

**ANTIRETROVIRAL TREATMENT ADHERENCE AMONG
ADOLESCENTS AT KENYATTA NATIONAL HOSPITAL.**

A DISSERTATION SUBMITTED TO THE SCHOOL OF MEDICINE,
DEPARTMENT OF COMMUNITY HEALTH IN PARTIAL FULFILLMENT
FOR THE AWARD OF A MASTERS DEGREE IN PUBLIC HEALTH (MPH)
OF THE UNIVERSITY OF NAIROBI.

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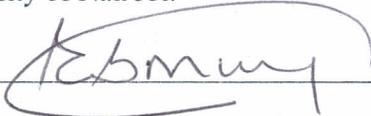
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DEDICATION

This dissertation is dedicated to my family for their constant support during its compilation and especially to my children Eunice, Jasmine and Jason who have sacrificed a lot of family time for me to complete this work. It is also dedicated to Nancy who selflessly and generously gave her time to take care of my children so that I can do this work peacefully.

ACKNOWLEDGEMENT

I would like to acknowledge the following people and institutions for their contribution towards the completion of this dissertation and without whose help this work would not have been possible.

My supervisors Prof Muchunga, Prof Ngugi and Dr Wamalwa who reviewed and gave suggestions from the proposal stage to completion. Their input and time are invaluable gifts that I will always feel very much indebted. I would also like to thank my mentors Dr Kiarie and Dr Farquhar who read different drafts of the proposal and also contributed greatly to my research training through the Fogarty program.

I would like to express my gratitude to those who assisted me with data collection including Agnes Kariuki and Mrs Muriuki and all the others who helped recruit participants. Kibidi and Nelima who conducted, recorded and transcribed data from the focus group discussions. Angela and Mary for data entry, friendship and encouragement throughout the process. The biostatisticians Frankline and Francis who helped me analyze the data.

To all those who read and gave comments on different parts of the proposal and dissertation including Mr Nyabola, Mr N'toburi, Dr Irene Inwani, Dr Rose Bosire and many others that I may not name here, I am forever grateful. Many thanks to my friends Freda and Diana who were a constant source of encouragement and to Rose Opiyo (former course coordinator) who kept calling to find out how I was progressing.

I am grateful to KNH and all the CCC staff who were very helpful and greatly assisted me during the data collection period. I am also grateful to the Department of Community Health for the learning opportunity and all the assistance I got during this period.

I would also like to acknowledge Fogarty International Clinical Research Scholars Programme (FICRS) and the National Institute of Health (NIH) who funded the study.

My sincere appreciation to the study participants for their time and contribution- the wonderful adolescents who so graciously shared their life stories with me and their parents/guardians who allowed me to talk to them.

Special thanks to my mom for her love, encouragement and for always believing in me, and to my brothers who kept nudging me to complete my MPH.

Last but not least, I would like to acknowledge the almighty God, without his grace and providence none of this would have been possible.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral drugs
ART	Antiretroviral therapy
CCC	Comprehensive Care Centre
DNA	Deoxyribonucleic Acid
FGD	Focus Group Discussion
FHI	Family Health International
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immune deficiency Virus
KAIS	Kenya AIDS Indicator Survey
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
MEMS	Medication Event Monitoring System
MOH	Ministry of Health
NACC	National Aids Control Council
NASCOP	National AIDS and STI Control Programme
NNRTIs	Non-Nucleoside reverse transcriptase inhibitors

NRTIs	Nucleoside reverse transcriptase inhibitors
PASW	Predictive Analytics SoftWare
PI	Protease Inhibitors
RNA	Ribonucleic Acid
SPSS	Statistical Package for the Social Sciences
STI	Sexually Transmitted Infections
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
VCT	Voluntary Counseling and Testing

DEFINITION OF OPERATIONAL TERMS

- ADOLESCENT:** Anyone between the age of 10-19 years.
- ADHERENCE:** Ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other medications.
- DISCLOSURE:** Revealing to an adolescent that he/she is HIV infected.
- GOOD ADHERENCE:** Taking a proportion of 95% or more of prescribed medication doses.
- POOR ADHERENCE:** Taking a proportion of less than 95% of prescribed medication doses.
- GOOD APPOINTMENT KEEPING:** Reporting to the health facility within one week of the scheduled visit.
- ARV/HAART:** Antiretroviral medicines used in combination for treatment of HIV infection.
- CD4 CELLS:** T helper lymphocytes with CD4 receptors that play a critical role in the function of the immune system to fight off infections.
- NON-ADHERENCE:** Not taking the medication at all, taking in reduced amounts, not taking at prescribed intervals or not following required food, fluid and alcohol restrictions.
- NEUROCOGNITIVE:** Having to do with the ability to think and reason, including the ability to concentrate, remember things, process information, learn, speak, and understand.
- EMANCIPATED ADOLESCENT:** Adolescent head of household, adolescent mothers, early marriage.
- VIRAL LOAD:** Levels of virus found in the blood of a HIV infected person.
- YOUTH :** Those aged between 15-24 years.

