403 respondents answered all adherence questions and were analyzed for non-adherence to HAART, treatment failure and a range of personal, social context and health system factors. Seventy two (18%) respondents scored 10 or less points (Table 4.10) on the CASE adherence questionnaire (Appendix 5), which means that they were non-adherence to treatment by CASE adherence index method of determining adherence.

4.1 Sociodemographic characteristics of respondents

Two hundred and sixty two (65%) of the 403 respondents analyzed were female and the rest (35%) were male (Figure 4.1), a ratio of almost 2:1. The 72 respondents found not to adhere to ARV therapy were 25 (35%) male and 47 (65%) female. Prevalence of non-adherence was found to be 18% for male and female both jointly and separately. Gender did not significantly influence non-adherence in this study ($\chi^2(1) = 0.003$, $p=0.958$) (Table 4.1a).

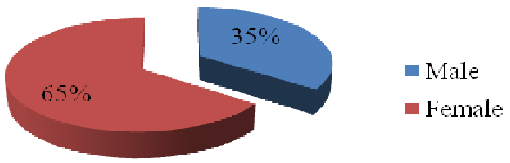

Figure 4.1: Distribution of respondents by gender

Four hundred and one respondents stated their age last birthday and ranged between 18-64 years. Eleven (3%) patients were 25 years old or less, 47 (12%) were between 26-30 years, 68 (17%) were 31 to 35 years old, 96 (24%) were between 36 and 40 years, 96 (24%) were between 41- 45 years old, 40 (10%) were between 46 – 50 years, 30 (7%) respondents were between 51 and 55 years, 8 (2%) were between 56-60 years, 5 (3%) were 61 years old or more (Figure 4.2). The mean and median age was 39.7 years (SD=8.2) and 39 years respectively. Mean and median age for male was 42.6 (SD=7.3) and 42 years respectively, and female 38.2 (SD=8.3) and 38 years respectively (Table 4.1b). Mean age for respondents refilling at Riruta was 37.8 years, 39.5 years at KEMRI and 41 years at KNH. Difference in mean age of respondents between sites was significant (F=4.227, *p*=0.015) (Table 4.1b).

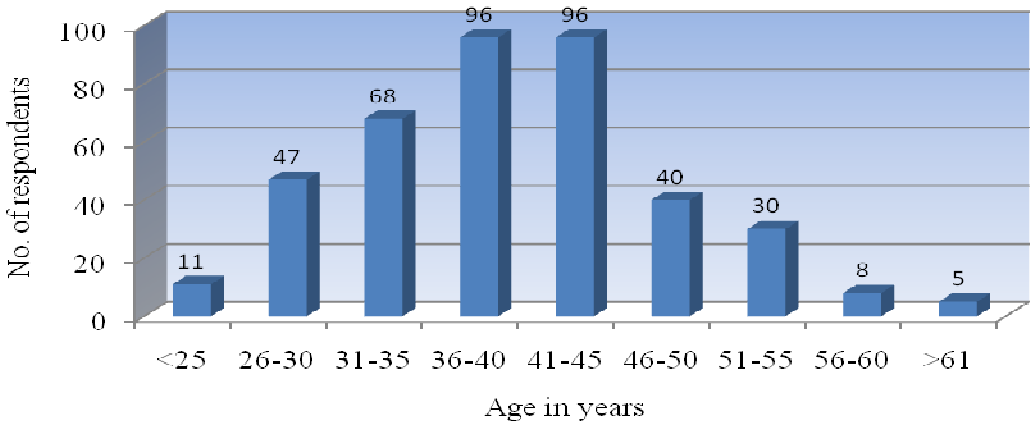

Figure 4.2: Age distribution of respondents

The mean age of non-adhering respondents was 37.6 years; 41.6 years for male and 35.4 for female, while average age for adhering respondents was 40.2 years; 42.8 years for male and 38.8 years for female. The age brackets of the 72 non-adhering respondents were: 1 respondent was less than 20 years, 2 were 21-25 years old, 10 were 26-30 years, 18 and 17 were 31-35 years and 36-40 years old respectively, 15 respondents were 41-45 years old, 5 were in 46-50 age category, 4 were more than 50 years old and 2 did not state their age (Table 4.1a). Non-adherence was found to differ significantly by age (t=-2.399, df=399, p=0.017). After stratifying by gender and site, non-adherence differed significantly by age among female (t=-2.517, df=258, p=0.012), and at Riruta Health Centre (t=-2.289, df=52, p=0.026) (Table 4.1b).

The highest rate of non-adherence (26%) was among respondents 31-35 years old, followed by 21% among 26-30 years old, 20% non-adherence was reported among 21-25 years old respondents, 18% among 36-40 year old,16% in 41-45 age group, 13% among 46-50 year old, 10% in 51-55 and 13% among 56-60 years old (Figure 4.3).

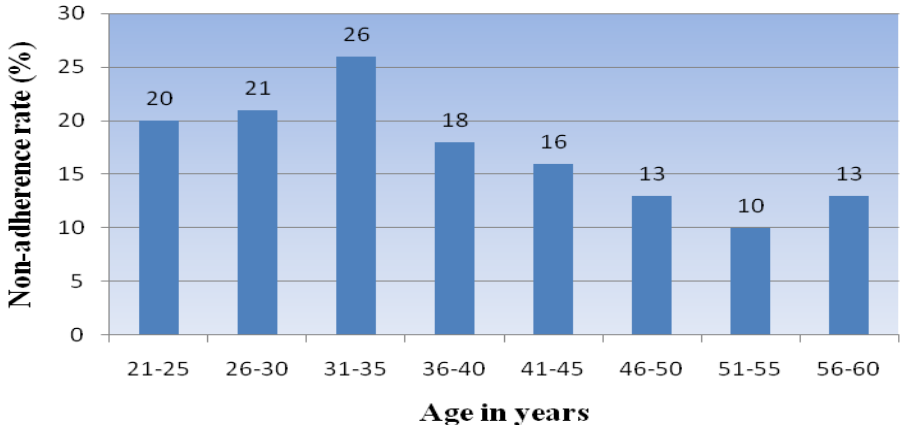

Figure 4.3: Prevalence of non-adherence to HAART by age of respondents

Three hundred and ninety nine (99%) of the 403 respondents analyzed stated their marital status, and 4 (1%) did not. Eighteen percent of the respondents had never married and 81% had ever married; currently married were 53.4%, 14.3% were widowed and 14.3% were either divorced or separated. 1% did not state their marital status (Table 4.1a). Fourteen (19%) of respondents who had never married were non-adherent to therapy, 40 (19%) among currently married, 13 (23%) among divorced and/or separated respondents, and 5 (9%) among widowed. Four (1%) respondents did not answer the question but were adherent. When respondents were grouped into never married, married, divorced/separated and widowed, marital status did not significantly influence non-adherence to HAART ($\chi^2(3)=4.361$, $p=0.225$). However, when respondents were dichotomized into ever widowed and never widowed, marital status was found to influence adherence marginally ($\chi^2(1)=3.867$, $p=0.053$) (Table 4.1a).

Table 4.1a: Demographic characteristics of respondents (n=403)

Characteristics	Adherent			*p*-value			
Variable	No *n (%)*	Yes *n (%)*	Total *n (%)*	All	Riruta	KNH	KEMRI
Gender distribution				0.958			
Males	25 (18)	116 (82)	141 (35)				
Females	47 (18)	215 (82)	262 (65)				
Age group (Yrs)							
20 <	1	0	1				
21 - 25	2 (20)	8 (80)	(3)				
26 - 30	10 (21)	37 (79)	(12)				
31 - 35	18 (26)	50 (74)	(17)				
36 - 40	17 (18)	79 (82)	(24)				
41 - 45	15 (16)	81 (84)	(24)				
46 – 60	9 (13)	69 (87)	(19)				
≥ 61	0	5	(1)				
Missing			2				
Marital status				0.225	0.578	0.480	0.582
Never married	14 (19)	58 (81)	72 (18)				
Married	40 (19)	173 (81)	213 (53)				
Divorced/Separate	13 (23)	44 (77)	57 (14)				
Widowed	5 (9)	52 (91)	57 (14)				
Missing	0	4	4 (1)				
Ever widowed?				0.053			
Yes	5 (9)	52 (91)	57 (14)				
No	67 (20)	275 (80)	342 (85)				

*Statistically significant at level $p<0.05$ by chi-square test

Table 4.1b: Demographic characteristics of respondents (n=403); Mean Age

Characteristics	Adherent			*p*-value			
Variable	No	Yes	Total	All	Riruta	KNH	KEMRI
Mean age							
All	37.6 yrs	40.2 yrs	39.7 yrs	0.017*	0.017*	0.519	0.185
Male	41.6 yrs	42.8 yrs	42.6 yrs	0.491	0.914	0.594	0.131
Female	35.4 yrs	38.8 yrs	38.2 yrs	0.012*	0.026*	0.556	0.599
Mean age at site				0.015*			
Riruta	34.7 yrs	38.9 yrs	37.8 yrs				
KEMRI	37.4 yrs	39.8 yrs	39.5 yrs				
KNH	40 yrs	41.2 yrs	41 yrs				

*Statistically significant at level $p<0.05$ by student's *t* test

Three percent of the respondents had no formal education, 36% were primary level, 50% secondary while 11% percent had post secondary level of education.

Two respondents did not answer the question. Respondents with post secondary level of education had the highest (22%) prevalence of non-adherence to ARV therapy, respondents with secondary school level of education were 16% non-adherent, primary education were 19% non-adherent and those with no formal education were 10% non-adherent. Prevalence of non-adherence among respondents did not differ significantly with level of education ($\chi^2(3)=1.577$, $p=0.665$) (Table 4.2a).

Thirty four percent of the respondents were unemployed while 41% earned Kshs.10,000 (US$.130) (Exchange rate 1USD=77 Kenya Shillings) or less per month (Table 4.2a). Prevalence of non-adherence was highest (24%) among patients who earned more than Kshs. 50,000 (US$650) per month, 20% among the unemployed, 21% among the group earning less than Ksh. 5000 (US$65), 19% for respondents earning Ksh.15000-20000 (US$ 195- 260), 15% for those earning between Kshs. 20000 and 50000 (US$260-650), 14% among Kshs. 5000 to 10000 (US$65 – 130) earners and lowest prevalence (9%) among Ksh.10000-15000 (US$ 130 – 195) earners (Figure 4.4). In the overall, income did not significantly determine non-adherence to therapy in this study ($\chi^2(6)=3.574$, $p=0.734$). However, it marginally influenced adherence among respondents attending Riruta health center ($\chi^2(4)=9.295$, $p=0.054$) (Table 4.2a).

Most patients interviewed reported spending US$ 2.6 (Mode) per day on food. Amount spent on food did not significantly influence non-adherence (t=0.415, df=380, *p*=0.678(Table 4.2b).

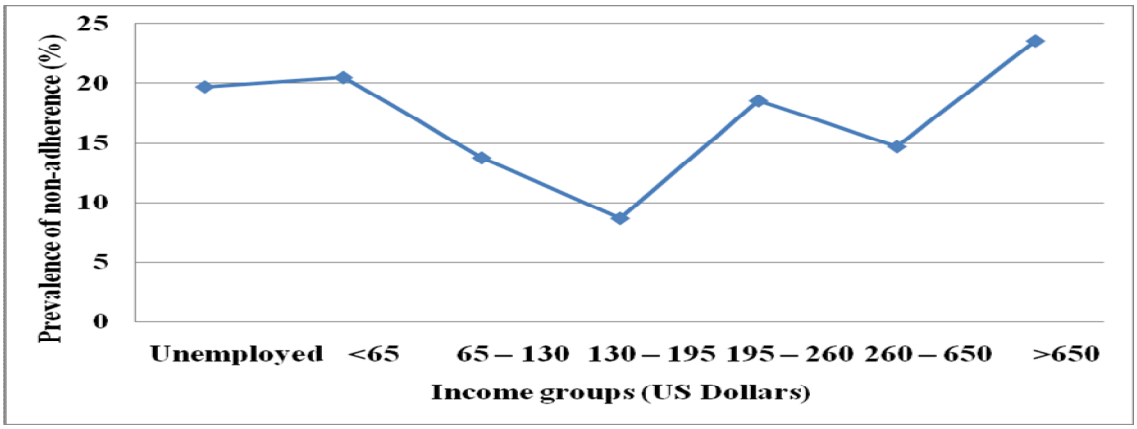

Figure 4.4: Prevalence of non-adherence to HAART by monthly income of respondents

Three hundred and ninety nine (99%) respondents answered both questions on education and income, and were analyzed for socioeconomic level. 4 (1%) did not answer. The 399 respondents who answered both questions were grouped into lower, middle and upper band. Overall, one hundred and eighty three respondents (45%) were in the lower stratum, 165(41%) in middle and 51(13%) in upper (Table 4.2a). At Riruta health center, 64 (79%) respondents were in lower socioeconomic band while 17 (21%) were middle and none was in the upper group. At KNH, 83 (54%) respondents were classified as lower socioeconomic level, 51 (33%) as middle while 19 (12%) were in upper level. At KEMRI, 36 (22%) respondents were classified in lower socioeconomic group, 97 (59%) in middle and 32 (19%) in upper. The clinics' difference in socioeconomic classification was found to be

significant ($\chi^2(4)=81.196$, $p=0.000$); clinic/site was found to predict socioeconomic index of respondents (Figure 4.5).

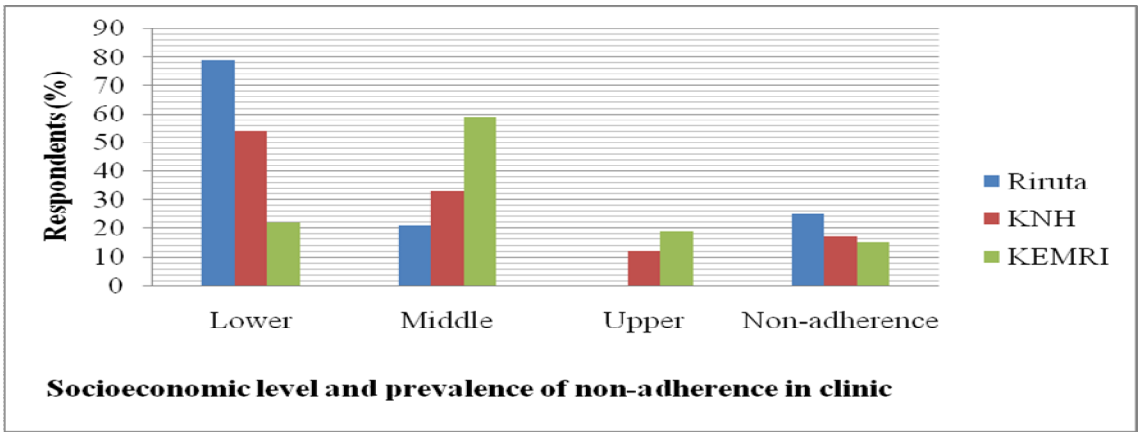

Figure 4.5: Distribution of respondents by socio-economic level and prevalence of non-adherence at clinic

Respondents spent between Kshs. 400 and 20000 (US$ 5 and 250) on house rent per month with most of them spending Kshs.1500 (US$ 19.5). House size varied from one room to more than three bedrooms. Forty six percent of respondents lived in a single room, 21% in two or three roomed house, 10% in a one bedroom house, 13% in two bedroom and 10% in three or more bedroom house. Out of 186 respondents who lived in a single room, 21% did not adhere to therapy. Among the 85 respondents who lived in two or three roomed house, 19% did not adhere while among respondents who reported living in one bedroom house, 17% did not adhere to therapy. Non-adherence among respondents living in 2, and 3 or more bedrooms houses were 8% and 15% respectively. When housing was dichotomized into 1-3 rooms and 1 or more bedroom houses, respondents living in one to three rooms were found to be 20% non-adherent compared to 13% among patients living in one or more bedrooms house. Size of house was found to

marginally influence adherence in this study ($\chi^2(1)=3.327$, $p=0.068$). Under any other house classification, adherence was found not to be significantly different ($\chi^2(4)=5.122$, $p=0.275$). Further analysis found that difference in adherence by house size was marginally significant ($\chi^2(1)=2.797$, $p=0.070$) among respondents attending KNH (Table 4.2a).

Table 4.2a: Socioeconomic characteristics of respondents (n=403)

Characteristics	Adherent			*p*-value			
Variable	No *n (%)*	Yes *n (%)*	Total *n (%)*	All	Riruta	KNH	KEMRI
Education level				0.665	0.284	0.649	0.231
No education	1 (10)	9 (10)	10 (3)				
Primary	28 (19)	117 (81)	145(36)				
Secondary	32 (16)	168 (84)	200(50)				
Post secondary	10 (22)	36 (78)	46 (11)				
Missing			2				
Income (KShs.)				0.734	0.054	0.677	0.921
Unemployed	27 (20)	110 (80)	137(34)				
<5000	17 (21)	66 (80)	83 (21)				
5001 – 10000	11 (14)	69 (86)	80 (20)				
10001 – 15000	2 (9)	21 (91)	23 (6)				
15001 – 20000	5 (19)	22 (82)	27 (7)				
20001 – 50000	5 (15)	29 (85)	34 (8)				
50000+	4 (24)	13 (77)	17 (4)				
Missing			2				
Socioecon Index				0.417	0.140	0.435	0.972
Lower	36 (20)	147 (80)	183(45)				
Middle	24 (15)	141 (85)	165(41)				
Upper	10 (20)	41 (80)	51 (13)				
Missing			4 (1)				
Housing				0.275	0.660	0.534	0.745
1 room	39 (21)	147 (79)	186(46)				
2-3 rooms	16 (19)	69 (81)	85 (21)				
1 bedroom	7 (17)	34 (83)	41 (10)				
2 bedrooms	4 (8)	48 (92)	52 (13)				
≥3 bedrooms	6 (15)	33 (85)	39 (10)				
1-3 rooms	55 (20)	216 (80)	271 67)	0.068	0.363	0.070	0.565
≥1 bedrooms	17 (13)	115 (87)	132 33)				

*Statistically significant at level p<0.05

Table 4.2b: Housing and food expenditure of respondents

Characteristics	Adherent?			*p*-value
Variable	No	Yes	Total	
Food expenditure per day in Ksh. (mode)	200	200	200	0.678
House rent per month in Ksh. (mode)	2000	1500	1500	0.343

4.2 Clinical characteristics of Respondents

CD4 assay values for 377 (94%) respondents were available for analysis and 26 (6%) were missing. Out of the 377 respondents whose CD4 cell counts data was analyzed, 69 (18%) did not adhere to therapy. Average CD4 cell count for non-adhering respondents was 307 cells/ml compared to 362 cells/ml for adherents. The difference in non-adherence by CD4 cell count was marginally significant (t=1.777, df=375, *p*=0.076) (Table 4.3a).