Results

The study surveyed 158 adolescents and held three FGDs. Majority, 143 (90.5%) were on first line treatment (two NRTIs and one NNRTI). The mean duration of treatment was 33 months (IQR 22-47). Overall, 148 (93.7%) of the adolescents had good self-reported adherence of more than 95%. Of the adolescents surveyed, 153 (96.8%) kept their scheduled clinic appointment and 151 (95.6%) refilled their drugs on time. Of the 24 adolescents who reported missing doses, forgetting to take medication 10 (41.7%), being away from home 6 (25%) and school schedule 4 (16.7%) were identified as the commonest reasons for not taking medication. In both the quantitative and qualitative methods, stigma and lack of social support were identified as significant barriers to adherence in adolescents. Extensive adherence counseling before treatment initiation as well as during treatment, peer counseling and support groups were important promoters of adherence.

Conclusion

Overall there was good adherence in adolescents in KNH hospital with 93.7% of all the adolescents reporting $\geq 95\%$ adherence. This illustrates that it is possible for adolescents in our setting to achieve and maintain optimal adherence levels. Common reasons for non adherence such as *forgetting and conflicting schedule can be addressed by reminder devices* and tailoring treatment to fit the adolescents' lifestyle. Adherence will be enhanced by addressing stigma, adherence counseling, peer counseling and support groups.

CHAPTER 1: INTRODUCTION/BACKGROUND

The global HIV/AIDS epidemic is one of the biggest challenges facing individuals, families, households, societies and nations today. It is a serious public health and economic problem affecting all nations.

Worldwide, UNAIDS estimates that about 33 million (30-36 million) people were living with HIV/AIDS in the year 2007 (1). Sub-Saharan Africa is the worst hit region with 67% of all HIV positive people living in this region (1). Adolescents and youth are currently the centre of new infections and UNAIDS estimates that as many as 45% of new infections worldwide occur in those between the ages of 15 and 24 (1). In addition, more children perinatally infected with HIV are surviving to adolescence due to improved treatment with increased availability of HAART (2)(3)(4).

Good adherence is *important in treatment of all illnesses and more so in chronic diseases* such as HIV/AIDS. However, being perfectly adherent is a challenge for all patients. In HIV, adherence poses a big challenge to both the patient and service provider. The fact that HAART does not cure HIV, is taken lifelong, has a high pill burden, side effects and food and fluid restrictions all contribute to low morale for adhering to treatment.

Studies have shown that very high levels of adherence to HAART, 95% and above are necessary to avoid treatment failure and emergence of resistant strains (5) (6). The need to maintain nearly perfect adherence indefinitely to achieve successful antiretroviral treatment is *a major challenge in the management of HIV/AIDS. In adolescence the challenge is even greater given the fact that this is a time of difficult emotional, neurocognitive and physical* developmental changes which are superimposed upon coping with a life threatening illness. The need to develop more strategies for improving adherence in this age group is therefore very important.

The focus of this study was to identify levels of adherence to antiretroviral treatment and factors that promote or hinder adherence in adolescents.

CHAPTER 2: LITERATURE REVIEW

2.1: ADOLESCENTS AND HIV IN KENYA

Adolescents in Kenya form a large part of the population constituting approximately 26% of the whole population (7) (8). Like in other regions, over 50% of new infections in Kenya occur among the youth (9). In the year 2007, HIV prevalence among adolescents aged 15-19 years was estimated to be 2.3% (10). Adolescent HIV infection in Kenya is growing due to various factors including early sexual debut, having multiple sexual partners, inability to make decisions regarding sex, sexual violence, not using preventive methods and most adolescents not knowing their HIV status.

In 2007, 20% of girls and 22.4% of boys have had sex at least once by the age of 15 years and by 18 years, 53.7% of girls and 56.4% of boys reported having had sex (10). This was a significantly higher percent of adolescents reporting having had their sexual debut before 15 years as compared to the 2003 KDHS. Adolescents who reported having had sex before 15 years of age were also significantly less likely to have used condoms at first sexual encounter as compared to those who reported sexual debut at an older age. Similarly, condom use among youth 15-24 years was low with only 25.5% females and 28.4% males using a condom at their first sexual encounter (10). *This early sexual encounter and more risky behavior increases the chances of adolescents contracting HIV.*

With respect to sexual violence, 10% of adolescents report having experienced sexual violence with 20% girls forced into their first sexual encounter. Reports indicate that 4% of HIV infections in adolescents 13-19 years in Nairobi are due to rape (11). In a study done in Kibera, 43% of girls experienced coerced or forced first sex, including their partner not taking 'no' for an answer, threats, money/gifts, or physical force. Coerced girls experienced sexual relations at significantly younger ages and with significantly older partners, compared to girls for whom sex was consensual (12).

Regarding testing, many adolescents in Kenya do not know their HIV status. Among *adolescents who had ever had sex*, only 45.8% of girls and 15.1% of boys had ever been tested for HIV (10). In the Kibera study 29 percent of girls and 14 percent of boys report having undergone VCT (12).

2.2: ADHERENCE

Adherence is important in the *treatment of HIV* as it determines success or failure and the resultant morbidity and mortality related to HIV/AIDS. High levels of adherence to HIV treatment are necessary for effective treatment and brief episodes of missed medication doses can permanently undermine HIV treatment, leading to reduced efficacy of and increased resistance to medications (13). While 80% adherence may be sufficient for most illnesses, adherence level of 95% and above, is crucial for HIV/AIDS management (5) (6). Patients with this level of adherence have a superior virologic outcome, a greater increase in CD4 lymphocyte count, and a lower hospitalization rate compared to less adherent patients (6). In one study, it was found that 22% of patients with more than 95% adherence, 61% with 80-94.9% adherence and 80% with less than 80% adherence demonstrated virologic failure (6).