Table 4.3a: Clinical characteristics of respondents (n=403); Mean CD4 cell count

Characteristics	Adherent?		Total	p-value			
	No	Yes		All	Riruta	KNH	KEMRI
CD4 cell count in (mean) *cells/ml*	307	362	352	0.076	0.237	0.312	0.385

*Statistically significant at level p<0.05 by student's *t* test

The mode, mean and median of the last CD4 cell count recorded were 220 cells/ml, 352 cells/ml (SD=232.4) and 295 cells/ml respectively. Mean and median CD4 cells count were 207 and 161 cells/ml respectively at 3-6 months, 272 and 247 cells/ml at 6-12 months, 378 and 324 cells/ml respectively at 1-2 years, and 427 and 382 cells/ml respectively at 3 or more years (Figure 4.6).

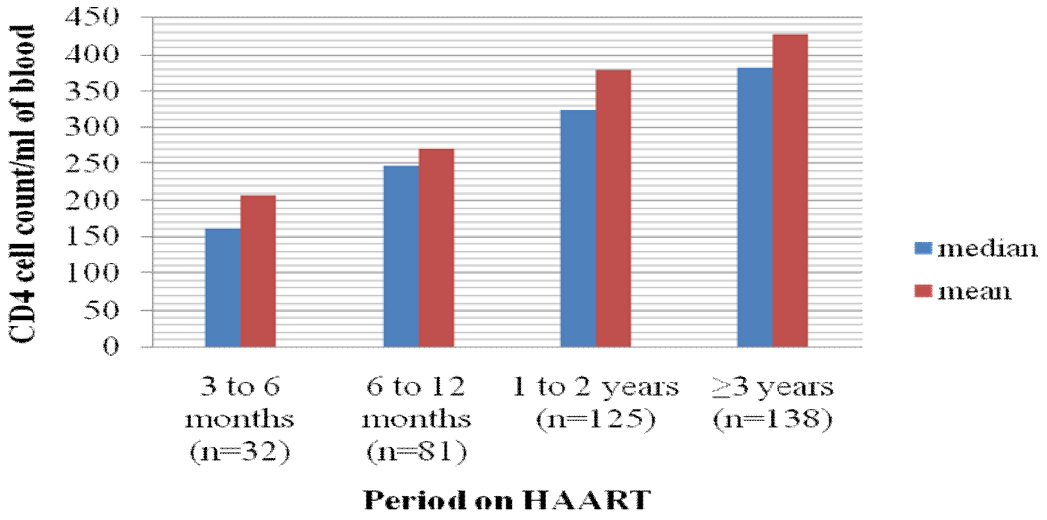

Figure 4.6: CD4 cell count among respondents by period on therapy

Out of the 377 respondents analyzed, 281 (75%) had CD4 cell count of 200 cells/ml or more while 96 (25%) respondents had less than 200 cells/ml. Among the non-adhering respondents, 25 (26%) had CD4 cell count ≤200 cells/ml and 44 (16%) respondents had CD4 cell count>200 cells/ml. The difference in non-adherence was significant (OR=1.897, df=1, *p*=0.025) (Table 4.3b). Forty nine percent of the respondents had a CD4 cell count more than 300 cells/ml, 26% had CD4 cell count between 201 cells/ml and 300 cells/ml, Sixteen had CD4 cell count between 101 cells/ml and 200 cells/ml, 5% had 51-100 cells/ml while 4% had CD4 cell count less than 50 cells/ml. Forty one percent of the non-adherents respondents had more than 300 cells/ml 23% had CD4 cell count between 201 cells/ml and 300 cells/ml, 22% had a count between 101 cells/ml and 200 cells/ml, 6% had 51-100 cells/ml while 9% had a CD4 count less than 50 cells/ml. Among adhering respondents, 50% had a CD4 cell count more than 300 cells/ml, 27% had

CD4 cell count between 201 cells/ml and 300 cells/ml, 15 had between 101 cells/ml and 200 cells/ml, 5% had 51-100 cells/ml while 3% had CD4 cell count less than 50 cells/ml (Figure 4.7).

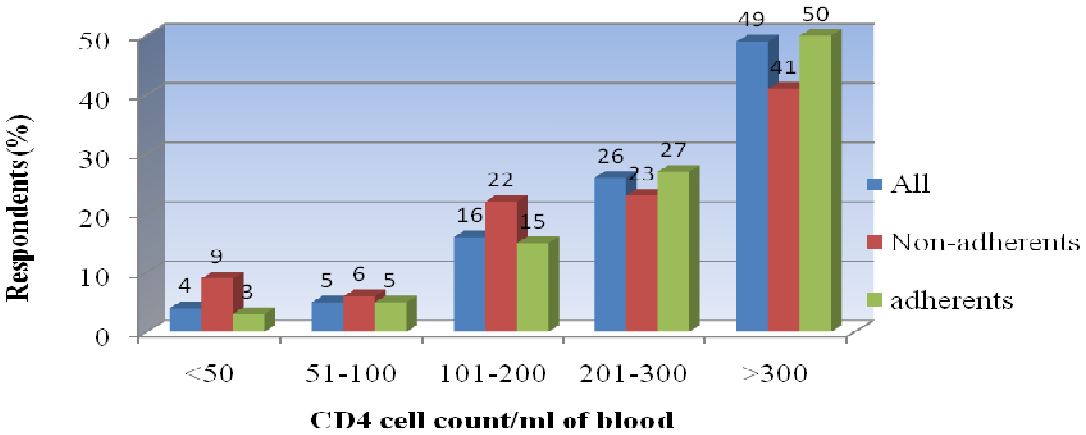

Figure 4.7: CD4 cell count among respondents by adherence status

Most (36%) respondents in this study had been on ART for at least 3 years, 135 (34%) for 1 to 2 years, 87 (22%) for 6 to 12 months and thirty five (9%) respondents for 3 to 6 months (Table 4.3b). Among respondents who had been on ART for 3 to 6 months, 37% were not adhering to therapy; among respondents on ART for between 6 and 12 months, 21% were non-adherence; prevalence of non-adherence among respondents who were on HAART for 1 to 2 years was 19%, while prevalence of non-adherence among respondents with 3 or more years on HAART was 11% (Figure 4.8). Time on ART significantly influenced non-adherence to therapy ($\chi^2(3)=13.959$, $p=0.003$). However, difference in adherence by duration on ART was significant ($\chi^2(3)=14.093$, $p=0.003$) only at KNH comprehensive care center (Table 4.3b).

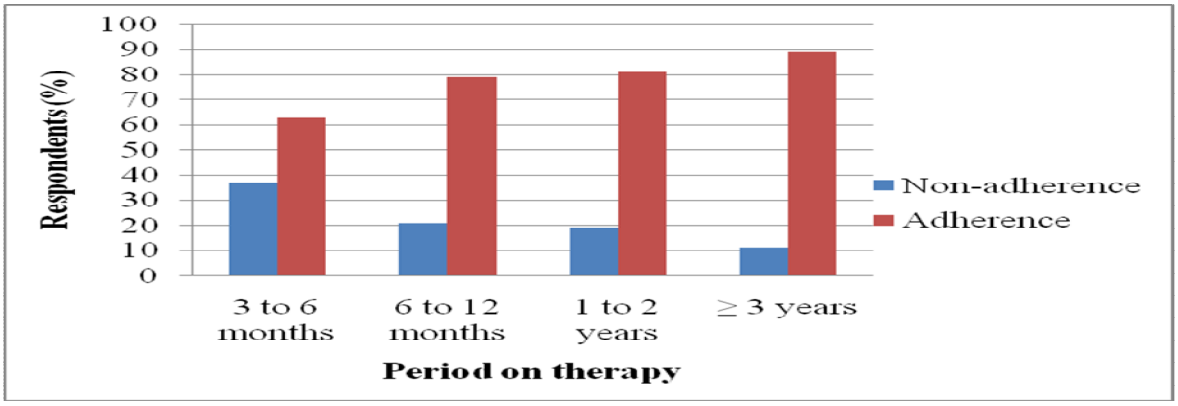

Figure 4.8: Prevalence of non-adherence among respondents by time on HAART

Among respondents on HAART for 3-6 months, 23 (66%) had CD4 cell count ≤ 200 cells/ml, 35 (40%) among respondents with HAART experience for 6-12 months, 35 (26%) for respondents with between 1 and 2 years, and 29 (20%) among respondents with 3 or more years on HAART (Figure 4.9).

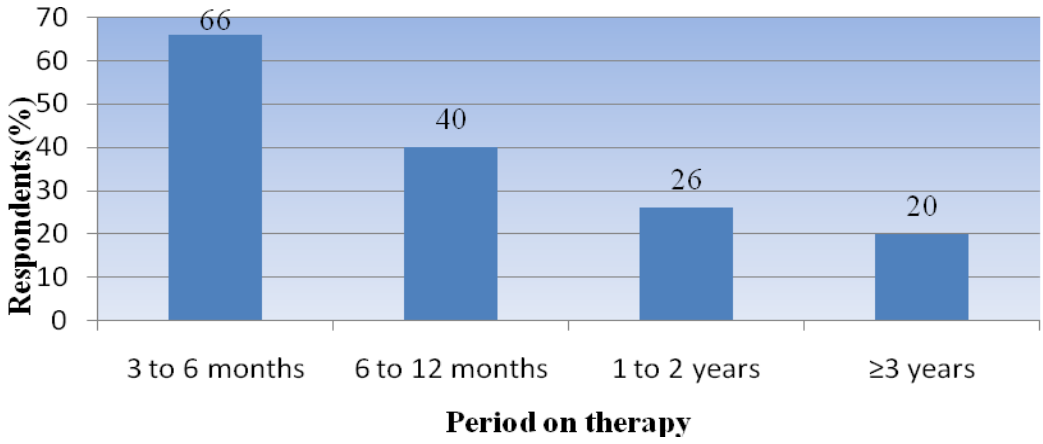

Figure 4.9: Distribution of respondents with CD4 cell count ≤200 cells/ml by period on ART

Fifty seven percent of respondents analyzed for side effect reported ever experiencing side effects while 43% had not. The most reported side effects

associated with HAART were rashes (13%), numbness (9%), itching (8%), nausea (7%), diarrhea (4%), vomiting (4%) and others (12%). Prevalence of non-adherence (17%) was the same for respondents who reported side effects and who did not. Respondents who reported nausea were 30% non-adherent, those who reported numbness were, 10% non-adherent, diarrhea 23% and itching 23%. Experiencing side effects did not influence non-adherence to HAART significantly ($\chi^2(1)=0.016$, $p=0.898$) (Table 4.3b).

Table 4.3b: Clinical characteristics of respondents (n=403)

Characteristics	Adherent?		Total	p-value			
	No *n (%)*	Yes *n (%)*	*n (%)*	All	Riruta	KNH	KEMRI
CD4 cell count ≤200 cells/ml				0.025*			
Yes	25(26)	71 (74)	96 (24)				
No	44(16)	237(84)	281(70)				
Missing			26 (6)				
Time on ART				0.003*	0.232	0.003*	0.195
3 to 6 months	13(37)	22 (63)	35 (9)				
6 - 12 months	18(21)	69 (79)	87 (22)				
1 to 2 years	25(19)	110(81)	135(34)				
3 years +	16(11)	129(89)	145(36)				
Missing			1				
Adverse effects							
Nausea	7 (30)	16 (70)	23 (7)	0.898	0.347	0.523	0.823
Vomiting	1 (8)	11 (92)	12 (4)				
Diarrhea	3 (23)	10 (77)	13 (4)				
Neuropathy	3 (10)	27 (90)	30 (9)				
Itching	6 (23)	20 (77)	26 (8)				
Rashes	5 (12)	36 (88)	41 (13)				
Others	6 (15)	33 (85)	39 (12)				
None	24(17)	114(83)	138(43)				
Treatment failed				0.400			
No	70(18)	314(82)	384(95)				
Yes	2 (11)	17 (89)	19 (5)				

*Statistically significant at level p<0.05 by chi-square test

Three hundred and eighty four (95%) respondents were on first-line regimen and 19 (5%) on second line. Fifty percent (202) of the respondents on first-line regimen were on 3TC/d4T/NVP combination, 75(19%) were on 3TC/d4T/EFV, 53(13%) on AZT/3TC/EFV and 22 (6%) on TDF/3TC/NVP cocktail. Nineteen (5%) were on 2nd line therapy. Respondents on first-line therapy were 18% non-adherent while those on second-line were 11%. However, it was not possible to do further statistical analysis to determine level of significant due to low numbers of respondents on 2nd line therapy (Table 4.4).

The 403 respondents analyzed reported having been counseled on adherence, condom use and or nutrition before initiating therapy. Three hundred and twenty nine (82%) respondents stated having been counseled on the importance of adherence in HAART uptake, 197(49%) stated safe sex or condom use, and 276 (68%) reported nutrition. Fifty seven (17%) of the respondents who stated adherence as important did not adhere, 35 (18%) of those who regarded condom use as important did not adhere while 43 (16%) of the respondents who reported nutrition as important did not adhere. Reporting adherence or condom use as important did not significantly influence non-adherence to therapy ($\chi^2(1)=0.357$, $p=0.550$) and ($\chi^2(1)=0.003$, $p=0.959$) respectively. However, reporting observing nutrition as part of therapy marginally influenced adherence to HAART ($\chi^2(1)=3.120$, $p=0.077$) (Table 4.4).

All respondents correctly identified ARV drugs they were taking and dosage, and 99% stated that HAART was a life-long therapy. However, among these respondents, 72 (18%) did not adhere to therapy (Table 4.4).

Table 4.4: Distribution of respondents by regimen and ART knowledge (n=403)

Characteristics	Adherent?		Total	p-value
	No *n(%)*	Yes *n(%)*	*n(%)*	All
ARV regimen				
First-line	70 (18)	314(82)	384 (95)	0.400
3TC/d4T/NVP			202 (50)	
3TC/d4T/EFV			75 (19)	
AZT/3TC/EFV			53 (13)	
TDF/3TC/NVP			22 (6)	
Second-line	2 (11)	17 (89)	19 (5)	
Health literacy Requirement				
Adhere	57 (17)	272 (83)	329 (82)	0.550
Condom use	35 (18)	162 (82)	197 (49)	0.959
Nutrition	43 (16)	233 (84)	276 (68)	0.077
Use				
Identify drugs	72 (18)	331 (82)	403 (100)	
Dosage	72 (18)	330 (82)	402 (100)	
Life-long therapy	72 (18)	328 (82)	400 (99)	

*Statistically significant at level $p<0.05$ by chi-square test

4.3 Social characteristics of respondents

Three hundred and twenty one respondents (80%) lived with family, 9 (2%) with friends and 72 (18%) lived alone. Prevalence of non-adherence to therapy among respondents who lived alone or with friends was higher (22%) compared to 17% among those who lived with family. The number of respondents (53) who did not adhere and lived with family were almost three times more than those who lived alone (2) and friends (16) combined. However, adherence to therapy did not differ

significantly between respondents who lived alone, with family or friends ($\chi^2(2)=1.451$, $p=0.484$) (Table 4.5).

In this study, 89% of the respondents had children; 285 (71%) respondents lived with them while 72 (18%) did not. Forty six (11%) respondents had no children. Prevalence of non-adherence among respondents with no children was 26% compared to 17% for those with children. Among respondents who had children but did not live with them 14% did not adhere while among those with children and lived with them 18% did not adhere to therapy. Neither, having or living with children significantly influenced adherence ($\chi^2(1)=2.392$, $p=0.122$) and ($\chi^2(2)=2.131$, $p=0.345$) respectively (Table 4.5).

Three hundred and twenty nine (82%) respondents had disclosed their HIV status to those they lived with, while 73 (18%) had not. Prevalence of non-adherence among respondents who had disclosed status was 18%, and equal to that among respondents who had not. Disclosure of HIV status by respondents did not significantly influence adherence to therapy ($\chi^2(1)=0.068$, $p=0.794$). However, further analysis found disclosure to marginally influence non-adherence among respondents attending KNH ($\chi^2(1)=2.832$, $p=0.092$) (Table 4.5).

Two hundred and eleven (52%) respondents reported being reminded by family to take medicine, 5 (1%) by friends, while 187 (46%) reminded themselves.

Seventeen percent of the respondents who reported being reminded by family did not adhere. Prevalence of non-adherence to therapy among respondents who reminded themselves to take medication was 19%. Prevalence of non-adherence to therapy of respondents who had someone to remind them to take therapy did not differ significantly ($\chi^2(2)=0.495$, $p=0.781$) from that of respondents who reminded themselves (Table 4.5).

On Likert scale, 205 (51%) respondents reported feeling supported always, 77 (19%) said often, 56 (14%) did not get any support from relatives and friends, 46 (11%) reported getting support sometimes while 18 (5%) respondents rarely got it. Respondents who reported not getting support had a prevalence rate of non-adherence to therapy of 23%. Twenty eight percent of respondents who rarely got support did not adhere to therapy, 26% non-adherence was found among respondents who sometimes got support, 22% among those who often got support and 18% among respondents who felt always supported. Felt social support was found to influence adherence significantly ($\chi^2(4)=10.730$, $p=0.030$) among respondents. However, further analysis found social support was significant only among respondents at Riruta clinic ($\chi^2(1)=0.388$, $p=0.004$) (Table 4.5).