Development of drug resistance poses a great challenge in the treatment of HIV as there are few treatment options and once these are exhausted there is no way to halt the disease progression. Drug-resistant strains of HIV selected through ongoing replication in the presence of ARV also can be transmitted to uninfected or drug-naïve patients, leaving them with fewer treatment options (14)(15). Among newly HIV-infected patients in North America, approximately 12.5% had phenotypic resistance and 20% had genotypic resistance to 1 or more antiretroviral drugs. At a public hospital in San Francisco, very high rates of drug resistance were found in recently infected individuals and in a consecutive case series of 225 untreated patients with recent HIV infection identified between 1996 and 2001, had genotypic resistance to 1 or more antiretroviral drugs ranging from 25% to 27.4%. In another study in Europe and Israel that evaluated more than 1,600 recently infected individuals, it was found that 9.6% of them had genotypic resistance to 1 or more antiretroviral medication (16). Though there are other factors that determine ARV failure or success including genetic differences in drug metabolism, severe baseline immune suppression, prior drug resistance, concurrent opportunistic infections, low potency of the antiviral regimen, drug-drug interactions and inadequate drug exposure, adherence to ARV is one of few potentially alterable factors determining outcomes for patients with HIV (6). Antiretroviral adherence is the second strongest predictor of progression to AIDS and death, after CD4 count (17).

Poor adherence to ARVs is common in all groups of treated individuals with a reported average rate of adherence to ARV being approximately 70%, despite the fact that long-term

viral suppression requires near-perfect adherence (17). Studies done in various settings have shown that adherence is a problem. For example in a study to assess adherence to protease inhibitors reported a mean adherence of 89% by self report, 73% by pill count and 67% by electronic medication monitor (MEMS) (18). In Kenya, a study done in western Kenya reported a mean adherence rate of 79% with only 60% patients achieving the optimal 95% or more adherence (19).

2.3: ADOLESCENTS AND ADHERENCE

Studies suggest that non-adherent behaviour is a problem in the adolescent period and in most chronic diseases such as diabetes, cystic fibrosis, liver and renal transplant recipients, adherence has been less than optimal (20) (21).

Adolescents face unique challenges to taking HIV medication properly. Coping with a life threatening illness during adolescence, a difficult period in life can be challenging. This is the period they begin to demand independence and often appear to be rebellious towards adults and traditions. During this period, adolescents are trying to establish their identity and autonomy separately from their parents and this may affect decisions regarding their treatment. They also have limited ability to anticipate abstractly the long term consequences of their immediate actions and this may negatively impact on their adherence.

Transition from paediatric care to adult care poses a challenge with regard to the appropriate timing and readiness for transition. Studies have suggested that the transition period is a vulnerable one with one study on liver transplant patients showing that medication adherence decreased significantly after transition (22). Being in school is likely to affect adherence as adolescents may have to face stigma and discrimination from peers, they may not get time to attend clinic visits and the school schedule may interfere with time to take medications. The United Nations Human Rights Committee on the Rights of the Child notes that children with HIV/AIDS are also heavily discriminated against in both formal and non-formal education.

The age at which an adolescent assumes the responsibility for their own treatment also affects their adherence. This is demonstrated by a study done to assess association of ART adherence to child and caregiver demographic characteristics. This study recommended that caregivers should avoid assigning treatment responsibility to a child prematurely (23). This

was consistent with the finding that children's responsibility for medication increased with age according to both children and caregivers but knowledge did not. This implies that consultation with a psychologist regarding the child's cognitive capacity can help tailor information given and responsibility allocated to a developmentally appropriate level rather than age (23).

Many adolescents living with HIV are also orphaned with the Ministry of Medical Services reporting a total of 2.4 million AIDS orphans in Kenya by 2006 (24). Many of these orphans have to deal with issues of poverty and being heads of household and this can greatly impact on their ability to adhere not only to medications but to clinic visits as well. Poverty also affects their food supply and it is well known that nutrition is an important factor in HIV treatment as some of these medications should not be taken on an empty stomach.

Perinatally infected children learn of the nature of their illness at around the adolescence age. Disclosure in adults has been associated with improved social support, greater self-esteem, and lower levels of depression. This improved social support resulting from disclosure in turn had positive effects on psychological well-being (25). Participants who report having disclosed their serostatus to others have demonstrated higher rates of adherence to ART (26). Other studies have shown that HIV disclosure and adherence can shape one another in different ways in such settings as work places, prisons and drug rehabilitation centres where some people try to hide medications or modify dosing schedules, which can contribute to non-adherence, and affect sexual behaviours. Disclosure of HIV and/or HAART may also result in antagonism from others who hold negative attitudes and beliefs about HAART, potentially impeding adherence. Alternatively, HIV disclosure can lead to support that facilitates initiation of, and adherence to treatment (27). In an unpublished study done at KNH on effect of disclosure to children and adolescents, some caretakers reported more improved and voluntary medication taking after disclosure to their child.

In a study done in adolescents and young adults in the United States of America, only 61% of the subjects had good adherence defined in this study as a self-report of more than 90% adherence to medication in the previous 90 days (28). Factors found to be associated with adherence were 'too many pills' which was associated with poor adherence; patients' belief that treatment improved their quality of life and prolonged life which were associated with

good adherence. Although disclosure was not shown to affect adherence, it was postulated that disclosure and social support may influence adolescent taking their medication.

Factors related to stigma and disclosures have been found to affect adherence in adolescents (29). In a cross sectional study of 170 children aged 2-18 years done at Mulago hospital Kampala, 89.4% had 95% or more adherence by self report, 94.1% by clinic based pill count and only 72% by home-based unannounced pill counts. Factors found to be associated with adherence included the number of people who knew the child's serostatus with disclosing the child's HIV serostatus only to the primary caregiver being associated with poor adherence. Those with a history of being hospitalized twice or more before starting HAART had a higher adherence of more than 95% as compared to those hospitalized only once or not at all (30).

In yet another study done to assess adherence and related factors in a cohort of African children in Abidjan, 33% reported less than full adherence in the month prior to the study. Forgetting to take medication accounted for 40% of non-adherence, drug stock exhaustion at central level 48.7%, refusal by child 8.1% and delays to refill prescription 2.7%. Being 13 years or older at the time of study was associated with less than full adherence. Receiving the drug efavirenz was also associated with less than full adherence even though this drug is easy to take and is usually prescribed to children known to be non-adherent in order to reduce the pill burden per day. In children receiving efavirenz, the main reasons for reporting non-full adherence were forgetting to take the treatment (47.3%) and shortage of drugs (42.1%) (31).

2.4: MEASURING AND EVALUATING ADHERENCE

No consistent effective monitoring method has been developed meaning there is no 'gold standard' or benchmark that exists by which adherence can be measured (32). In the past, different methods have been used to determine adherence including *biological markers, self-report, pill count, pharmacy refill* and *electronic medication monitor*. Each of these methods has its own strengths and limitations (16). *Viral load* is the most frequently used biological marker although it is an indirect measure of adherence. It is however not conclusive of adherent behaviour since other factors can affect viral load levels. Pill count is usually done at each visit or some other impromptu counts to assess number of pills remaining and compare with what is expected. This method does not ensure that pills were actually taken or when they were taken but it has been shown to correlate with viral load in several studies.

Monitoring prescription refill to ascertain if refilled at expected times is another method that has been used though it does not ensure the pills were actually taken or taken at the right time. Electronic medication monitor (MEMS cap) uses a computerized pill bottle lid which counts the number of times the lid is opened. This neither guarantees that pills were taken out, were swallowed or taken at the right time (16).

Self-report is the most commonly used method in clinical setting where the patient reports on the number of doses taken during a given period of time. This method is prone to recall bias and desire to please the provider. This usually leads to an overestimation of adherence. It is advantageous in that it is cheap, convenient and can be used to detect underlying causes of non-adherence (16).

2.5: FACTORS AFFECTING ADHERENCE AND NON-ADHERENCE

Various factors have been reported to influence adherence in different settings. Patient variables such as socio-demographic factors and psychosocial factors (16). Studies report conflicting evidence about the association between socio-demographic factors and adherence behaviour. Nonetheless, when an association is found, the direction is consistent: younger age, non-white race, lower income, lower literacy, and unstable housing are associated with non-adherence in resource-rich settings. Sex, insurance status, and HIV risk factors generally are not associated with adherence behaviour. Common predictors of non-adherence include depression/psychiatric morbidity, active drug or alcohol use, stressful life events, lack of social support, and the inability to correctly identify the drug regimen or describe the relationship between adherence and drug resistance (16). Depression and self-perceived social support have been found to predict regimen adherence in adults with HIV. In a study done in Addis Ababa, correlates of adherence included having regular follow-up, not being depressed, having no side effects, a regimen that fitted the daily routine and satisfaction with the relationship with doctors. In this study 81.2% of all patients reported having taken 95% or more of prescribed medication in the previous one week. Recommendations given to improve adherence were provision of regular follow-up for patients, management of depression, forewarning of side effects of HAART, and creating medication schedules appropriate to patients' daily routines (33). Patient belief in the effectiveness of treatment motivates them to adhere to treatment guidelines. Those who do not believe in the treatment or believe that the illness is a curse or an act of God are less adherent.

Disease characteristics including the stage and duration of HIV infection, associated opportunistic infections, and HIV-related symptoms have also been found to predict adherence to treatment. The very sick patients may not be able to take their medication as required while those who are well may see no reason to continue treatment. Some studies report improved adherence in those who have had opportunistic infections (34)(35).

Factors related to the treatment regimen including the number of pills prescribed, the complexity of the regimen (dosing frequency and food instructions), the specific type of antiretroviral drugs, and the short- and long-term medication side effects affect adherence with complex regimens involving taking medication many times, a high pill burden, many dietary restrictions and side effects resulting in poor adherence (16).

Another key issue in adherence is the patient-provider relationship with certain characteristics having been reported as affecting adherence. These include the patient's overall satisfaction and trust in the provider and clinic staff, the patient's opinion of the provider's competence, the provider's willingness to include the patient in the decision-making processes, the nature of the relationship (openness, cooperation, etc), the concordance of race between patient and provider, and the adequacy of referrals (16). A qualitative study done in five centres in Boston and Providence using focus groups of HIV-positive men and women reported improved adherence when a patient had a longstanding and trusting relationship with a single provider (36).