Table 4.5: Social support from family and friends among respondents

Characteristics	Adherent			p-value			
	No *n (%)*	Yes *n (%)*	Total *n (%)*	All	Riruta	KNH	KEMRI
Living with				0.484	0.212	0.263	0.888
Family	53(17)	268(83)	321(80)				
Friends	2 (22)	7 (78)	9 (2)				
Alone	16(22)	56 (78)	72 (18)				
Living with children?				0.345	0.910	0.173	0.874
No	10(14)	62 (86)	72 (18)				
Yes	50(18)	235(82)	285(71)				
Have no children	12(26)	34 (74)	46 (11)	0.122			
Has children	60(17)	297(83)	357(89)				
HIV Status disclosed				0.794	0.793	0.092	0.782
Yes:	58(18)	271(82)	329(82)				
No:	13(18)	60 (81)	73 (18)				
Reminded dose by				0.781	0.607	0.663	0.540
Self	36(19)	151(81)	187(46)				
Family	35(17)	176(83)	211(52)				
Friends	1 (20)	4 (80)	5 (1)				
Level of social Support							
Never (0%)	13(23)	43 (77)	56 (14)				
Rarely (25%)	5 (28)	13 (72)	18 (5)				
Sometimes (50%)	12(26)	34 (74)	46 (11)				
Often (75%)	17(22)	60 (78)	77 (19)				
Always (>75%)	24(18)	181(88)	205(51)				
Missing			1				
Felt social Support				0.030*	0.004*	0.798	0.466
< Sometimes	18(24)	56 (76)	74 (21)				
> Sometimes	41(14)	241(86)	282(79)				

*Statistically significant at level p<0.05 by chi-square test

4.4 Health beliefs and attitudes towards HAART among respondents

Three hundred and ninety six (99%) respondents believed that their present and future good health depended on proper uptake of medication, 2 did not believe and 5 (1%) did not answer all questions required to compute the composite score for HAART necessity and could not be analyzed. In all questions about necessity of HIV medication, respondents in agreement that HAART was highly effective for HIV treatment varied between 95% and 98% (Table 4.6).

Table 4.6: Beliefs about HIV medication among respondents

Necessity of HIV medication	*n (%)*
My health, at present, depends on my medicines	
Agree	391 (97)
Disagree	4 (1)
My life would be impossible without my medicines	
Agree	389 (95)
Disagree	8 (2)
Without my medicines I would become very ill	
Agree	390 (96)
Disagree	6 (1)
My health in the future will depend on my medicines	
Agree	389 (95)
Disagree	9 (2)
My medicines protect me from becoming worse	
Agree	396 (98)
Disagree	3 (<1)
Composite score of necessity	
Positive	396 (99)
Negative	2 (<1)
Missing	5 (1)

Using a composite score developed from individual concern items, 307 (76%) respondents reported positive concerns about ARVs while 96 (24%) were negative. Among the 96 respondents with negative concerns about medication, 21% were poor adherents compared to 17% among respondents whose concern was positive. The difference in non-adherence to therapy between the two groups was not significant ($\chi^2(1)=0.756$, $p=0.385$) in the overall. However, the difference was significant ($\chi^2(1)=7.079$, $p=0.008$) among respondents at Riruta health center (Table 4.7).

Seventy four (18%) respondents reported being worried of having to use HAART, 319 (79%) were not worried while 10 (3%) were not sure. One hundred and sixty

six (41%) were worried about the long term effects of the drugs on their health and 221 (55%) were not, while 16 (4%) were not sure. One hundred and forty three (35%) respondents had no idea of how HAART works, 237 (59) knew while 23 (6%) were not sure. Sixty nine (17%) reported therapy was disrupting their lives (had difficulty with dosing schedule) compared to 323 (80%) who managed to fit it into their life-style, while 11 (3%) were not sure. One hundred and eighty six (46%) respondents were embarrassed if other people knew they were on HAART, 206 (51%) were not while 11 (3%) were undecided (Table 4.7).

Prevalence of non-adherence among respondents who worried about taking ART was higher (22%) compared to 17% among respondents who did not. However, the difference in non-adherence was not statistically significant ($\chi^2(1)=0.779$, $p=0.378$). Among respondents who reported worrying about long-term effects of medication use, 19% did not adhere compared to 18% among those who did not worry. The concern did not significantly influence non-adherence to therapy ($\chi^2(1)=0.021$, $p=0.885$). Respondents who did not understand how therapy worked were 20% non-adherent to therapy compared to 17% among those who knew. The difference in non-adherence was not statistically significant in the overall ($\chi^2(1)=0.443$, $p=0.505$) but, was marginally significant among respondents at Riruta health center ($\chi^2(1)=3.713$, $p=0.054$). Respondents who said they felt embarrassed if known to be using ART were 20% non-adherent compared to 15%

among those who were not. However, prevalence of non-adherence between the two groups was not statistically significant ($\chi^2(1)=1.952$, $p=0.162$) (Table 4.7).

Respondents who reported HAART disrupted their daily schedules had a prevalence of non-adherence to therapy of 29% compared to 15% among those who did not (Table 4.7). The difference in non-adherence between respondents who stated that therapy disrupted their life and their counterparts was significant ($\chi^2(1)=7.482$, $p=0.006$). Controlling for comprehensive care center, difference was only significant ($\chi^2(1)=11.986$, $p=0.001$) among respondents refilling at KEMRI (Table 4.7).

Table 4.7: Concerns about HIV medication among respondents

Concerns	Adherent		Total	p-value			
	No *n(%)*	Yes *n(%)*	*n(%)*	All	Riruta	KNH	KEMRI
Concern about Therapy (Index)				0.385	0.008*	0.567	0.730
High/Good	52 (17)	255 (83)	307 (76)				
Low/Poor	20 (21)	76 (79)	96 (24)				
Taking ART worries me							
Agree	16 (22)	58 (78)	74 (18)	0.378	0.194	0.932	0.849
Disagree	55 (17)	264 (83)	319 (79)				
Not sure			10 (3)				
I Worry about long-term effects of ART							
Agree	31 (19)	135 (81)	166 (41)	0.885	0.350	0.670	0.690
Disagree	40 (18)	181 (82)	221 (55)				
Not sure			16 (4)				
Lack understanding of how ART works							
Agree	28 (20)	115 (80)	143 (35)	0.505	0.054	0.771	0.508
Disagree	40 (17)	197 (83)	237 (59)				
Not sure			23 (6)				
Therapy disrupt my life							
Agree	20 (29)	49 (71)	69 (17)	0.006*	0.132	0.769	0.001*
Disagree	49 (15)	274 (85)	323 (80)				
Not sure			11 (3)				
I am embarrassed taking ARV							
Agree	38 (20)	148 (80)	186 (46)	0.162	0.106	0.780	0.459
Disagree	31 (15)	175 (85)	206 (51)				
Not sure			11 (3)				

*Statistically significant at level $p<0.05$ by chi-square test

4.5 Characteristics of study sites

Eighty one (20%) respondents refilled at Riruta comprehensive care centre, 165 (41%) at KEMRI and 157 (39%) at KNH. Prevalence of non-adherence to therapy at Riruta Health Centre was 25%, 15% at KEMRI and 17% at KNH. The difference

in non-adherence between sites was not significant ($\chi^2(2)=3.448$, $p=0.178$) (Table 4.8).

Three hundred and ninety nine (99%) respondents reported that health personnel at the comprehensive care centers were friendly and understanding. Four hundred and one respondents stated time spent in clinic when they came to refill. Seventy two percent spent less than 2 hours, 18% spent between 3 and 4 hours, 10% estimated at whole morning while 1% said whole day. Prevalence of non-adherence varied with time; 15% non-adherence among respondents who reported spending less than 2 hours at clinic, 16% among respondents who reported 3-4 hours and 40% among respondents who waited for a whole morning. The difference in non-adherence between the groups was significant ($\chi^2(3)=15.479$, $p=0.001$). Specifically, non-adherence to therapy by time spent refilling was significant at Riruta Health center ($\chi^2(2)=9.857$, $p=0.007$) and KEMRI ($\chi^2(1)=6.623$, $p=0.010$) (Table 4.8). Eighty three percent of respondents refilling at Riruta spent more than 3 hours when they attended clinic to refill compared to 1.9% and 27.6% at KEMRI and Kenyatta respectively.

Three hundred and sixty four (90%) respondents found waiting time for treatment and medication at the clinic acceptable while 39 (10%) said waiting for therapy was too long. The prevalence of non-adherence among respondents who found waiting time at the centre acceptable was 17% compared to 23% among respondents who

found it too long. The difference in non-adherence between the groups was not significant ($\chi^2(1)=0.799$, $p=0.371$) (Table 4.8).

Further analysis revealed that 19% of the respondents refilling at Riruta reported waiting time at the clinic was too long compared to 12.7% at KNH and 2.4% at KEMRI. Prevalence of non-adherence among patients who reported waiting time to be too long at Riruta was 33.3% compared to 22.7% for those who found it acceptable ($\chi^2(1)=0.739$, $p=0.390$), 15% versus 17.5% ($\chi^2(1)=0.078$, $p=0.780$) at KNH and 25% versus 15% ($\chi^2(1)=0.309$, $p=0.578$) at KEMRI.

Eighty four (24%) respondents wanted waiting time at CCCs improved and 24 (7%) wanted number of healthcare staff increased to reduce congestion especially at pharmacy. Fifteen (4%) respondents implicitly expressed financial difficulties and wanted financial support, 39 (11%) wanted services improved, 15 (4%) suggested ≥ 2 months dose to reduce visits to clinic to refill while 179 (44%) were content with the services. Of the 179 respondents who were content with the services offered, 18% did not adhere. Respondents who wanted waiting time at the clinic improved had 18% prevalence of non-adherence to HAART. Prevalence of non-adherence among respondents who wanted more staff was 21% and 40% among those who wanted financial support. Suggesting improvements to service delivery at CCC did not significantly influence adherence to therapy ($\chi^2(5)=7.971$, $p=0.158$) (Table 4.8).

Three hundred and ninety nine respondents gave reasons for choosing the CCC they attended and 4 did not. The reasons were proximity to home 61 (15%), being referred by others 176 (44%), good health services 94 (24%), being provided with free ARV 25 (6%), tested in the clinic 37 (9%) and privacy 6 (2%). Prevalence of non-adherence among respondents who gave proximity as reason for choosing clinic was 26%, 22% among respondents who said they refilled in the clinic because they were tested there, 17% prevalence of non-adherence among those who said privacy, 16% among respondents referred by others and 14% among those who reported good services. Respondents who chose clinic because it offered free ART were 12% non-adherent. However, reasons for choosing clinic did not significantly influence adherence ($\chi^2(5)=5.406$, $p=0.368$) (Table 4.8).

Three hundred and twenty nine (82%) respondents resided in Nairobi while 74 (18%) lived in neighbouring districts in Central, Eastern and Rift Valley province. Prevalence of non-adherence to therapy among respondents living in Nairobi was higher (19%) compared to 14% among those who lived in other districts, but, the difference in non-adherence was not significant ($\chi^2(1)=1.170$, $p=0.279$). However, difference in non-adherence was marginally significant ($\chi^2(1)=3.320$, $p=0.068$) among respondents who refilled at Riruta health centre (Table 4.8).

Two hundred and twenty eight (57%) respondents spent more than Kshs.100 (US$ 1.3) per month on transport to access HAART, 73 (18%) spent between Kshs 70-100 (US$0.9-1.3), 26 (6%) between Kshs.50 and 70 (US$0.7 – 0.9), 32 (8%) respondents spent up to Kshs. 40 (US$ 0.5) and 44 (11%) walked to CCC to refill. Prevalence of non-adherence to therapy was highest (34%) among those who walked to the clinics to refill. Prevalence of non-adherence among respondents who spent up to Kshs.40 was 16%, respondents who spent between Kshs.50 and 70 were 19% non-adherent, non-adherence among respondents who spent between Kshs.70 to 100 was 12% and 17% among those who spent more than 100 shillings on transport to the centers for review and medication. Cost of transport from respondents' house to clinic significantly influenced adherence to HAART ($\chi^2(4)=9.785$, $p=0.044$) (Table 4.8).

Table 4.8: Health care system factors that supposedly influence non-adherence to ART

	Adherent			p-Value			
Health care system	No *n(%)*	Yes *n(%)*	Total *n(%)*	All	Riruta	KNH	KEMRI
Study sites				0.178			
Riruta	20(25)	61 (75)	81 (20)				
KEMRI	25(15)	140(85)	165 (41)				
KNH	27(17)	130(83)	157 (39)				
Health personnel friendly				0.323			
Yes	70(17)	329(83)	399 (99)				
No	1 (50)	1 (50)	2 (<1%)				
Time spent in clinic							
<2hrs	44 15)	244(85)	288 (72)	0.001*	0.007*	0.677	0.010*
3-4 hrs	11(16)	60 (84)	71 (18)				
Whole morning	16(40)	24 (60)	40 (10)				
Whole day	0 (0)	2	2 (1)				
Waiting time				0.371	0.390	0.780	0.578
Acceptable	63(17)	301(83)	364 (90)				
Too long	9 (23)	30 (77)	39 (10)				
Suggested improvements				0.158			
Time	15(18)	69 (82)	84 (24)				
More staff	5 (21)	19 (79)	24 (7)				
Financial support	6 (40)	9 (60)	15 (4)				
Services	4 (10)	35(90)	39 (11)				
≥2 months dose	1 (7)	14 (93)	15 (4)				
Nothing	33(18)	146(82)	179(44)				
Reason for choosing clinic				0.368			
Proximity	16(26)	45 (74)	61 (15)				
Referrals	28(16)	148(84)	176 (44)				
Good service	13(14)	81 (86)	94 (24)				
Free ARV	3 (12)	22 (88)	25 (6)				
Tested here	8 (22)	29 (78)	37 (9)				
Privacy	1 (17)	5 (83)	6 (2)				
Residence				0.279	0.068	0.622	0.772
Nairobi	62(19)	267(81)	329 (82)				
Away from Nairobi	10(14)	64 (86)	74 (18)				
Cost of transport (Kshs.)				0.044*	0.330	0.460	0.513
Walk	15(34)	29 (66)	44 (11)				
≤40	5 (16)	27 (84)	32 (8)				
50 - <70	5 (19)	21 (81)	26 (6)				
70 - <100	9 (12)	64 (88)	73 (18)				
≥100	38(17)	190(83)	228 (57)				

Statistically significant at level p<0.05

4.6 Uptake of HAART among respondents

Two hundred and eighteen (54%) respondents rarely had difficulty taking medicine on time, 171 (42%) never had difficulty, while 14 (4%) respondents reported having difficulties taking HAART most of the time (Table 4.9).

Two (.5%) respondents reported missing at least a dose of therapy every day in a week, 6 (1.5%) reported missing doses for between 4 and 6 days in a week, 28 (7%) respondents missed for 2 to 3 days while 38 (9%) respondents reported missing a dose once a week. One hundred and twenty nine (32%) respondents missed taking medication less than once a week while 200 (50%) respondents never missed therapy (Table 4.9).

Twenty eight (7%) respondents reported missing a dose within the week of interview, 25 (6%) had missed in the last 1 to 2 weeks to the interview, 39 (10%) had missed medication between 3 and 4 weeks ago, 44 (11%) reported missing dose within the last 1 to 3 months to the interview, 70 (17%) had missed a dose more than 3 months ago and 197 (49%) had never missed therapy (Table 4.9).

Table 4.9: Missed doses of HAART among respondents

Adherence	*n (%)*
No. of times failed to take medication on time	
Rarely	
Never	218 (54)
Most of the time	171 (42)
	14 (4)
Days missed dose per week	
Every day	2 (.5)
4 to 6 days	6 (1.5)
2 or 3 days	28 (7)
Once a week	38 (9)
<once a week	129 (32)
Never	200 (50)
Last time ARV dose was missed	
Within the week of interview	28 (7)
1 to 2 weeks to the interview	25 (6)
3 to 4 weeks to the interview	39 (10)
Between 1 and 3 months to the interview	44 (11)
More than 3 months to the interview	70 (17)
Never	197 (49)

4.7 Non-adherence to therapy among respondents

Based on the CASE adherence scoring method, 72 (18%) respondents scored 10 or less on the CASE adherence index scale. This was interpreted as non-adherence while 331 (82%) scored more than 10 suggesting adherence (Table 4.10).

Seventy four (18%) respondents reported missing a dose at least once a week which is interpreted as prevalence of non-adherence at 93% level and is less than the recommended 95% cut off point for adherence (Table 4.10).

Ninety three (23%) respondents were reported missing therapy at least once a week (<95% adherence) or scored at most 10 points on the CASE adherence index scale (Table 4.10).

Table 4.10: Prevalence of non-adherence to HAART among respondents

	Adherent?	
Methods of determining adherence	Yes *n (%)*	No *n (%)*
a)CASE adherence Index; i.e. ≤ 10 (non-adherent)	72 (18)	331 (82)
b)missed at least once a week method (<95 adherence)	74 (18)	329 (82)
(a) and (b) combined	93 (23)	310 (77)

Two hundred and six (51%) respondents gave varied reasons for missing doses (implied <100% adherence) and were 24% non-adherence while 197 (49%) had never failed to take medicine and were 11% non-adherent. One hundred and fifty four (38%) respondents reported being busy and forgetting as the reason for missing therapy and were 29% non-adherent, while 5 (2%) missed therapy because they were hiding from colleagues and were 60% non-adherent. Forty seven (11%) respondents gave other reasons for missing doses and were 6% non-adherence. The difference in non-adherence between respondents who gave reasons for missing therapy and those who did not was significant ($\chi^2(1)=11.784$, $p=0.001$) (Table 4.11).