Effective communication is crucial for treatment success. Consistent relationship, empathy, trust and respect improves adherence. Provider's lack of time to adequately counsel and assess adherence results in poor adherence. Provider lack of knowledge and training to implement adherence strategies may lead to poor adherence (16).

Accessibility of the care centre is crucial for patients to be able to easily refill their treatment. This is especially so in developing countries where poverty and poor transport networks interfere with the patient's ability to access their care centre. Quality of service provided in a centre and the number of clients served influence how the patients take their medication (16).

CHAPTER 3: STATEMENT OF RESEARCH PROBLEM

3.1: RESEARCH PROBLEM

Adherence problems are common among adolescents with chronic illnesses and more so in HIV infected adolescents. Adherence to antiretroviral therapy is of critical importance to avoid development of viral resistance which leads to increased HIV related morbidity and mortality, reduced treatment options and transmission of resistant mutants to treatment naive patients.

As a result of the introduction of effective ART in children, many children perinatally infected with HIV have improved life expectancy and are currently living to adolescence and adulthood. According to a government report, there were 430,000 adults and 23,000 children in need of ARVs and only 181,458 were on ARVs by the year 2007 (24). The Kenyan government is scaling up provision of ARVs and therefore the number of adolescents on antiretroviral drugs is increasing. Being a challenging developmental stage when adolescents are experiencing physical, psychological, social and emotional changes, adolescents face unique challenges in taking their medications. The level of adherence and factors that influence adherence in adolescents in Kenya is not well documented.

3.2: JUSTIFICATION

Although adolescents are an important group in the treatment and control of HIV, research in this group is limited as most programmes focus on either children or adults. A report from Kenya noted that though much emphasis has been placed on treatment and care, there is not enough attention being paid to meeting the special needs of youth in this area (FHI).

Treatment programmes tailored for adolescents are lacking, and interventions found to be effective in either adults or children do not necessarily hold for adolescents. In recognizing that there are differences between adolescents and adults, the government through the MOH has established youth friendly services which aim at providing trained staff, conducive environment and flexible hours to the youth. These services mainly deal with reproductive health, provision of HIV information and preventive services and voluntary counseling and testing (VCT) but do not extend to treatment of HIV/AIDS.

Data on adherence levels and factors that promote or deter adherence in adolescents in Kenya is limited. This study therefore aims to fill this knowledge gap by establishing the pattern of adherence and exploring factors that influence adherence in adolescents. The findings of this study will be useful in designing interventions to promote adherence and making appropriate recommendations to policy makers as to who should be targeted for these interventions.

3.3: OBJECTIVES

3.3.1: MAIN OBJECTIVE:

To describe the adherence levels and the factors that influence adherence to HAART among adolescents on antiretroviral treatment in KNH.

3.3.2: SPECIFIC OBJECTIVES:

The specific objectives were:

- i. To describe adherence levels to HAART treatment among adolescents in KNH hospital;
- ii. To describe appointment keeping to scheduled visits among adolescents in KNH hospital;
- iii. To determine socio-demographic factors (age, sex, education, marital status, type of school/occupation) associated with adherence to HAART treatment;
- iv. To determine psychosocial factors including stigma, disclosure, counseling and substance use associated with adherence to HAART;
- v. To describe the relationship between knowledge and attitude regarding HAART treatment and adherence to HAART.

CHAPTER 4: METHODOLOGY

4.1: STUDY DESIGN

This was a cross-sectional study in which data on adherence to HAART and keeping of scheduled appointments and data on socio-demographic factors, psychosocial factors, knowledge and attitude from participating adolescents was collected. Both qualitative and quantitative methods of data collection were used in this study. Focus group discussions were used to collect qualitative data, while quantitative data were collected using a structured interviewer administered questionnaire and abstraction of clinical records. Data collection took place between March and June 2009 during which period 158 adolescents were interviewed and three focus group discussions held.

4.2: STUDY AREA

The study was carried out in KNH hospital which is the largest National referral, teaching and research hospital in Kenya. Kenyatta National Hospital Comprehensive Care Centre (CCC) is situated at the Rahimtulla Wing opposite KNH-Post Office. It was established in 2002 and currently has about 5000 clients.

The patients seen at the CCC are referred from the main hospital, other health institutions within Nairobi and even outside Nairobi. Patients who are not referred can also walk in and access treatment from the centre. It serves both adults and children and has its ground floor reserved for adults and first floor for children. Over 400 adolescents are currently registered at the CCC.

KNH being a national referral hospital was considered an appropriate location for this study because of the very diverse nature of its population drawn from all parts of the country.

4.3: STUDY POPULATION

The study population consisted of HIV-infected adolescents who were receiving HAART at the CCC.

4.4: SAMPLING AND RECRUITMENT PROCEDURE

The sampling frame included all the adolescents on follow up in KNH CCC. Adolescents aged 10-19 years were eligible to participate. Enrolment was done daily during the regular clinic hours, and consecutive subjects who met the inclusion criteria were enrolled until required sample size was obtained.

The regular clinic staff identified adolescents who were potential study participants. After the adolescent was seen in the clinic for regular follow-up, he/she was referred to the researcher/research assistant. The researcher/research assistant explained the study aims and procedures, assessed participant eligibility and invited the adolescent to participate. Those willing to participate were taken through the informed consent process. For adolescents who were accompanied, the parent/guardian signed the consent and the adolescent signed an assent form. The emancipated adolescents who were not accompanied signed their own consent. To ensure that one subject was not recruited twice, the subjects' hospital file number was noted on the questionnaire and the interviewer kept a list of the file numbers to countercheck with during the recruitment process. Enrollment was done daily during the regular clinic hours and consecutive subjects who met the inclusion criteria were enrolled until required sample size was attained.