Table 4.11: Reasons for not taking HAART

	Non-adherent	Adherent	Total	p-value
Implied missed therapy				0.001*
Gave reason for not taking	50 (24)	156 (76)	206 (51)	
Never failed	22 (11)	175 (89)	197 (49)	
Reason for not taking medicine	*n (%)*	*n (%)*	n (%)	0.000*
Being busy and forgetting	44 (29)	110 (71)	154 (38)	
Hiding from colleagues	3 (60)	2 (40)	5 (2)	
Others	3 (6)	44 (94)	47 (11)	

Statistically significant at level p<0.05

4.8 Factors influencing non-adherence to therapy among respondents

With the Pearson Chi-Square, student's *t* test and odds ratio determination, prevalence of non-adherence to HAART among respondents differed significantly at *p-value*<0.05 by patient characteristics: age (*p*=0.017), (OR=1.817, $CI._{95}$=1.170-4.286); difficulty fitting therapy in own daily schedule (29% vs. 15%; *p*=0.006), (OR=2.282, $CI._{95}$=1.250,4.169); and by social support (25% vs. 15%; *p*=0.015), (OR=1.913, $CI._{95}$=1.129, 3.241). Non-adherence to therapy among respondents also differed significantly by period on therapy (37 vs. 16; *p*=0.002), (OR=3.095, $CI._{95}$=1.477,6.487); missed therapy reported by giving reasons for missing (implied missed therapy) (24% vs. 11%; *p*=0.001), (OR=2.550, $CI._{95}$=1.477,4.401); proximity to clinic where respondents refilled (34% vs. 16%; *p*=0.003), (OR=2.740, $CI._{95}$=1.382,5.434) and time spent at clinic per visit (15% vs. 38%; *p*=0.000), (OR= 3.401, $CI._{95}$=1.712,6.757) (Table 4.12a).

Table 4.12a: Factors influencing non-adherence to HAART significantly

Risk factors	Non-adhering (% within variable)	OR (95%CI)	p-value
Age	72 (18)	1.817 (1.170,4.286)	0.017*
Difficulty fitting therapy in own daily schedule?		2.282	0.006*
Yes	20 (29)	(1.250,4.169)	
No	49 (15)		
Feel satisfied with social support		1.913	0.015*
Never, Rarely and sometimes	30 (25)	(1.129,3.241)	
Often and always	42 (15)		
Time on ARV		3.095	0.002*
Up to six months	13 (37)	(1.477,6.487)	
More than six months	59 (16)		
implied missed therapy	(24)	2.550	0.001*
Never missed therapy	(11)	(1.477,4.401)	
Proximity to clinic where refilled			
Within walking distance	15 (34)	2.740	0.003*
Farther	57 (16)	(1.382,5.434)	
Time spent at clinic per visit		3.401	0.000*
< Half day	55 (15)	(1.712,6.757)	
≥ Half day	16 (38)		
Health literacy (Nutrition) Yes	(16)	1.603	0.077
No	(23)	(0.947,2.715)	

*Statistically significant at level p<0.05

Prevalence of non-adherence differed marginally by marital status (ever/never widowed) (9% vs. 19%; *p*=0.053), 2.534 (OR=2.497, $CI._{95}$=0.974, 6.590); housing (20% vs. 13%; *p*=0.068), (OR=1.722, $CI._{95}$=0.956, 3.104) and CD4 cell count <220 cells/ml (24% vs. 16%; *p*=0.077), (OR=1.619, $CI._{95}$=0.946, 2.770). Non-adherence among respondents also differed marginally by health literacy (nutrition) (16 vs. 23; *p*=0.077), (OR=1.603, $CI._{95}$=0.947, 2.715) (Table 4.12b).

Table 4.12b: Factors influencing non-adherence to HAART marginally

Risk factors	Non-adhering (% within variable)	OR (95%CI)	p-value
Marital status – ever widowed?		2.534	0.053
Yes	5 (9)	(0.974,6.590)	
No	67 (19)		
Housing		1.722	0.068
≤ 3 rooms	55 (20)	(0.956,3.104)	
≥ 1 bedroom	17 (13)		
CD4 cell count <220 cells/ml		1.619	0.077
Yes	(24)	(0.946,2.770)	
No	(16)		
Health literacy (Nutrition)	(16 vs. 23)	1.603 (0.947, 2.715)	0.077

p-value≥ 0.05 but, < 0.1

Statistically, prevalence of non-adherence to therapy among respondents did not differ significantly by level of education (19% vs. 17%; *p*=0.727), living with children (18% vs. 14%; *p*=0.758) and gender (18% vs. 18%; *p*=0.958). Rate of non-adherence to HAART did not also differ significantly by acceptance of waiting time at clinic (25% vs. 17%; *p*=0.215), salary (20% vs. 28%; *p*=0.220) and having children (26% vs. 17%; *p*=0.122). Adherence did not differ significantly by respondents disclosing their HIV status (19% vs. 18%; *p*=0.794) and by belief about medication (21% vs. 17%; *p*=0.385). Prevalence of non-adherence among respondents did not also differ significantly by whom they lived with (22% vs. 17%; *p*=0.287) and by having people to remind them to take medication (19% vs. 17%; *p*=0.499) (Table 4.13).

Table 4.13: Factors not influencing non-adherence to HAART

Risk factors	Non-adhering (% within variable)	OR (95%CI)	p-value
Formal education		0.911	0.727
Primary and none	29 (19)	(0.541-1.534)	
Secondary and higher	43 (17)		
Living with children		0.758	0.459
Yes	50 (18)	(0.364-1.580)	
No	10 (14)		
Gender		0.986	0.958
Male	25 (18)	(0.577-1.684)	
Female	47 (18)		
Wait time acceptable		0.618	0.215
Yes	62 (17)	(0.287-1.329)	
No	10 (25)		
Salary		1.384	0.220
≤ 5000 and unemployed	44 (20)	(0.822-2.329)	
>5000	28 (28)		
Has children		0.572	0.122
Yes	60 (17)	(0.280-1.169)	
No	12 (26)		
HIV status known to house/workmate		1.090	0.794
Yes	58 (18)	(0.571-2.082)	
No	14 (19)		
Concern about taking medicine		1.290	0.385
Positive	52 (17)	(0.726-2.295)	
Negative	20 (21)		
Whom do you live with		0.713	0.287
Alone	16 (22)	(0.381-1.332)	
Family and friends	56 (17)		
Reminder to take medicine		1.192	0.499
No	36 (19)	(0.716-1.985)	
Yes	36 (17)		

*Statistically significant at level p<0.1

4.9 Predictors of non-adherence to HAART

Factors found to influence non-adherence to therapy (Table 4.12a&b) by chi-square and student's *t*-test were entered in a multivariate (stepwise) logistic model and analysed. Table 4.14 shows the logistic regression coefficient, adjusted odds ratio and p-value for each of the predictors. Employing a p<0.05 criterion of

statistical significance, having difficult fitting therapy in lifestyle (OR=2.310, $CI._{95}$=1.211-4.408, *p*=0.011), giving reason for missing doses (OR=2.264, $CI._{95}$=1.261-4.064, *p*=0.006) and proximity to clinic where respondents refilled (OR=2.387, $CI._{95}$=1.155-4.931, *p*=0.019) were found to predict non-adherence to HAART in Nairobi. Ever widowed (OR=2.629, $CI._{95}$=0.980-7.050, *p*=0.055) and time on therapy (OR=2.163, $CI._{95}$=0.918-5.098, *p*=0.078) did not predict non-adherence to therapy but were retained in the model as potential confounders.

From the odds ratio, respondents who had difficulty fitting therapy in own daily schedule were more than 2 times more likely not to adhere to therapy compared to respondents who did not. Respondents who gave reasons for missing doses were more than 2 times more likely not to adhere to therapy than those who did not. Users of ARV who walked to comprehensive care centres were more than 2 times more likely not to adhere to treatment than those who paid for transport to the health facility. Respondents who have ever been widowed were more than 2.5 times less likely not to adhere to therapy compared to those who had never, while those on therapy for 6 months or less were 2 times more likely to fail to adhere to therapy compared to more experienced users (Table 4.14).

Logistic regressions were performed individually on each comprehensive care centre to determine factors significantly associated with non-adherence to ARV therapy. Having difficulty fitting therapy in own daily schedule (OR=9.142, *p*=0.002

and giving reason for non-adherence (OR=8.344, *p*=0.045) predicted non-adherence to therapy at KEMRI CCC, while felt social support (OR=4.621, *p*=0.037) and age of respondents (OR=7.443, *p*=0.024) predicted non-adherence at Riruta health centre. House size marginally predicted non-adherence among respondents refilling at KNH site (OR=2.685, *p*=0.064) (Table 4.14).

Table 4.14: Predictors of Non-adherence to HAART among respondents

	Crude OR	B (coefficient)	Adjusted OR	95% CI	*P* value
All respondents					
Difficult fitting therapy in own daily schedule	2.282	0.837	2.310	1.211-4.408	0.011*
Giving reason for missing dose	2.550	0.817	2.264	1.261-4.064	0.006*
Proximity to clinic where respondents refilled	2.740	0.870	2.387	1.155-4.931	0.019*
Ever widowed	2.534	0.966	2.629	0.980-7.050	0.055
Time on HAART	3.095	0.771	2.163	0.918-5.098	0.078
KEMRI					
Finding HAART taking inconveniencing	6.947	2.213	9.142	2.213-37.771	0.002*
Giving reason for missing dose		2.122	8.344	1.049-66.343	0.045*
Riruta					
Social support	5.760	1.531	4.621	1.095-19.504	0.037*
Age		2.007	7.443	1.300-42.625	0.024*
KNH					
House size	2.259	0.988	2.685	0.945-7.632	0.064

*Statistically significant at the level of P<0.05 by logistic regression

4.10 Confounders and effect modifiers of predictors of Non-adherence to HAART

The relationships among predictor variables were analyzed by the Mantel-Haenszel method and the Breslow-Day test of homogeneity to determine whether they were confounders or effect modifier respectively.

Crude odds ratio (COR) for proximity to clinic where refilled (COR=2.740, $CI_{.95}$=1.382-5.434) and its stratum-specific ORs stratified by social support (OR=2.714, *p*=0.062 vs. OR=2.036, *p*=0.193, Mantel Haenszel OR=2.405) and waiting time (OR=1.869, *p*=0.179 vs. OR=2.714, *p*=0.188, Mantel Haenszel OR=2.133) were similar but not conditionally independent ($\chi^2(1)=6.116$, *p*=0.013 and $\chi^2(1)=4.091$, *p*=0.043 respectively) by Cochran-Mantel-Haenszel's test of conditional independence. Stratum-specific ORs by CD4 count (OR=3.850, *p*=0.015 vs. OR=1.822, *p*=0.246; Mantel Haenszel OR=2.595) and house size (OR=2.740, *p*=0.010 vs. OR=1.152, *p*=1.000, Mantel Haenszel OR=2.490) differed from each other and were homogenous ($\chi^2(1)=1.066$, *p*=0.302 and $\chi^2(1)=1.186$, *p*=0.276) by Breslow-Day test of homogeneity (Table 4.15a).

Table 4.15a: Confounders and Modifiers of Association between Proximity to clinic where refilled and Non-adherence to HAART

Factors	OR ($CI_{95\%}$) of strata	Homogeneity	Independency	AOR ($CI_{95\%}$)
		P-value	*P-value*	
Proximity to clinic				
Social support?		0.693	0.013	2.405(1.187-4.870)
No	2.714(1.050–7.013)			
Yes	2.036 (.698–5.937)			
Waiting time		0.645	0.043	2.133(1.022-4.453)
< Half day	1.869(0.757-4.616)			
≥ Half day	2.714(.734-10.041)			
CD4 count		0.302	0.006	2.595(1.294-5.202)
<220 cells/ml	3.85(1.366–10.854)			
≥220 cells/ml	1.822(0.685–4.848)			
House size		0.276	0.010	2.490(1.232-5.033)
≤3 rooms	2.740(1.332–5.637)			
>3 rooms	1.152(1.077–1.232)			

* Confounder; ** Effect modifier

Stratification analysis of association between giving reason for missing doses and non-adherence found stratum specific ORs by time on ART (OR=3.529, *p*=0.377 vs. OR=2.213, *p*=0.007; Mantel Haenszel OR=2.289), age of respondents (OR=3.633, *p*=0.001 vs. OR=1.394, *p*=0.528; Mantel Haenszel OR=2.395), waiting time (OR=1.757, *p*=0.078 vs. OR=0.500, *p*=0.007; Mantel Haenszel OR=2.201) and social support (OR=5.976, *p*=0.000 vs. OR=1.611, *p*=0.182; Mantel Haenszel OR=2.477) were not similar to each other. Stratum specific ORs by time on ART ($\chi^2(1)=0.154$, *p*=0.694) and age of respondents ($\chi^2(1)=2.809$, *p*=0.094) were homogenous while waiting time ($\chi^2(1)=4.686$, *p*=0.030) and social support ($\chi^2(1)=4.454$, *p*=0.035) were effect modifiers of the association between giving reason for missing doses and non-adherence (Table 4.15b).

Crude OR of gave reason for missing therapy (COR=2.550, $CI_{.95}$=1.477, 4.401) and stratum specific ORs by CD4 count (OR=2.471, *p*=0.109 vs. OR=2.399, *p*=0.009; Mantel Haenszel OR=2.422) were similar but the variables were not conditionally independent ($\chi^2(1)=10.250$, *p*=0.001) (Table 4.15b).

Table 4.15b: Confounders and Modifiers of Association between Giving Reason for Missing Doses and Non-adherence to HAART

Factors	OR ($CI_{95\%}$) of strata	Homogeneity	Independency	AOR ($CI_{95\%}$)
		P-value	*P-value*	
Gave reason				
Time on ART		0.694	0.004	2.289(1.309-4.004)
≤ 6 months	3.529(0.364-34.185)			
> 6 months	2.213 (1.241-3.945)			
Age		0.094	0.002	2.395 (1.382-4.152)
≤ 39.7 years	3.633 (1.686-7.828)			
> 39.7 years	1.394 (0.609-3.191)			
Waiting time **		0.030	0.006	2.201 (1.259-3.848)
< Half day	1.757 (0.979-3.153)			
≥ Half day	0.500 (0.354-0.707)			
Social support?**		0.035	0.001	2.477 (1.437-4.269)
No	5.976(2.100-17.007)			
Yes	1.611 (0.828-3.136)			
CD4 count		0.962	0.001	2.422(1.395-4.206)
<220 cells/ml	2.471 (0.907-6.733)			
≥220 cells/ml	2.399 (1.239-4.646)			

* Confounder; ** Effect modifier

The association between non-adherence and having difficult fitting therapy in own daily schedule was stratified by social support (OR=1.238, *p*=0.803 vs. OR=3.089, *p*=0.007, Mantel Haenszel OR=2.056), house size (OR=1.730, *p*=0.137 vs. OR=5.048, p=0.031; Mantel Haenszel OR=2.059), waiting time (OR=1.869, *p*=0.107 vs. OR=3.500, *p*=0.091, Mantel Haenszel OR=2.139), time on ART 9.500 (0.015 (OR=9.500, *p*=0.015 vs. OR=1.766, *p*=0.122, Mantel Haenszel OR=2.236)

and CD4 count (OR=5.029, *p*=0.004 vs. OR=1.660, *p*=0.202, Mantel Haenszel OR=2.367) and stratum specific ORs were different. By Breslow-Day test of homogeneity, stratum specific ORs for social support ($\chi^2(1)=2.147$, *p*=0.143), house size ($\chi^2(1)=1.989$, *p*=0.158), waiting time at clinic ($\chi^2(1)=0.613$, *p*=0.433), time on ART ($\chi^2(1)=3.004$, *p*=0.083) and CD4 count ($\chi^2(1)=2.724$, *p*=0.099) were homogenous (Table 4.15c).

Table 4.15c: Confounders and Modifiers of Association between Difficult fitting ART in own lifestyle and Non-adherence to HAART

Factors	OR ($CI_{95\%}$) of strata	Homogeneity	Independency	AOR ($CI_{95\%}$)
		P-value	*P-value*	
Difficult fitting therapy				
Social support		0.143	0.016	2.056 (1.124-3.762)
No	1.238 (0.476-3.221)			
Yes	3.089 (1.416-6.737)			
House size		0.158	0.016	2.059 (1.124-3.774)
≤3 rooms	1.730 (0.879-3.404)			
>3 rooms	5.048(1.288-19.782)			
Waiting time		0.433	0.016	2.139 (1.150-3.981)
< Half day	1.869 (0.925-3.774)			
≥ Half day	3.500(0.854-14.342)			
Time on ART		0.083	0.010	2.236(|1.212-4.125)
≤ 6 months	9.500(1.501-60.107)			
> 6 months	1.766 (0.896-3.482)			
CD4 count		0.099	0.005	2.367 (1.289-4.347)
<220 cells/ml	5.029(1.695-14.927)			
≥220 cells/ml	1.660 (0.774-3.561)			

* Confounder; ** Effect modifier

Time on therapy was stratified by giving reason for missing doses (OR=2.582, *p*=0.033 vs. OR=1.619, *p*=0.513, Mantel Haenszel OR=2.442) and the stratum-specific ORs were similar but not conditionally independent ($\chi^2(1)=7.838$, *p*=0.005). Stratum specific ORs by CD4 count (OR=3.348, *p*=0.025 vs. OR=1.865,

p=0.408; Mantel Haenszel OR=2.751), waiting time (OR=2.071, *p*=0.158 vs. OR=7.200, *p*=0.038, Mantel Haenszel OR=2.846) and difficulty with dosing schedule (OR=10.071, *p*=0.006 vs. OR=1.873, *p*=0.240, Mantel Haenszel OR=3.006) differed from each other. Stratum specific ORs by CD4 count ($\chi^2(1)=0.478$, *p*=0.489), waiting time at clinic ($\chi^2(1)=1.577$, *p*=0.209) and having difficult fitting therapy in own daily schedule ($\chi^2(1)=3.005$, *p*=0.083) were homogenous (Table 4.15d).