4.5: ELIGIBILITY CRITERIA

Inclusion criteria:

Aged between 10 to 19 years.

On HAART for more than six months.

Attending KNH CCC.

Willing to give informed written assent and parents/guardians willing to give informed written consent.

Exclusion criteria:

Adolescents on HAART for less than six months.

Adolescents who declined to give informed consent/assent.

Those requiring immediate medical attention.

4.6: MEASUREMENT OF ADHERENCE

Adherence was measured by self report defined as the number of doses taken in a given duration divided by the total number of doses prescribed expressed as a percentage.

Adherence was assessed for the three days and also for the one month prior to the visit. Good adherence was defined as taking 95% of all prescribed medication. This was correlated to appointment keeping of scheduled visits and pharmacy drug refill.

4.7: LEVEL OF KNOWLEDGE SCORE

Different attributes of knowledge on HAART and importance of adherence to HAART were consolidated into a score of adequate and inadequate knowledge. A maximum score of ten was given to all participants who answered correctly all the questions posed. The scores were classified as adequate knowledge if one scored 5 and above and inadequate knowledge if one scored below 5.

4.8: DATA COLLECTION PROCEDURES

Assistants were recruited and trained by the researcher prior to the onset of the study. They were trained on the aims of the study and use of the data collection instruments.

After recruitment and signing of informed consent, interviewer administered questionnaire was then administered in a private room.

This questionnaire consisted of the following parts:

- Part 1 Socio-demographic data
- Part 2 Disclosure
- Part 3 Adherence

This part had an introductory statement that acknowledged that difficulties taking ARV are common and inevitable at some point. That the purpose of the interview was to help identify these difficulties and try to make it easier for the patient to take medications. The patient was then asked to:

- i. Identify the regimen/drugs that they were taking, how they were taking them and any special instructions regarding each drug.
- ii. Self-reported adherence was assessed for both 3 days and 1 month preceding the visit. Day by day review of doses missed in the last three days was done and a general review of the whole month was done.
- iii. The patient was then asked to identify the reasons that may have led to missing doses. If patient could not give a reason, they were prompted with reasons suggested on the questionnaire.
- iv. The interviewer then reassured the patient and offered suggestions to overcome specific obstacles the patient may have raised. Where deemed necessary, the patient was referred for further counseling with the CCC adherence counselor.
- v. Appointment keeping was assessed and good appointment keeping defined as reporting to the clinic within seven days of the scheduled visit.

Part 4 Knowledge/ Attitude/ Psychological factors

Part 5 Clinical records

Clinical records were reviewed for CD4 counts, number of admissions and opportunistic infections suffered. We also reviewed pharmacy refill records as a measure of adherence.

FGD procedure:

Focus group discussions were carried out at the study site to validate the quantitative data. To facilitate the FGDs, trained facilitators who had past experience in conducting FGDs in both adults and adolescents were used. There were two facilitators with one acting as the

lead moderator and the other taking notes. Purposive sampling technique was employed in recruiting the FGD participants. The principal investigator and the two facilitators enrolled and consented the adolescents who met the inclusion criteria and were willing to participate in the FGD. Oral consent was obtained from the caregiver and written assent from the adolescents. The sessions were held at the CCC in a room reserved for that purpose. The participants sat in a semi circle facing one another. The facilitators introduced themselves and explained the purpose of the discussion and the participants in turn introduced themselves one at a time. Participants went on to lay down the group norms they wanted followed. This was a participatory exercise where each participant mentioned one rule they wanted to apply during the FGD session. The FGD sessions began with facilitators emphasizing and ensuring that the norms were observed. The investigator reassured the participants on confidentiality by stating that all information derived from FGDs would be treated with utmost confidentiality and at no time would names be used in reporting information obtained.

Three FGDs were held, one of the FGDs was held in one day and the other two FGDs were held a week later on the same day at different times. The first FGD comprised of 9 participants, the second had 6 participants and the third had 7 participants. The age and sex for each participant was recorded. Each discussion lasted between one hour to one and half hours. Topic guide questions were used and responses recorded in written form and tape recorded with participants consent.

4.9: DATA HANDLING

4.9.1: STUDY VARIABLES

Table 4.1: Predictor Variables

Variable	Operational Definition	Measurement/Indicator
Age	Age at last birthday	Age in complete years
Sex	State of being man or woman	Male/ Female
Marital Status	Legal union between a man and a woman	Single.never married/ Married monogamous/ Married polygamous/ Widowed/Divorced or separated
Education level	Level of educational institution last attended	None/Primary incomplete/ Secondary incomplete/ College
Type of school	Type of educational institution last attended	Public/Private/Mission Boarding/Day school
Knowledge and attitude to ARVs	What the adolescents know and feel about ARVs	Knowledge on purpose/use/ efficacy/ side effects of ARVs Attitudes on use of ARVs
Occupation	Nature of work	Unemployed/Self-employed/ Formal employment

Stigma	Being treated differently as a result of HIV status	Prejudice/negative attitudes/abuse/maltreatment
Disclosure	Knowing that one is HIV infected	If child knows her/his HIV status
Counseling	Advice and instructions given by a trained health care provider regarding HAART	Had one or more sessions with a counselor
Appointment keeping	Reporting to hospital within a specified duration of the scheduled appointment	Attending hospital within seven days of the scheduled appointment
CD4 levels	Level of CD4 count	Amount of CD4 positive cells in the blood

Table 4.2: Outcome variables

Variable	Operational Definition	Measurement/Indicator
Good adherence	Able to take 95% or more of prescribed doses	Adherence \geq 95%
Poor adherence	Able to take less than 95% of prescribed doses	Adherence $<$ 95%

4.9.2: CONCEPTUAL FRAMEWORK

The conceptual framework of the determinants of adherence and non-adherence is shown in figure 4.1 below.

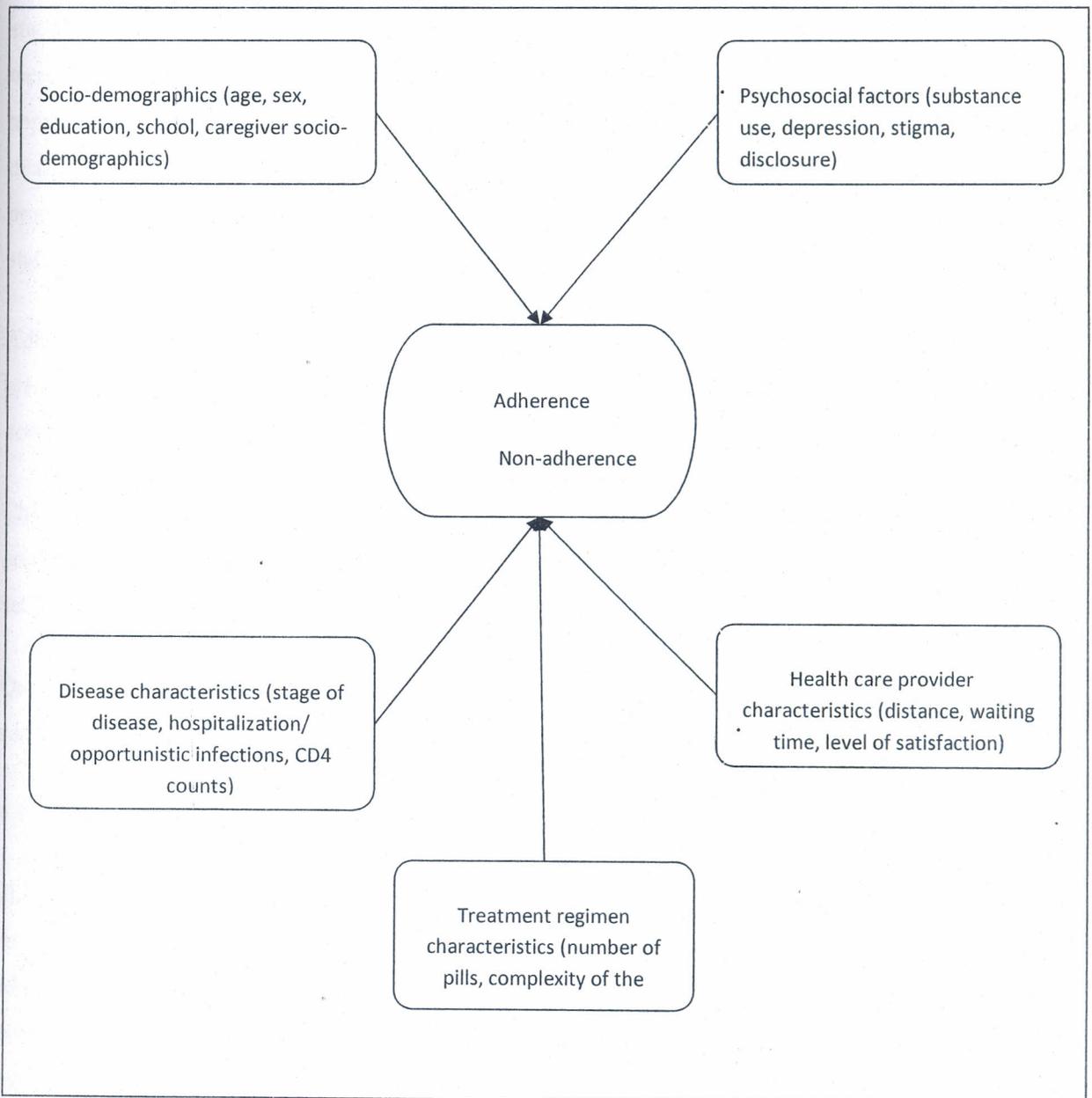


Figure 4.1: Conceptual framework of determinants of adherence in adolescents

4.9.3: DATA ENTRY AND ANALYSIS

Data were entered into a Windows 2007 Access database. It was cleaned for errors and any inconsistencies in responses. The Statistical Package for the Social Sciences (SPSS) version 13.0 software (currently known as Predictive Analytics SoftWare; PASW) was used for statistical analysis of the data. Descriptive statistics for the socio-demographic characteristics were obtained to characterize the study participants. Depending on the type of a variable, appropriate summary statistics appropriate for the measurement scale were used to describe distribution of these variables. This included mean for continuous variables such as age and proportions for categorical variables such as sex, education level etc. These summary statistics were then presented in tables.