Table 4.15d: Confounders and Modifiers of Association between Time on Therapy and Non-adherence to HAART

Factors	OR ($CI_{95\%}$) of strata	Homogeneity	Independency	AOR ($CI_{95\%}$)
		P-value	*P-value*	
Time on ART				
Gave reason for missing dose:Yes	2.582 (1.136-5.871)	0.695	0.020	2.442(1.138-5.243)
No	1.619(0.180-14.530)			
CD4 count		0.489	0.010	2.751(1.263-5.993)
<220 cells/ml	3.348 (1.259-8.909)			
≥220 cells/ml	1.865 (0.485-7.175)			
Waiting time		0.209	0.008	2.846(1.313-6.170)
< Half day	2.071(0.831-5.162)			
≥ Half day	7.200(1.236-41.940)			
Difficult fitting ART		0.083	0.005	3.006(1.374-6.579)
Yes	10.071(1.825-55.571)			
No	1.873 (0.708-4.955)			

* Confounder; ** Effect modifier

Based on the mean age of the population, cut-off point of 39.7 years was used to define 'older and younger' respondents. Association between age of respondents and non-adherence to HAART was stratified by widowhood, time on therapy, house size and waiting time. Stratum-specific ORs by widowhood (OR=1.666,

p=0.075 vs. OR=1.810, *p*=0.613; Mantel Haenszel OR=1.676) and crude OR for age (OR=1.817, $CI_{.95}$=1.170-4.286, *p*=0.017) were similar. Stratum-specific ORs by time on therapy (OR=1.618, *p*=0.689 vs. OR=1.613, *p*=0.115; Mantel Haenszel OR=1.614) were similar to each other but not to crude OR, and age and non-adherence conditionally independent ($\chi^2(1)=3.027$, *p*=0.082) by Cochran's test. Time on ART is a confounder in the association between age and non-adherence. Stratification by house size (OR=2.002, *p*=0.033 vs. OR=1.197, *p*=0.796; Mantel Haenszel OR=1.643) and waiting time (OR=1.371, *p*=0.307 vs. OR=5.571, *p*=0.044, Mantel Haenszel OR=1.643) were not similar but were homogenous ($\chi^2(1)=0.707$, p=0.401 and $\chi^2(1)=2.558$, p=0.110) by Breslow-Day test of homogeneity (Table 4.15e).

Table 4.15e: Confounders and Modifiers of Association between Age of Respondents and Non-adherence to HAART

Factors	OR ($CI_{95\%}$) of strata	Homogeneity	Independency	AOR ($CI_{95\%}$)
		P-value	*P-value*	
Age				
Ever widowed		0.935	0.053	1.676(0.981-2.865)
Yes	1.666 (0.953-2.912)			
No	1.810(0.273-11.992)			
Time on ART*		0.998	0.082	1.614 (0.938-2.776)
≤ 6 months	1.618 (0.266-9.852)			
> 6 months	1.613 (0.914-2.849)			
House size		0.401	0.040	1.744 (1.022-2.974)
≤3 rooms	2.002 (1.062-3.772)			
>3 rooms	1.197 (0.431-3.326)			
Waiting time		0.110	0.068	1.643 (0.960-2.811)
< Half day	1.371 (0.769-2.445)			
≥ Half day	5.571(1.042-29.790)			

* Confounder; ** Effect modifier

4.11 Treatment failure among respondents

Complete data about line of therapy and when respondents were put on treatment was available for 402 respondents. Nineteen (5%) respondents were on 2nd line therapy after 1st line therapy had failed (Table 4.4). Out of the 19 respondents, none had been on therapy for 3 to 6 months, 2 on therapy for 6 to 12 months, 4 patients for 12 to 24 months and 13 had been on HAART for more than 36 months. Patients on HAART for less than 3 months did not meet criteria to participate in this study (Figure 4.10).

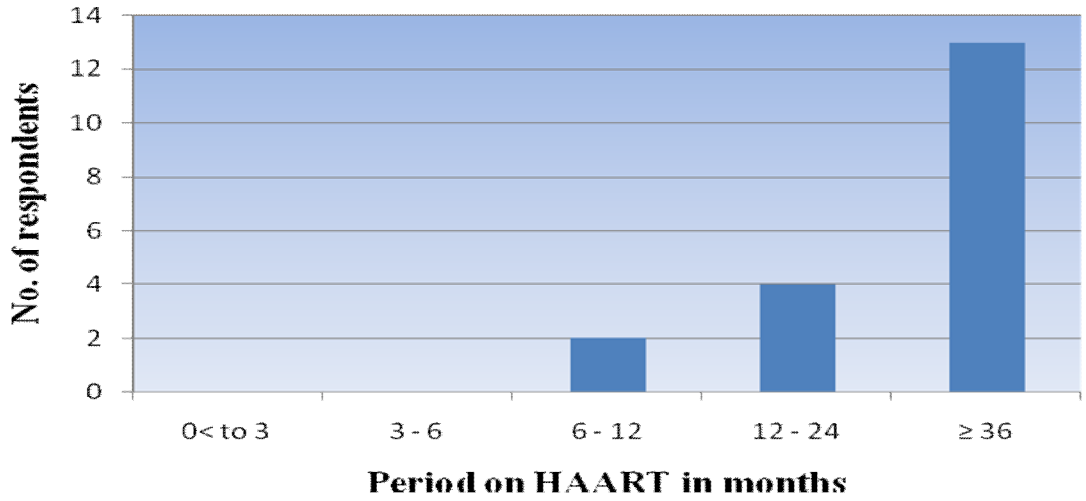

Figure 4.10: Distribution of cases of treatment failure by period on treatment

Among the 19 respondents, 5 respondents had been started on 2nd line therapy (treatment failure) within the last 1 year to the study. The other 14 respondents were on 2nd line for more than one year and therefore did not qualify to be included in the calculation of rate of incidence of treatment failure (Table 4.16). The 5 respondents where treatment failure occurred within the year of study had a total of 34.5 months of 1st line HAART uptake within the year (person months). The 383

respondents on 1st line therapy took HAART for a total of 4096 months in the year of study (person months). The respondents therefore had a total of 4130.5 person months (344.2 person years) of HAART uptake free from treatment failure in the one year prior to this study.

Table 4.16: Cases of Treatment failure among respondents

Eligible cases	No. of respondents	Contribution(person month)	Person years
Experienced treatment failure			
Before the year of study	14	0	0
Within the year of study	5	34.5	
Total	**19**	**34.5**	**2.9**
Had not experienced treatment failure.			
5 months	35	175	
9 months	85	765	
12 months	263	3156	
Group Total	**383**	**4096**	**341.3**
Gross total	402	4130.5	344.2

Cases were eligible to contribute to person time if date of initiating HAART was provided

Incidence rate of HIV treatment failure=

$$\frac{\text{Cases of treatment failures in the year}}{\text{Total person years}} \times 100 = \frac{5 \times 100}{344.2} = 1.45 \text{ per } 100 \text{ person years}$$

In 344.2 person-years of monitoring incidence of treatment failure, there were 5 cases of treatment failure reported **(incidence rate = 1.45 per 100 person-years)**.

Prevalence of HIV treatment failure $= \frac{\text{Respondents on } 2^{nd} \text{ line}}{\text{Study population}} \times 100 = \frac{19 \times 100}{402} = 4.7\%$

For every 100 respondents, 4.7 were on 2nd line therapy after 1st line HIV therapy had failed.

CHAPTER FIVE

DISCUSSION

5.1 Prevalence of non-adherence to HAART among respondents

In this study, level of non-adherence to HAART and incidence of treatment failure were determined, and association of factors militating against non-adherence and adherence among patients on free HAART in Nairobi, Kenya explored. Non-adherence was assessed by CASE adherence index method and 18% of respondents were not adhering; a rate that is comparable to prevalence of non-adherence in most countries in sub-Saharan Africa. The continental prevalence of non-adherence for Africa is 23% (Mills *et al.,* 2006). Twenty one percent and 24% prevalence of non-adherence have been reported in Southwest Ethiopia (Amberbir *et al.,* 2008), 22% in Cote d'Ivore (Eholie *et al.,* 2007) and 13% in Cameroon (Marcellin *et al.,* 2008). Prevalence of non-adherence reported in other studies in Kenya varied from 48% in Kibera, Nairobi (Ellis *et al.*, 2006), 56.8% in Eldoret (Talam *et al.*, 2008) to 64% in Mombasa (Munyao *et al.,* 2005).

The inconsistency of the findings in this study with the findings of the Eldoret study could be attributed to differences in assessment methods of non-adherence. The Eldoret study based non-adherence on failure to take therapy on time, while in this study, a composite score; CASE adherence index was used. Based on similar measurement (failure to take pills on time), this study found prevalence of non-adherence consistent with the findings of Talam *et al.* (2008). The inconsistency

with the findings of Kibera and Mombasa studies can be attributed to difference in treatment periods (2005) when ART knowledge among patients and clinicians was low (IRIN, 2007) compared to the universal belief in benefits of HAART and high knowledge about ART found in this study. It can also be speculated that adherence to HAART in Kenya is improving. Higher prevalence of non-adherence in other studies in developing countries was attributed to limited access to therapy due to cost of medication (Eholie *et al.,* 2007; Byakika *et al*., 2005; Weiser *et al*., 2003).

5.2 Factors associated with non-adherence to HAART

Published data on factors associated with non-adherence to ARV therapy in Kenya is limited. Elucidating these barriers is critical if policy makers in Kenya are to identify pitfalls in current treatment strategies that should be addressed while devising effective AIDS treatment programs. This study found age, difficulty with dosing schedule, felt social support, time on ART, giving reason for missing doses, accessing therapy in a clinic within walking distance from home, time taken in clinic to refill, marital status (widowhood), house size and CD4 cell counts were associated with non-adherence to HAART. These findings correlate with other research findings that, personal factors, social context factors and health system factors influence adherence (Munro *et al.,* 2007; WHO, 2003). However, only, accessing ART in a clinic within a walking distance from home, having difficulty with dosing schedule and giving reason for missing therapy were independently

associated with non-adherence to HAART by multivariate regression model. Time on ARV was a confounder while felt social support and time spent at clinic to refill were effect modifiers.

5.2.1 Age of respondents

This study found that for every two HIV patients accessing free HAART in Nairobi, one was between 36 and 45 years old. The age distribution of respondents was similar to the national HIV/AIDS distribution by age for Kenya (NASCOP and MOH, 2008). However, age distribution curve for HIV/AIDS found in KAIS peaked (25-34 age group) earlier by 10 years compared to age distribution of respondents in this study. The proportion of respondents between 18 and 25 years in this study and the Eldoret study (7%) (Talam *et al*., 2008) were very low, compared to the 23% among HIV patients in Kenya (NASCOP and MOH, 2008). The finding suggested a delay in HIV testing and initiating HAART among HIV patients in Nairobi. This was confirmed by other findings in this study that the mean age of respondents accessing ARV in Nairobi was 39.7 years. It was speculated that patients delayed initiating ART until they started developing AIDS-related symptoms. The delay was attributed to fear of stigma; a powerfully discrediting and tainting social label that radically changes the way individuals view themselves, and how they are viewed by others. Fear of stigma among respondents was confirmed by about half of respondents in this study who stated they would be embarrassed if others knew

they were on ART. Other studies have also found delay in care seeking behaviour due to stigma (Odusanya, *et al*., 2004) which creates self-denial among patients.

Univariate analysis revealed significantly higher non-adherence in younger age but, the association was confounded by time period on ART in multivariate analysis. However, respondents in younger age were more than one and half times more likely not to adhere to therapy than the older adults. The finding that younger adults were more likely not to adhere are consistent with the findings of Iliyasu *et al.* (2005) in Nigeria, Wenger *et al.* (1999) in the United States, Carballo *et al*. (2004) in Spain and Orrell *et al*., (2003) in South Africa. More specifically, this study found younger females (<38.2 years) were more likely not to adhere to therapy. Poor adherence to HAART in younger respondents (<39.7 years) was speculatively attributed to psychosocial difficulties associated with the life–stage. They include educational and employment challenges, and care of young children which is a potentially stressful phase especially for women (Brown and Harris, 1978; Christoffersen, 2000). In addition, older individuals are more likely to have prior experience taking long-term medication for age-related illnesses and may already have become more accustomed to such a routine and lifestyle. Older age may also be associated with increased recognition of mortality and therefore greater motivation to follow illness prevention strategies and treatment recommendations set forth by health care providers. Alternatively, increased medication adherence among older adults may be explained, in part, by a survivor

effect in that, individuals who maintain greater compliance with treatment recommendations may actually outlive those who are non-adherent.

The finding in this study that age is significantly associated with non-adherence was inconsistent with the finding of Talam *et al*. (2008) in Eldoret. This can be attributed to difference in mean age of respondents; respondents in the Eldoret study were younger (mean age 36.1years in contrast to 39.7 years).

5.2.2 Gender of respondents

In this study, 2 out of 3 patients interviewed were female. These findings are consistent with the findings of Talam *et al*. (2008) in Eldoret, Kenya. The proportion of females on HAART was comparable to the proportion of females reported with HIV/AIDS in Kenya (CBS, 2004; NACC/OP Kenya, 2008 and NASCOP, 2008).

Regarding gender and adherence, the study found prevalence of non-adherence to therapy among male equal to that among female. Gender did not predict non-adherence to HAART in Nairobi. These findings correlated with the findings of Byakika *et al*. (2005) in Uganda, Iliyasu *et al.* (2005) in Nigeria, Weiser *et al.* (2003) in Botswana, Wenger *et al.* (1999) in the United States of America and Talam *et al.* (2008) in Eldoret, Kenya.

5.2.3 Proximity and cost of Transport from respondents homes to HAART clinics

This study found a significant percentage of patients accessed therapy from comprehensive care centers within walking distance from their homes; a demonstration of expanded access to free HAART in Nairobi. However, more than half of respondents preferred attending HAART clinics far away from home and spent more than Ksh.100 on transport per visit to access therapy. The motivating factor for accessing therapy in a far clinic was speculated to be fear of stigma. Respondents did not give stigma as a reason for choosing a clinic but was deduced from the study finding that one half of respondents were uncomfortable or embarrassed if others knew they were on HAART. This suggests that societal stigma associated with ART was an important factor in adherence.

With regards to cost of transport and proximity to clinic where respondent refilled and non-adherence, this study found proximity to clinic to be significantly associated with non-adherence. Respondents who accessed therapy in clinics within a walking distance from their homes were about two and a half times more likely not to adhere than patients who refilled in far away clinics. Where respondents paid for transport, cost of transport did not significantly influence non-adherence to HAART. The finding that cost of transport did not significantly affect adherence was consistent with the finding of Byakika *et al*. (2005) in Uganda. This study found most respondents were introduced to ART clinics by friends and relatives

and it was therefore hypothesized that these friends and relatives also provided respondents with material support such as means of transport to ART clinic, making it possible to overcome the cost barrier that has been associated with non-adherence to therapy in other studies (Byakika *et al*., 2005). Ware *et al*. (2009) in a study in Tanzania, Nigeria and Uganda found that such "helpers" make their expectations for the patients to adherence known to them, thus, creating a responsibility on the part of patients who consequently, adhered to therapy to promote good will with the helpers.

This study found proximity to clinic was not a strong motivator to adherence in Nairobi. Respondents who reported proximity as the reason for choosing ART clinic had the highest prevalence of non-adherence (27%). Almost one half of respondents who reported to be motivated by proximity in choice of clinic and walked to clinic to refill did not adhere. These findings together with the social stigma associated with ART use suggested that most respondents who accessed free therapy in clinics within walking distance to their homes did so due to lack of choice; speculatively, could not afford transport cost to alternative HAART clinics.

When controlled for social support, waiting time at clinic, CD4 count and house size, proximity to clinic where respondents refilled predicted adherence among respondents in both strata by house size, respondents with inadequate social support and CD4 count below average.

5.2.4 Time spent in clinic by respondent

Results of this study indicate a need to shorten time taken to refill at HAART clinics; more than a quarter of the respondents suggested clinics reduce time spent at clinics. Waiting time to be seen by clinician was acceptable but not at pharmacy. There is therefore need for innovative ways of dispensing. Long hours at clinic may result in loss of income for respondents and consequently increased cost of accessing and adhering to therapy.

In this study, respondents who reported spending on average at least half a day at clinic to refill were more than three times more likely not to adhere to therapy than their counterparts who reported shorter time. This finding is consistent with the findings of Hardon *et al*. (2007) in Uganda. The higher non-adherence found among respondents who reported long hours at clinic was speculatively attributed to inadequate time respondents had with the healthcare worker to discuss health issues or therapy. However, waiting time at clinic did not predict non-adherence to therapy but modified the association between giving reason for missing doses and non-adherence.

5.2.5 Living conditions and income

This study did not find living in poor socio-economic circumstances (income) to significantly influence adherence. This finding is consistent with the findings of

Orrell *et al*. (2003) in South Africa but inconsistent with findings of Byakika *et al.* (2005) in Uganda who found that where patients paid for ARV therapy, living in poor socio-economic circumstance resulted in non-adherence. In this study, however, at the Riruta health center, where unemployment and low income rates were very high, income was found to significantly influence non-adherence. This finding at Riruta was speculatively attributed to lack of food which could have made respondents skip medication until food was available or their nature of work did not allow proper therapy scheduling. The finding therefore suggested that resource poor patients could have better treatment outcomes if indirect financial barriers to treatment could be overcome.

5.2.6 Level of Education of respondents

This study found about two thirds of respondent had formal education. This finding is consistent with the finding of United Nations Development Programme (UNDP) (2008) for Kenya. Level of formal education did not significantly influence non-adherence in this study. This finding is inconsistent with the findings of Carballo *et al*. (2004) in Spain where literacy was a univariate predictor. The inconsistency was attributed to poor understanding of treatment regimen (Murri *et al*., 2004). However, the study findings were consistent with the findings of Weiser *et al.* (2003) in Botswana and Wenger *et al*. (1999) in United State of America. In addition, this study found high ART knowledge and positive belief about ART among most respondents. These findings demonstrated that it is not the level of

education that motivated patients to adhere but could be speculated to be ART knowledge and belief in the benefits of therapy (Murri *et al*., 2004) gained through training and counseling at an appropriate level of patients understanding.

In this study, socioeconomic level; education and income considered together, did not significantly influence non-adherence among respondents. However, socioeconomic level was inversely related to non-adherence: Riruta health centre with most of the respondents in lower socioeconomic stratum had highest prevalence of non-adherence, while KEMRI CCC with most of the respondents in the middle stratum had lowest prevalence of non-adherence. This knowledge is important when prioritizing and estimating required efforts to implement adherence interventions.

5.2.7 Marital status of respondents

Most respondents were married, about one fifth had never married, and the rest were widowed or divorced/separated and in equal proportion. The study found an increase in people living in widowhood compared to findings of other studies (Talam *et al.,* 2008; Olowookere *et al.,* 2008). This is in agreement with the KAIS, (2007) (NASCOP and MOH, 2008) that reported the population in widowhood in Kenya had tripled since 2003. In realization of this growth, this study, beside the traditional dichotomizing marital status into ever married and married, grouped respondents into widowed and never widowed to elicit the influence of the unique

experience; nursing spouses until death on adherence to therapy among widowed. Grouping widowed together with others; ever married or divorced/separated obscures the influence of the experience on non-adherence.

When adherence to HAART among ever married was compared to never married, the two groups did not differ significantly. Other studies have reported mixed results; Byakika *et al.* (2005) found an association between marital status and non-adherence to ARV therapy in Uganda while, Weiser *et al.* (2003) in Botswana did not. This study found a protective effect of widowhood on non-adherence. Never widowed respondents were two and half times more likely not to adhere than the widowed.

This study did not determine reasons for high adherence found among widowed population. However, further analysis revealed that three-quarters of the widowed (male and female), lived with their children. Adherence may therefore, firstly, been welfare motivated; desire to stay alive for the sake of own children (Aspeling and Van Wyk, 2008). Secondly, increased recognition of death through loss of a spouse and possibly from HIV related causes may have motivated uptake of therapy among widowed to avoid similar eventuality.

5.2.8 Knowledge and belief in benefits of HAART

The study found respondents knew and believed adherence to HAART, safe sex and nutrition were important ingredients of ARV therapy. This knowledge was translated into positive belief about necessity of HIV medication almost universally. Belief in the benefit of therapy found in this study together with availability of free HAART, is speculated resulted in the 18% non-adherence to therapy among the respondents. This finding correlates with findings of Aspeling and Van Wyk (2008) in South Africa where adequate pre-therapy counseling and HIV education impacted adherence positively. However, more than a third of respondents in this study did not understand how ARVs work but, surprisingly, that did not influence adherence among them. These findings are inconsistent with findings of Aspeling and Van Wyk (2008) where insufficient information and continuous uncomfortable side-effects caused participants to adjust medication dose or temporarily discontinue treatment. The inconsistency with the finding in the South African study can be attributed to the strong positive belief about necessity of HAART and the finding that respondents were well informed and consequently tolerated side effects in this study.

5.2.9 CD4 cell count of respondents

Suppression of HIV replication by HAART results in increased CD4 cell count (Florence *et al*., 2003). In response to successful ART, CD4 count typically increases by >50 cells/µL within weeks after viral suppression, and then increases

by 50-100 cells/µL per year thereafter until a threshold is reached (Bartlett *et al*., 2005). In this study, in spite of all respondents being on ART for more than 3 months, a quarter had less than <200cells/ml (WHO immunological criteria for putting patients on ART). This percentage is high considering 49% of the respondents with CD4 cell count<200cells/ml had been on HAART for more than 1 year. The high percentage of respondents with low CD4 cell count found in this study suggested that patients were not adhering to therapy or initiated ART late in the disease when CD4 cell counts were very low and, speculatively when they started developing AIDs-related symptoms thus exposing themselves to unnecessary morbidity and mortality risks.

This study found CD4 cell count was associated with adherence. This was consistent with the finding of Orrell *et al*. (2003). Respondents with CD4 cell count<200cells/ml had a higher prevalence of non-adherence than those with CD4>200cells/ml. Initiating HAART when CD4 cell count is very low has been associated with treatment failure (Lohse *et al*., 2005). However this study did not investigate the association between treatment failure and CD4 cell count as cases of treatment failure were few (4.7%) and data on CD4 cell counts prior to treatment failure was lacking.

5.2.10 ARV therapy related factors

In this study, more than half of the respondents reported experiencing side effects to HAART. The reported adverse effects were mainly rashes, itching and neuropathy. The low level of cases of side effects reported can be attributed to the long experience most respondents had with HAART, acceptance and willingness to tolerate common adverse effects associated with ART as they believed therapy was effective. Side effects did not significantly influence non-adherence in this study. This is consistent with findings of Weiser *et al*. (2003) in Botswana, and Aspeling and Van Wyk (2008) in South Africa. The finding in this study can speculatively be attributed to easy access and proximity to CCC where side effects were promptly attended to, and the high ART knowledge and awareness found among respondents, psychologically, prepared them; anticipation of side effects and equipped with information about self-management. Aspeling and Van Wyk (2008) also found in the South Africa study that informed HIV patients tolerated side effects and adhered to therapy.

5.2.11 Social Support from family and friends

This study found perceived lack of social support to be significantly associated with non-adherence but did not however, predict non-adherence. Perceived social support also modified the relationship between giving reason for missing doses and non-adherence. ART recipients interviewed, who rated their overall social support from friends and family lowly were two folds more likely to be non-adherent

than those who rated it highly. These findings are consistent with many ARV therapy adherence studies (Remien *et al.,* 2003; Vervoort *et al*. 2007; Ammassari *et al*., 2002; WHO 2003; Amberbir *et al*., 2008; Aspeling and Van Wyk*,* 2008) where lack of social support from family and friends was found to affect adherence negatively. The social support reported in literature varied from reminding patients to take medication, actual giving out the medication and/or offering food and drink to accompany the intake of medication (Remien *et al.,* 2003). This study found half of the low income adherents reminded themselves to take medications. The study speculatively attributed the higher non-adherence found in respondents who got inadequate social support to, first lack of emotional support that lead to taking medicine in privacy for fear of stigma associated with ART uptake and with no one to remind them or encourage them, may have sometimes missed their dosing schedules. The advanced reasons were confirmed by the finding that the main reason for missing medication was being busy and forgetting. Secondly, lack of material support among respondents in the lower socioeconomic stratum. Byakika *et al*. (2005) in a study to assess level of adherence and associated factors in Uganda did not find social support to predict adherence. The difference found was attributed to use of different scales to measure social support. This study did not investigate use of practical aids such as pill boxes and alarms to alert respondents to take medicine. Such alerts have been found to improve adherence (Vervoort *et al*., 2007).

5.2.12 House size/social stability

In this study, over two-thirds of respondents lived in houses with three or less rooms. These respondents were more than 1.7 times more likely not to adhere to therapy than respondents living in bigger houses. The difference in non-adherence to therapy in the two groups was marginally significant. These findings are consistent with findings of other studies (Schilder *et al.,* 1998; Bangsberg *et al.,* 2004, Carballo *et al*., 2004), where poor housing and homelessness was associated with non-adherence. It was speculated that the small size of the house may not have provided privacy that respondents required to take pills especially where they had not disclosed to housemates their HIV status or were on HAART. Respondents living in small size houses were also more likely to belong to the lower socioeconomic stratum where income influenced non-adherence.

5.2.13 Inconvenience of therapy among respondents

The results in this study support the hypothesis that components of Health Belief Model (HBM); self-efficacy and perceived treatment utility are influential in determining adherence behavior. Almost all respondents believed ART was necessary and adherence to the regimen important. This was attributed to the high ART knowledge and speculatively in line with Remien *et al*. (2003) finding in America to life saving changes patients had experienced with HAART. Respondents in this study initiated treatment late as demonstrated by the finding that a quarter of respondents had low CD4 cell counts after being on ART for more

than 6 months. Belief in the benefits of HAART found in this study translated to improved adherence to therapy compared to findings of other studies in Kenya (Ellis *et al.,* 2006; Munyao *et al.,* 2005; and Talam *et al.*, 2008).

However, a fifth of the respondents reported difficult fitting medication into their daily schedules. This concern; ability to fit therapy in respondents schedule was significantly associated with and predicted non-adherence to therapy. The respondents who said were unable to fit therapy in their daily schedule were more than 2 times more likely not to adhere to ARV therapy than those who were able. These findings were consistent with the findings of Munro *et al.* (2007) and Wenger *et al*. (1999). It was speculated, in line with Vervoort *et al.* (2007) finding that when medication scheme did not fit in the respondents' normal daily activities, it caused them to forget to take medications and consequently resulted in poor adherence. Further analysis of results in this study found more than half of the respondents who reported ART to disrupt their daily lives, admitted to failure to take all prescribed medication. Three quarters of these respondents, reported being busy and forgetting as reasons for failure to take medications as prescribed.

More than one-third of respondents did not understand how HAART works. Although this concern was not significantly associated with non-adherence in the overall, the difference was significant among respondents at Riruta health centre. The respondents at Riruta who reported lack of understanding of how therapy

worked were more than three times more likely not to adhere to therapy. This finding is consistent with the findings of Vervoort *et al*. (2007) in a review of various HAART adherence studies published from 1996 to 2005. Aspeling and Van Wyk (2008) in South Africa also found patients adjusted medication dose or temporarily discontinued treatment where information was insufficient.

This study found some respondents depended on themselves to remember take medication. However, their uptake of HAART was not significantly different from those who had friends and family to remind them. From these findings, it can be speculated that respondents with no one to remind them relied on special alerts to maximize their adherence. This study did not investigate alternative reminders and recommends future studies identify such important cues to adherence.

Overall, a quarter of respondents had negative concerns about HAART. However, among the individual concerns tested, only inability to fit therapy into daily schedule (dampened feelings of self-efficacy) predicted non-adherence.

Difficult fitting therapy into daily schedule predicted non-adherence among respondents who reported inadequate social support, lived in bigger houses, had less than six months experience taking HAART and CD4 count less than average.

5.2.14 Length of time on HAART among respondents

The results in this study indicate that majority of the respondents had been on ART for more than one year. Immunological and adherence to therapy among respondents improved with time on therapy. These findings correlate with the findings of Bartlett *et al.* (2005).

Time period on HAART was a confounder of the association between age of respondents and non-adherence in this study. It was significantly associated with non-adherence but did not predict adherence to therapy. Respondents who were on therapy for a period of six months or less were two fold more likely not to adhere to ARV therapy than those with longer experience. The findings that adherence to therapy increased with duration on ARV medicine are consistent with findings of Mannheimer *et al*. (2006) but, inconsistent with the findings of Byakika *et al*. (2005) in Uganda. The inconsistency was attributed to the shorter experience with ARVs reported in the Uganda study; 70% of respondents were on ART for 6 months or less and paid for therapy compared to 30% in this study and on free HAART. Where drugs are paid for, many studies have found shortage of drugs due to economic barriers, as the most common reason for non adherence (Byakika *et al*., 2005).

Explanatory factors that can be offered for this finding are: it may be that respondents with long experience with HAART may have been accustomed to

therapy routine thus fitting it easily in their lifestyle. They may have also overcome stigma associated with HIV and did not need privacy to take medicine. Living with HIV for a long time may also be associated with increased recognition of mortality and therefore greater motivation to follow illness prevention strategies and treatment recommendations. Increased medication adherence among long time users of therapy may also be explained, in part by a survivor effect in that individuals who maintain greater compliancy with treatment recommendations may actually outlive those who are non-adherent.

Time on ART predicted non-adherence among respondents with CD4 count less than average, gave reason for skipping dose, difficult fitting therapy in lifestyle and where time at clinic to refill is more than half day.

5.2.15 Reasons for non-adherence among respondents

Respondents owning up to skipping therapy and giving reason for it predicted non-adherence in this study. Its association with non-adherence however, was modified by social support and length of time at clinic to refill. The study found three quarters of the respondents who gave reason for not taking all medication failed because of being busy and forgetting. A third of them were non-adherent to therapy. This finding is consistent with findings of Nieuwkerk *et al.* (2001) and Byakika *et al*. (2005) in Uganda. In this study, missing doses was more common among respondents in the first six months of initiating therapy. Adverse effects

were not found to be associated with non-adherence. However, among respondents who reported nausea, about a third were non-adherent to HAART, but did not significantly influence adherence to therapy. Other reasons for non-adherence reported by respondents were concerns about medication; inability to fit therapy in patients' own daily schedule and lack of adequate knowledge of how therapy works among respondents refilling at Riruta health center.

Giving reason for missing doses predicted non-adherence among respondents who have been on ARV for more than 6 months, respondents who are younger, those who report inadequate social support, CD4 count above average and where time spent at clinic to refill is more than half day.

5.3 Incidence of treatment failure

Majority of the respondents in this study were on First line ARV regimen which correlates with the low prevalence of non-adherence found. The results also indicated that risk of treatment failure increase with time on ART. Published data about incidence rate of treatment failure in Kenya is lacking. Incidence rate (IR=1.45 per 100 person years) found in this study was less than what was found by Mocroft *et al.* (2004) and Lohse *et al*. (2005) in Britain and Denmark respectively. However, the finding compared well with predictions of Lohse *et al*. (2005) that IR declines with time. The low IR in this study was attributed to new knowledge about HIV and improved adherence to therapy. This study found

prevalence of treatment failure (4.7%) in Nairobi was lower than the finding of Lohse *et al.* (2005) and higher than the finding of Kocholla *et al*. (2007) at Mbagathi hospital in Nairobi. This suggests that prevalence of treatment failure is increasing in Nairobi. The increase is expected and can be attributed in part to the high momentum generated in earlier years due to non-adherence resulting from limited access to therapy before the free HAART rollout in Kenya, and speculatively, low mortality among respondents with failed 1st line therapy as they are put on equally potent 2nd line therapy. The inconsistency with finding of Kocholla et al (2007) can also be attributed to difference in methodology: limiting recruitment of respondents to those with more than 3 months of HAART experience in this study may have biased IR upwards.

The inconsistency with finding of Lohse *et al*. (2005) can be attributed to different study designs (cohort versus cross sectional) and time periods (2005 versus 2009) in which case, regimen and patient counseling for ART could have improved.

5.4 Study limitations and strengths

This study had the following limitations:-

- Information regarding patients' experience with ART, including their adherence is based on self report which is prone to recall bias and tends to overestimate prevalence of adherence.

- Data about treatment failure was derived from reported change of regimen from 1st to second line drugs based on immunological tests and clinical assessment as opposed to viral load.
- Due to lack of data, it was not possible to corroborate the non-adherence to therapy found with respondents' viral load and CD4 cell count.
- The cross-sectional nature of the study hindered the ability to identify the exact predictor of adherence.
- Limiting recruitment of respondents to those with more than 3 months of HAART experience may have marginally biased IR upwards.

Despite the stated limitations, the study had several strengths, including

- using a relatively large sample size,
- inclusion of 3 treatment centers resulted with a sample representative of Kenya's population based on income and education level indicators,
- the respondents were representative of Kenya's population with HIV in terms of gender, literacy, poverty levels and age distribution.
- use of more than one method of adherence assessment, use of composite index to determine non-adherence,
- inclusion of large set of variables to determine predictors of non-adherence, confounders and effect modifiers
- use of person years to determine incidence of treatment failure.

5.5 Conclusions

Findings revealed that,

- Non-adherence rate for Nairobi, Kenya is 18% and is comparable to other developing countries and better than in resource rich countries.
- Non-adherence to HAART in Nairobi is significantly associated with young age, failure to fit medication into normal daily schedule (therapy not fitting into the daily routine), short experience with HAART, lack of social support, refilling from clinics within walking distance to patients' home, long time in clinic to refill and stating reason for missing medication.
- Given the complex array of factors associated with non-adherence, no single strategy is likely to be effective for every patient.
- Predictors of non-adherence are: patient accessing ART in a clinic within a walking distance from home, difficulty fitting therapy in own daily schedule and giving reason for skipping doses.
- The most common reasons mentioned for missing medication was forgetfulness (38%).
- Time period on therapy is a confounder while waiting time at clinic and social support are effect modifiers in non-adherence association.
- Comprehensive care centers with higher percentage of respondents in lower socioeconomic level (education and income level combined) are more likely to have higher prevalence of non-adherence compared to others.

- Prevalence of treatment failure among respondents in Nairobi is 4.7% and Incidence rate (IR), 1.45 per 100 person years.

5.6 Recommendations

There is need for adherence interventions particularly for patients accessing therapy from ARV clinics within walking distance from their homes, patients with short experience with HAART and in younger age. The interventions should address social support needs, forgetfulness and other reasons associated with non-adherence, strategies for fitting therapy in patients' daily schedules, long time spent at clinic to refill and societal stigma associated with ART uptake.

Based on the findings in this study, comprehensive individualized interventions employing behavioral and educational strategies, cue-dose training, social support as well as time management at clinics is recommended.

Particularly, there is need to/for:

- Provide adequate information on how ART works in pre and post HAART initiation counseling sessions.
- Support development of strong social groups to provide social support especially among patients living in the informal settlements. Invite patients to become active partners in care, for example, utilize patients who have ever been widowed as motivational speakers for other patients to benefit from the protective effect associated with widowhood.

- Stimulate patients to fit therapy in their daily routine by offering one-on-one individualized educational sessions about importance of adherence and managing adherence problems. During subsequent visit to the clinic, hold booster sessions to discuss and work through personal barriers to adherence.
- Facilitate patients to develop/identify personalized reminder cues such as meal times or other regular activities and train them to time their doses based on the cues to address forgetfulness.
- Better time management at clinic to improve waiting time to refill.
- Confirm treatment failure using viral load test to minimize misdiagnosis.

There is need for research to

- determine whether indirect costs associated with ART have an impact on non-adherence among patients of low socioeconomic status.
- explain the high non-adherence prevalence among patients accessing therapy in clinics within walking distance to their homes and stigma associated with HAART uptake. The research should investigate preference for clinics for refilling and the underlying reason.
- investigate use of cues for adherence to therapy where friends and relatives are not available to remind PLWHA on HAART to take medication.

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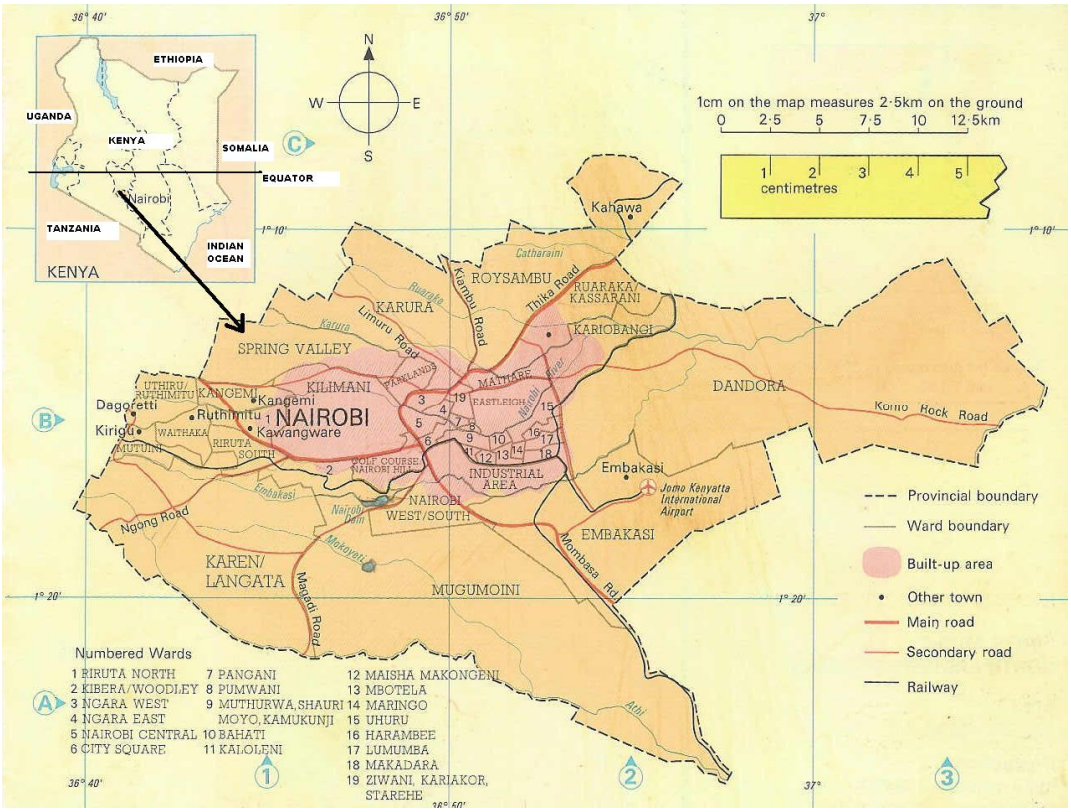
Appendices

Appendix 1 Study Area- Map of Nairobi Province in Kenya



Appendix 2 Consent Form

English

CONSENT TO PARTICIPATE IN THE STUDY

Title: Prevalence and predictors of non-adherence, and incidence of treatment failure among patients on free HAART in Nairobi, Kenya

Introduction

The Principal Investigator, Samwel N. Wakibi; a Student at the Institute of Tropical Medicine and Diseases (ITROMID) of Jomo Kenyatta University Agriculture and Technology (JKUAT) invites you to participate in a quantitative study to determine the prevalence and predictors of failure to take medication as prescribed among patients on free HIV medication in Nairobi, Kenya.

Investigator's statement: May I take your time to explain about a research I am conducting in this clinic? The purpose of this consent form is to give you the information you need to know in order to decide whether or not you would like to participate.

Purpose: I am carrying out a study to determine factors associated with failure to take HIV medication according to instructions in adults; 18 and above years old.

The purpose of the study is to find out how many HIV+ patients on treatment are taking medication as prescribed, how many HIV+ patients on HIV treatment have changed medication for failure to respond to treatment, and the reason why a patient fails to take medications as prescribed.

Procedure: If you are willing, I will interview you about your HIV condition, treatment and experience in this clinic. All this information I will enter in the attached questionnaire. I will also get more information from your hospital file.

Risk, Stress and confidentiality: The interview will take 20 to 30 minutes of your time. Your participation in this study involves no physical risk. However, there is the possibility of psychological risk if your answers to interviews were made public at any point or question are distressing. Because of that risk, interviews will be conducted in private and I will maintain strict control over all data. Personal data will be kept confidential in a password-protected electronic file and access to the file will be limited to me. Where psychological risk arises from emotive questions, the respondents may decline to answer such questions.

Benefit of taking part in the study: There may be no direct benefits to you for taking part in this study, but to society. The outcome of this study will be used to help HIV+ patients take medication according to instructions.

Voluntariness: Participation in this study is entirely voluntary. You may refuse to participate if you wish, or withdraw from the interview at any point.

Do you have any questions?

If you are willing to participate, please sign or put your thumb print in the space below

Respondent's Signature: _____ or thumb print _____ Date _____

If thumb print above, Witness's Signature: _____ Date _____

Investigator's Signature:_____ Date _____

Contacts:

If you have any issues about your rights of participation in this study, you may contact: Principal Investigator: **Samwel N. Wakibi, Student, ITROMID** or the Chairperson, Ethical Review Committee, KEMRI/NERC; P.O. Box 54840 00200 Nairobi, Tel. 2722541, 0722205901, 0733400003.

Kiswahili

IDHINI YA KUSHIRIKI KATIKA UTAFITI

Kichwa: Prevalence and predictors of non-adherence, and incidence of treatment failure among patients on free HAART in Nairobi, Kenya

Utangulizi

Mtafiti mkuu, Samwel N. Wakibi, mwanafunzi katika Institute of Tropical Medicine and Diseases (ITROMID) ya chuo kikuu cha Jomo Kenyatta University Agriculture and Technology (JKUAT) anakualika kushiriki kwenye utafiti kufumbua ni wagonjwa wa ngapi wa ukimwi wanatumia madawa kulingana na maagizo, napia, mambo yaliyo na uhusiano na kutozingatia matibabu ya ukimwi kwa wagonjwa wa miaka 18 na zaidi mjini Nairobi

Taarifa ya mtafiti: Naomba kuchukua muda wako kukujulisha juu ya utafiti ninaoufanya kwenye kituo hiki cha matibabu. Lengo la ombi hili nikukujulisha mambo unayohitajika kujua ili uweze kuamua kama ungetaka kushiriki

Nia: Nina fanya utafiti ili kujua mambo ambayo yana uhusiano na kutozingatia matibabu ya ukimwi kwa watu wa miaka 18 na zaidi. Nia ya utafiti huu ni kujua ni wagonjwa wangapi wa ukimwi wanameza madawa kulingana na maagizo ya

dakitari, ni wangapi wamebadilishiwa madawa kwa sababu zimeshindwa kupunguza wingi wa virusi kwenye damu, zimeshindwa kuongezea askari wa kupambana na virusi mwilini (CD4) au wamepata magonjwa ya maambukizo miezi 3 baada ya kuanza matibabu, na sababu za kutozingatia matibabu kama ilivyo agizwa na daktari.

Utaratibu: Kama unakubali kushiriki, nitakuuliza maswali juu ya maradhi ya ukimwi, matibabu na unayoshuhudia katika kituo hiki. Yote utakayo nielezea, nitayanukuru kwenye fomu hii. Mambo zaidi, nitayapata kutoka kwa faili yako ya hospitali.

Madhara na usiri: Zoezi hili litachukua mda wa dakika 20 hadi 30. Kushiriki kwako hakuna madhara yoyote ya kimwili. Lakini kuna uwezekano wa kimafikira kama majibu yako yatafikia uma wakati wowote. Kwa sababu hiyo, mazungumzo haya hayatafanyika hadharani na yote nitakayonukuru nitayaweka pahala pa siri.

Faida ya kushiriki: Hakuna faida ya moja kwa moja utakayopata kutokana na utafiti huu lakini utafiti utafaidi uma. Matokeo ya utafiti huu, yatatumiwa kuwasaidia wengine walioadhirika na ukimwi kuzingatia matibabu/tiba.

Uhiari: Kushiriki kwenye utafiti huu ni kwahiari. Unaweza kukataa kushiriki au ujiondoe wakati wowote.

Una maswali?

Kama unakubali kushiriki, tafadhali weke sahihi au alama ya kiganja kwa sehemu ilyo achwa hapa chini.

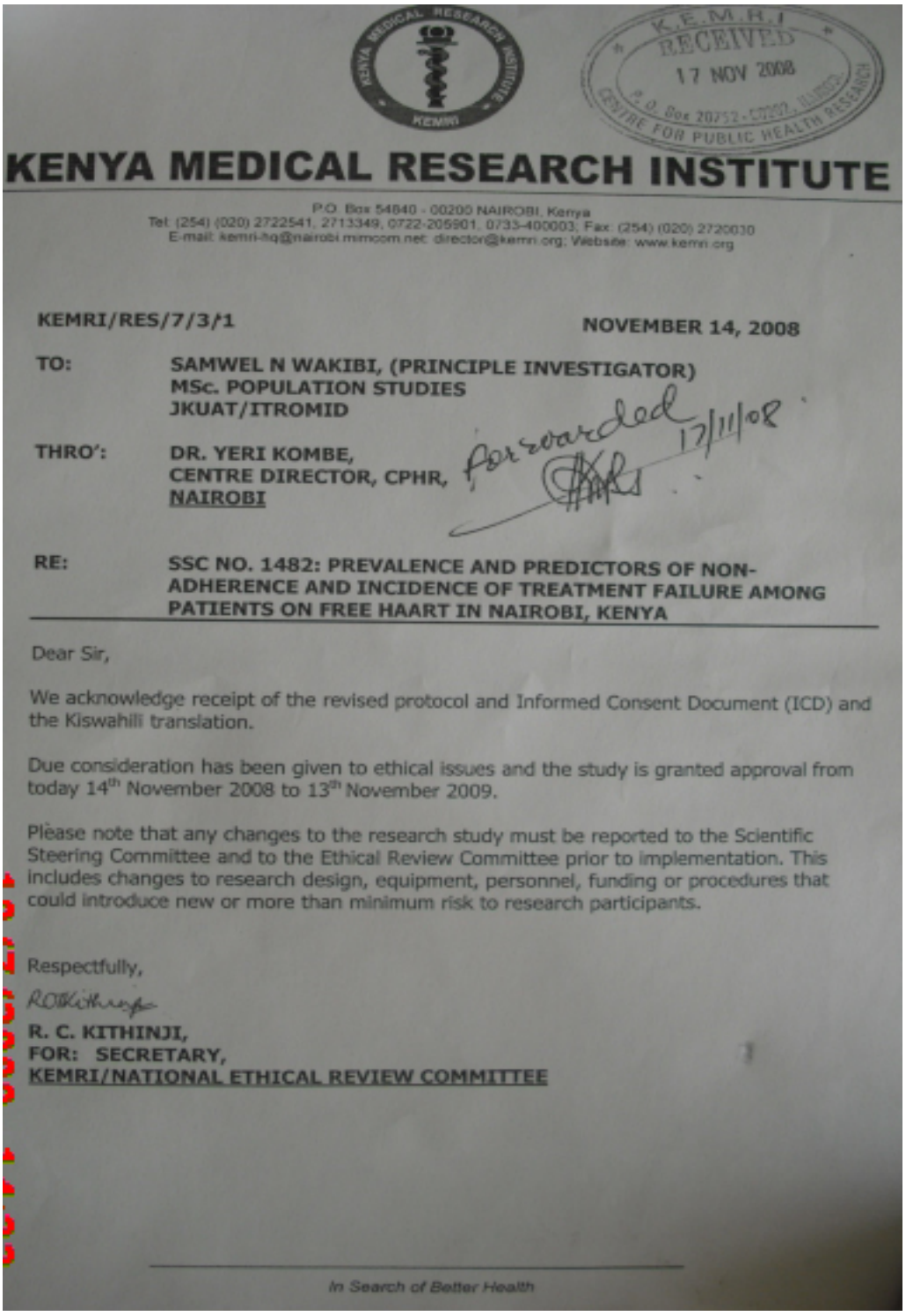
Sahihi ya muhusika:……. au kiganja:……. Tarehe:…….

Sahihi ya mtafiti: ……. Tarehe…….

Mawasiliano

Ukiwa na jambo lolote kuhusu haki yako ya kushiriki, unaweza kuwasiliana na mtafiti mkuu: Samwel N. Wakibi, Student, ITROMID au mwenyekiti wa kamati ya maadili, KEMRI/NERC; Sanduku la barua 54840 00200 Nairobi, nabari za simu. 2722541, 0722205901, 0733400003.

Appendix 3 Ethical Approval



KENYA MEDICAL RESEARCH INSTITUTE

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Tel: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: kemri-hq@nairobi.mimcom.net; director@kemri.org; Website: www.kemri.org

K.E.M.R.I
RECEIVED
17 NOV 2008
P. O. Box 20752-00202, NAIROBI
CENTRE FOR PUBLIC HEALTH RESEARCH

KEMRI/RES/7/3/1 NOVEMBER 14, 2008

TO: SAMWEL N WAKIBI, (PRINCIPLE INVESTIGATOR)
MSc. POPULATION STUDIES
JKUAT/ITROMID

THRO': DR. YERI KOMBE,
CENTRE DIRECTOR, CPHR,
NAIROBI

Forwarded 17/11/08

RE: SSC NO. 1482: PREVALENCE AND PREDICTORS OF NON-ADHERENCE AND INCIDENCE OF TREATMENT FAILURE AMONG PATIENTS ON FREE HAART IN NAIROBI, KENYA

Dear Sir,

We acknowledge receipt of the revised protocol and Informed Consent Document (ICD) and the Kiswahili translation.

Due consideration has been given to ethical issues and the study is granted approval from today 14th November 2008 to 13th November 2009.

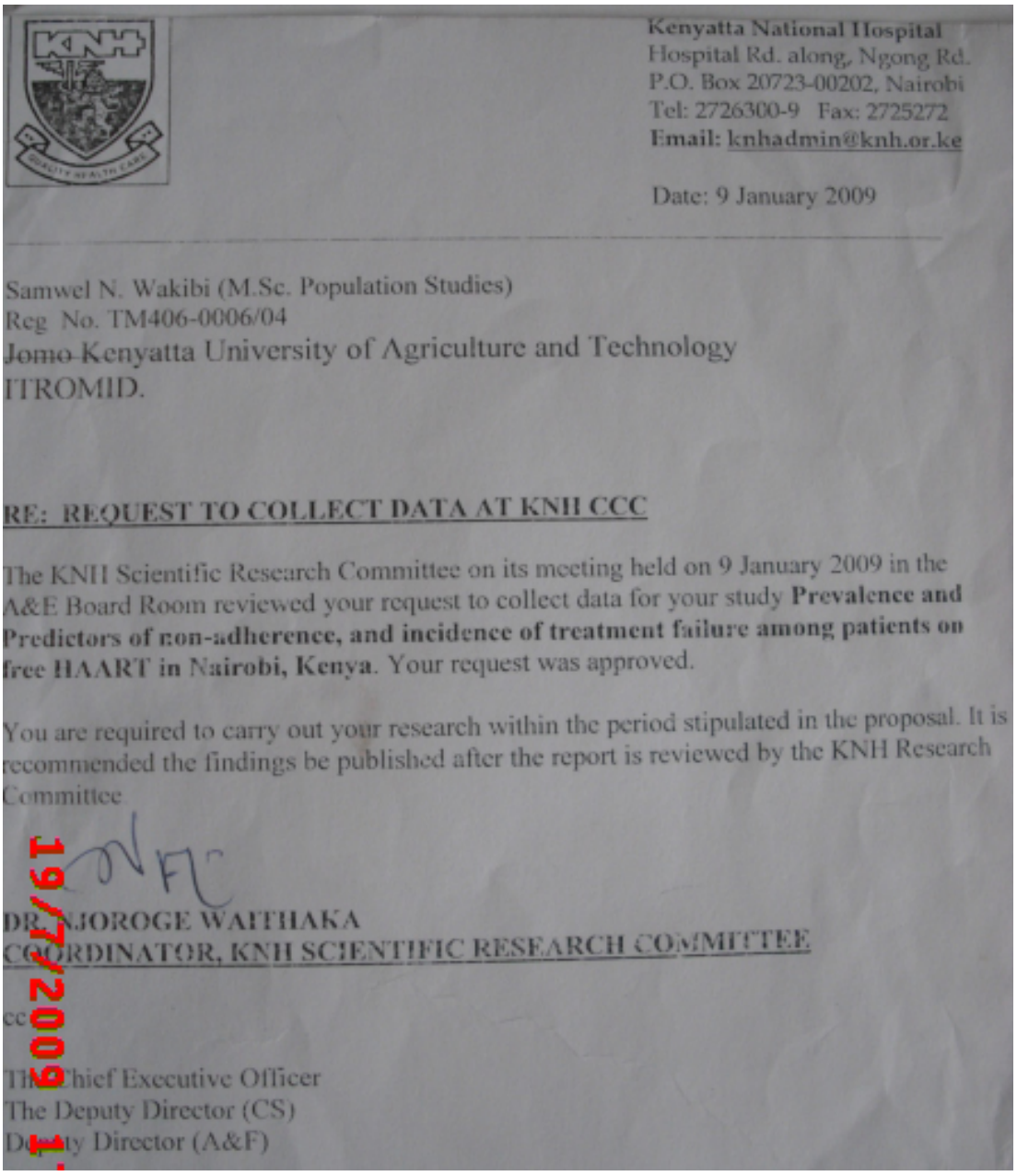
Please note that any changes to the research study must be reported to the Scientific Steering Committee and to the Ethical Review Committee prior to implementation. This includes changes to research design, equipment, personnel, funding or procedures that could introduce new or more than minimum risk to research participants.

Respectfully,

R.C. KITHINJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICAL REVIEW COMMITTEE

In Search of Better Health

Appendix 4 Approval to collect data



Kenyatta National Hospital
Hospital Rd. along, Ngong Rd.
P.O. Box 20723-00202, Nairobi
Tel: 2726300-9 Fax: 2725272
Email: knhadmin@knh.or.ke

Date: 9 January 2009

Samwel N. Wakibi (M.Sc. Population Studies)
Reg No. TM406-0006/04
Jomo Kenyatta University of Agriculture and Technology
ITROMID.

RE: REQUEST TO COLLECT DATA AT KNH CCC

The KNH Scientific Research Committee on its meeting held on 9 January 2009 in the A&E Board Room reviewed your request to collect data for your study **Prevalence and Predictors of non-adherence, and incidence of treatment failure among patients on free HAART in Nairobi, Kenya**. Your request was approved.

You are required to carry out your research within the period stipulated in the proposal. It is recommended the findings be published after the report is reviewed by the KNH Research Committee

DR. NJOROGE WAITHAKA
COORDINATOR, KNH SCIENTIFIC RESEARCH COMMITTEE

cc

The Chief Executive Officer
The Deputy Director (CS)
Deputy Director (A&F)

19/1/2009

Appendix 5 Questionnaire

English and Kiswahili

Prevalence and Predictors of non-adherence, and incidence of treatment failure among patients on free HAART in Nairobi, Kenya

Study Questionnaire

Patient data

Abstraction from patient file

1. Health facility Code: ……. Health facility Name: .....
2. Patient Number: .....
3. Interview date: day.....Month.....Year.....
4. Sex; Male [ ] Female [ ]
5. Last CD4 Count: .....cells/mm^3; Viral load: .....copies/ml; Date reviewed: day.....Month.....Year.....
6. Has treatment failure been reported in the last six months? [ ] Yes [ ]No
7. If yes, when? []This month []Last month []2months []3months []4months []5months []6 months

Face to face interview/ Mahojiano ya ana kwa ana

Personal and household information

8. What is your date of Birth? Day.... Month.....Year....; Age last birthday..... years

Tarehe yako ya kuzaliwa? Siku..... Mwezi..... .Mwaka.....; Miaka yako ya kuzaliwa ulioadhimisha majuzi.....

9. What is your marital status? [] single [] married [] divorced/separated

[] widowed

Hali yako ya kijamii []sijao/sijaolewa [] nimeoa/nimeolewa

[] nimetalaki/nimetalakiwa []Mjane

10. Where do you live? [] Nairobi (Estate/Village) .....;

[] Others (district/Town/Estate/village) .....; distance to this CCC .....km

Unaishi wapi? [] Nairobi (mtaa/kijiji) .....*;[]Kuingineko (Wilaya/town/mtaa/kijiji)* .....*; ubali* ..... *kilomita*

11. How big is the house? []1 room []2 -3 rooms []1 bedroom []2 bedrooms []3+bedroom

Ukubwa wa nyumba unayoishi ni? []Chumba 1 []vyumba 2-3 []chumba cha kulala kimoja [ ] vyumba viwili vya kulala [ ] vyumba vitatu na zaidi vya kulala

12. How much rent do you pay for your house per month? [] I don't, its my/our house [] I do not known []Kshs. .....

Kodi ya nyumba ni pesa Ngapi kwa mwezi? [] silipi, nyumba ni yangu/yetu []sijui []Shiling……

13. Whom do you live with? []alone []family []friend(s)

Unaishi na nani? []peke yangu [] familia/jamii []rafiki/marafiki

14. Do you live with your children? [] I have no children []No []Yes

Unaishi na watoto wako? []Sina watoto []La []Ndiyo

15. How much fare do you pay from your house to this health facility **and back** (in Kshs.)? [] I walk []<=40 []50 to <70 []70 to 100 [] 100+

*Nauri ya gari ni pesa ngapi kutoka kwako hadi hapa **na kurudi** (Shiling)? [] nina tembea []<=40 []50 hadi <70 []70 hadi 100 [] 100 au zaidi*

16. Is bus fare always available? [ ] Yes [ ]No [ ] I do not pay

Nauli hupatikana wakati wote? [ ] Ndiyo [ ]La [ ]Silipi

17. How much do you earn per month? [ ] unemployed [ ] <5000 [ ] 5001 – 10000 [ ] 10001 – 15,000 [ ] 15,001 – 20, 000 [ ] 20,001 – 50,000 [ ] 50,000+

Mushahara wako ni pesa ngapi kwa mwezi? []Sijaajiriwa [ ]<5000 [ ]5001–10000 [ ]10,001–15,000 [ ] 15,001 – 20, 000 [ ] 20,001 – 50,000 [ ] 50,000+

18. In average how much do you spend on food? [ ]Daily__(Kshs); []Weekly__(Kshs) [ ]I get it from the farm

Kwa kawaida, unatumia pesa ngapi kununulia chakula? [] Kwa siku..... (Kshs); [] Kwa wiki..... (Kshs) []si nunui, ninatoa kwa shamba

19. What is your level of education? []None []Primary []Secondary []Post secondary

Umesoma hadi kiwango gani? [] sijasoma [] msingi []upili [] chuo cha juu

Health condition

20. Do people you live/work with know of your HIV status? [ ] yes [ ] No

Watu unaoishi au kufanya kazi nao, wanajua hali yako ya ugonjwa? [] Ndiyo [] La

21. When did you start medication in this clinic? []less than 3 months []3 to 6 months []6 to 12 months [] 1 to 2 years [] 3 years +

*Ulianza kupewa dawa **hapa** lini? []chini ya miezi 3 iliyopita [] miezi 3 hadi 6*

[]miezi 6 hadi 12 [] Mwaka 1 hadi 2 [] miaka mitatu na zaidi

22. Had you ever taken HIV medication before coming to this clinic? [ ] yes [] No; goto 26

*Uliwahi kutumia daya za HIV kabla ya kuanza matibabu **hapa**? []Ndiyo []La ; swali la 26*

23. Where (provider)? [] Another CCC [] other health care facilities [] Self medication/from friends [ ] herbalist [ ] others: specify …….

Ulizipata dawa wapi? []Clinic nyingine ya (CCC) [] Zahanati/hospitali [] nilinunua mwenyewe au nilipewa na rafiki [] tabibu wa kienyeji [] wengine: elezea ……..

24. Did you have a break from medication before coming to this clinic? [] yes [] No ; goto 26

Uliwahi kuacha kunywa dawa kwa muda kabla ya kuja clinic hii? []Ndiyo []La; swali la 26

25. How long was the break? []one day []one week []one month []up to six months [] >6months

Kama ndiyo, uliacha kunywa dawa kwa muda gani? []siku moja [] siku 1 hadi wiki 1 []wiki 2 hadi mwezi 1 [] miezi 2 hadi 6 [] zaidi ya miezi 6

26. Why did you choose this clinic? .....

Kwanini ulichagua clinic hii? ……..

27. Were you offered ART education here? [] Yes [] No

Ulipewa masomo ya matibabu hapa kabla ya kuanza kutumia madawa? []Ndiyo []La

28. Name 3 things you can remember from the education [] Cannot remember

[1]…… [2]…… [3]……

Taja mambo matatu unayokumbuka kutoka kwa masomo haya [] sikumbuki

[1]…… [2]…… [3]……

29. When you look back, did the health personnel here adequately explain to you the need for treatment compliance before putting you on therapy? [ ] Yes [] No

Ukiangalia nyuma, wauguzi hapa walikuelezea kikamilifu umuhimu wa kuzingatia matibabu kabla ya kukuanzishia madawa? [] Ndiyo []La

Health care system

30. Are drugs always available each time you visit this facility to refill? []Yes []No

Madawa huwepo wakati wote unapotembelea clinic hii? [] Ndiyo []La

31. How long do you usually take at the facility every time you come to refill? [ ]< 2 hours [] 3 to 4 hours [] whole morning [] whole day

Unapotembelea clinic hii, hukuchukua muda gani kumaliza kuhudumiwa? []hadi masaa 2 [] kati ya masaa 3 na 4 [] asubuhi nzima [] siku nzima

32. Today, how long did you wait before being attended to? ..... (hours)

Leo imekuchukua muda gani kabla ya kumuona muuguzi? ……masaa)

33. Waiting time at the facility is... [] acceptable [ ] too long

Muda unaongoje kabla ya kupata matibabu. [] unakubalik []ni mrefu sana

34. Do you find the health personnel friendly and understanding? []Yes [] No

Kwa maoni yako, wauguzi hapa ni wachangamful kwa wagonjwa na wenye kuelewa? [] Ndiyo [] La

35. What would you like improved? …….

Ni mabadiliko gani ungetaka kuyaona ili kuimalisha huduma hapa? ……

Treatment (Knowledge) Matitabu

Now I'm going to ask some questions about your HIV medications

Sasa nitakuuliza maswali juu ya madawa ya ukimwi unayotumia.

36. Which antiretroviral medications have you been prescribed to take within the last 30 days? Name/identify them (show boxes/wrappers)

Taja madawa ambayo umekuwa ukiyatumia kwa muda wa siku 30 zilizopita?

DRUG A: **DRUG C:**

DRUG B: **DRUG D:**

37. How many tablets of each drug do you take every time?

Ni tembe ngapi za kila dawa unazomeza kwa wakati mmoja?

DRUG A: **DRUG C:**

DRUG B: **DRUG D:**

38. What are dietary restrictions for?

Taja mahitaji ya chakula unapokuwa ukitumia dawa?

DRUG A: **DRUG C:**

DRUG B: **DRUG D:**

39. What are the drugs possible adverse/side effects? []Nausea []vomiting

[]diarrhea []Neuropathy

Madhara kutokana na matumizi ya madawa haya ni yapi? []kusikia kutapika []kutapika []kuhara []kufa ganzi

40. How long are you to take the HIV therapy? [] for ever [] Do not know [] Others; specify: ……

Unahitajika kutumia madawa ya ukimwi kwa muda gani? [] maisha yote [] sijui [] jibu lingine, elezea……..

Beliefs about medicine/*Musimamo kuhusu madawa*

Necessity of HIV medication/*Umuhimu wa dawa za ukimwi*

41. My health, at present, depends on my medicines. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Hali yangu ya afya inategemea haya madawa. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

42. My life would be impossible without my medicines. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Maisha yangu yangekuwa magumu bila haya madawa. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

43. Without my medicines I would become very ill. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Bila madawa, inatukwa mgonjwa sana. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

44. My health in the future will depend on my medicines. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Hali yangu ya afya wakati ujao itategemea madawa haya. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

45. My medicines protect me from becoming worse. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Madawa haya husaidia afia yangu kutozorota. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

Concerns about HIV medication/*wasiwasi kuhusu madawa*

46. Having to take this medicine worries me. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Kutumia madawa haya Kunaniogofisha.[1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

47. I sometimes worry about the long-term effects of my medicines. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Wakati muingine ninahofia madhara ya utumiaji wa madawa haya kwa muda mrefu.

[1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

48. I have no good understanding of how my HIV medicine is to improve this illness. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Sielewi vizuri jinsi madawa haya yanavywo tibu ugonjwa huu. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

49. My medicines disrupt my life. [1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Madawa haya yanahitilafitiana na maisha yangu ya kawaida. [1] sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

50. I am uncomfortable or embarrassed if others knew I am taking HIV medicines.[1]strongly disagree [2]disagree [3]Not sure/neutral [4]Agree [5]strongly agree

Sijiiskii sawa watu wengine kujua ninatumia madawa ya ukimwi. [1]sikubaliani kamwe [2]sikubaliani [3]Sina uhakika [4]Ninakubaliana [5]Ninakubaliana sana

Adherence/*Kutumia kulingana na maagizo*

Many people find it hard to always remember to take their pills or medicines. For example:

Some people get busy and forget to carry their pills with them.

Some people find it hard to take their pills according to all the instructions, such as "with food" or "on an empty stomach," "every 8 hours," or "with plenty of fluids."

Some people decide to skip taking pills to avoid adverse effects or to just not take pills that day.

Some people feel better and stop taking medications

Kwa watu wengi, huwa ni vigumu kukumbuka kutumia madawa; kwa mfano:

Wengine huwa na shughuli nyingi kiasi kusahao kubeba madawa

Wengine huwa na ugumu kutumia kulingana na maagizo kama vile na chakula au na njaa, kila baada ya masaa 8 au na vinywaji

Wengine huamua kuhailisha kwa kuhofia madhala au kutojisikia kutumia madawa tu

Wengine hujisikia nafuu na kuwacha kutumia madawa

51. For you, how often do you feel that you have difficulty taking your HIV medications on time? By “on time” we mean no more than 2 hours before or 2 hours after the time your doctor told you to take it.

    [1]All the time [2]Most of the time [3]Rarely [4]Never

Wewe, mara ngapi hujisikia mwenye ugumu wa kumeza madawa haya?

[1]*Kila wakati* *[2]Mara nyingi* *[3]Mara chache* *[4]Huwa sisikii ugumu*

52. When are you most likely to miss doses? [1] Morning [2] Lunch [3]Evening [4]Others; specify…….

Ni lini huenda ukakosa kumeza dawa? [1] Asubuhi [2]Saa ya lunch [3]jioni [4]mengine; elezea …….

53. On average, how many days PER WEEK would you say that you missed at least one dose of your HIV medications?

[1]Every day [2]4 to 6 days [3]2 or 3 days [4] Once a week

[5]Less than once a week [6] Never

Kwa kawaida, ni mara ngapi kwa WIKI/JUMA unaweza kusema huwa unakosa kunywa dawa hata mara moja

[1]Kila siku [2]Siku 4 hadi 6 kwa wiki [3] Siku 2 au 3 kwa wiki

[4]Mara moja kwa wiki [5]Chini ya mara moja kwa wiki [6]sijawahi

54. When was the last time you missed at least one dose of your HIV medications?

[1]Within the past week [2]1 to 2 weeks ago [3]3 to 4 weeks ago

[4]Between 1 and 3 months ago [5]More than 3 months ago [6]Never

Ni lini ulikosa kunywa dawa hata mara moja?

[1]Wiki hii [2]Wiki moja au mbili zilizopita [3]Wiki 3 hadi 4 zilizopita

[4]Mwezi 1 hadi 3 iliyopita [5]Zaidi ya miezi mitatu [6]Sijawahi

Reasons for non-adherence/sababu za kutozingatia matibabu

55. In the overall, what percentage of your medications do you think you take?

[]<50% [] 50-60% []60-70% []70-80% []80-90% []90-95% [] >95%

Kwa jumla, unafikiria ni asilimia gapi ya dawa unatumia? [ ]<50%

[] 50-60% []60-70% []70-80% [ ]80-90% [ ]90-95% [ ] >95%

56. What reasons do you have for not taking medications 100%?

Una sababu gani za kutozingatia matibabu kama ulivyo agiziwa kwa asilimia mia moja (100%)?

1. Side effects; *Kuhofia madhala yanayotokana na matumizi*
2. Health has improved; *Hali ya afya kuimalika/kujisikia nafuu*
3. No improvement; *Kutopata nafuu*
4. Being busy and forget;*Shughuli nyingi kiasi cha kusahau*
5. Hiding from colleagues/family;*Kujificha wenzangu au jamii yangu*
6. I believe amount of medicine I take is enough treatment/ *Nina amini kiasi cha dawa ninachotumia kinatosha kutibu*
7. Others; specify……;*Sababu zingine; elezea ……*

57. What do you believe adherence rates needed to be for one to benefit from medication? []<=50% [ ]51-75% [ ]75-90% [ ]90-95% [ ] >95%

Una amini inahitajika kuzingatia asilimia ngapi ya utumiaji wa dawa ili kufaidika kikamilifu? []<=50% [ ]51-75% [ ]75-90% [ ]90-95% [ ] >95%

58. What are the consequences of not taking medications as prescribe by the doctor? []Nothing []treatment failure [] do not know

Matokeo yakutozingatia utumiaji wa madawa kama ilivyo agizwa ni yapi? []Hakuna []ukosefu wa tiba [] sijui

59. Do you feel out of control managing your treatment/regimen? [] yes/always []sometime [] No, am always in control

Huwa unajisikia kushindwa kudhibiti/kuhimili matibabu? []Ndiyo/kila wakati []wakati mwingine []La, huwa ninadhibiti vikamilifu

Social support/Usaidizi wa kijamii

60. Who helps you remember to take your medication? [ ] no one [] family [] coworkers [] friends

Ni nani hukukumbusha kunywa dawa? [] hakuna [] familia [] Tunaofanya kazi nao [] marafiki

61. I feel satisfied with the overall support I get from my friends and family; []never []rarely []sometimes []often []always.

Unaweza kusema kuwa unajisikia kutosheka na usaidizi unaopata kutoka kwa marafiki na jamii? [] la, hasha [] wakati mwingine []mara kwa mara []mara nyingi []wakati wote.

PREVALENCE AND PREDICTORS OF NON-ADHERENCE, AND INCIDENCE OF TREATMENT FAILURE AMONG PATIENTS ON FREE HIGHLY ACTIVE ANTIRETROVIRAL THERAPY IN NAIROBI, KENYA

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