Adherence was calculated as number of doses actually taken divided by total number of doses prescribed multiplied by 100. Good adherence was defined as taking 95% or more of the doses.

Chi square test was used to compare categorical variables and to test for relationship between predictor and outcome variables. All the p_values were 2-tailed with the significance level set at 0.05.

Qualitative data from focus group discussions were transcribed, coded, analysed and summarized according to themes.

4.9.4: SAMPLE SIZE:

The standard statistical approach to determining sample size for a cross-sectional survey requiring specification of an estimate of the proportion (prevalence) in the population (of adolescents) to be estimated; the level of confidence desired for the survey prevalence estimates and a tolerance error margin (a measure of precision of the estimate) was used. The sample size was determined by the following epidemiological formula for cross-sectional descriptive studies:

$$n = \frac{z^2 \times p(1-p)}{d^2}$$

Where

n = desired sample size

Z = Reliability coefficient at a (0.05) level of significance = 1.96

p = estimated proportion of adolescents on ART with adherence level at 95% or more (this being the level with optimal viral suppression), in this case 89.4 % (30)

d = degree of precision (5%)

n =

$$\frac{1.96^2 \times 0.894 \times 0.106}{0.05^2}$$

=145.62

=146

The sample size was increased by 10% (14.6) to cater for non-response (incomplete interviews) giving a total sample size of 161 participants.

4.10: MINIMIZATION OF ERRORS AND BIAS

To minimize errors and bias a standard structured questionnaire was used.

The filled questionnaires were edited to ensure completeness and accuracy as soon as possible after the interview.

The number of interviewers was limited to the researcher and two assistants trained on the administration of the questionnaire.

4.11: ETHICAL CONSIDERATIONS

Ethical approval for this study was obtained from KNH Ethics Committee prior to study commencement. Permission was also obtained from the CCC manager to conduct the study.

Confidentiality of the participants was strictly kept and their names did not appear in any questionnaire or in the report of the study.

Each participant signed a consent/assent form after being explained to the nature and purpose of the study. The participant had the option to participate or decline to-participate.

4.12: LIMITATIONS OF THE STUDY.

The study was done in one centre, although initially planned for two centres as it was not possible to obtain approval from the second centre. The study was also carried out in an urban centre. Therefore, adolescents from other areas especially the rural areas may be under-represented as most participants were from within and around Nairobi. This limitation however is not expected to significantly affect the outcome given that KNH is a national referral centre and clients come from all parts of the country.

The FGD consisted of some of the participants who had been interviewed in the study and this could have influenced their responses during the FGD. This is not expected to significantly affect the results as the number of participants who participated in both was low.

Biomarkers such as CD4 and viral load; clinical outcomes such as weight and opportunistic infections as well as other measures such as pill count were not included in the analysis. This would have been important to correlate these to self reported adherence. However, this was not possible due to a lot of missing data in these variables.

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CHAPTER 5: RESULTS

A total of 161 adolescents were interviewed and 158 adolescents included in the analysis as the other three had incomplete data. Three FGDs each lasting between one to one and half hours and comprising 6-9 adolescents were conducted. The baseline characteristics of the population study are shown in table 5.1.

Table 5.1: Socio-demographic characteristics of the study population (n=158)

		NUMBER	% / IQR
Gender	Female	85	53.8
	Male	73	46.2
Age	Median age (years)	13	11-15
	10-15	124	78.5
	>15	34	21.5
Orphan status	Orphaned	39	24.7
	Not orphaned	119	75.3
Attending School	Yes	152	96.2
	No	6	3.8
Education level	Primary	109	71.7
	Secondary	38	25.0
	Tertiary	5	3.3
Median duration of treatment(months)		33	22-47
Drug regimen	st 1 line	143	90.5
	nd 2 line	17	9.5
Disclosure to adolescent of own HIV status	Knows status	77	48.7
	Do not know status	81	51.3

5.1: SOCIO-DEMOGRAPHIC CHARACTERISTICS

Of the total population studied 46.2% were males and 53.8% were females with a male to female ratio of 1: 1.2. In FGDs females comprised 77.3% of the total FGD participants. This is consistent with the HIV situation in Kenya where the prevalence is higher among females than males by 2:1 (24). In regard to age, adolescents studied were mainly in their early adolescence with 61.5% of the total population being 13 years and below. The median age was 13 years and the mean was 13.01 years.

Practically all respondents 152 (96.2%) were in school with 109 (71.7%) being in primary schools, 86 (56.6%) in public schools and only 22 (14.5%) in boarding schools.

Tertiary/college education was under-represented with only 5(3.3%) and was therefore combined with secondary school to form the post primary education group which was used in the analysis. There was no clear distinction between mission schools and public school as the former often received some kind of government support and therefore the two were analyzed as one. Of those who reported not being in school, one (16.7%) had never gone to school, two (33.3%) did not complete primary school, two (28.6%) had completed primary school, one (16.7%) had incomplete secondary school and one (16.7%) had completed secondary school.

Table 5.2: Type of school adolescent is attending,(n=152)

Type of School	Number	%
Day School	129	84.9
Boarding School	22	14.5
Not known	1	0.7
Primary School	109	71.7
Post primary school	43	28.3
Public School	86	56.6
Private School	63	41.4
Not known	3	2.0

5.1.1: Caregiver socio-demographic characteristics:

Of the adolescents interviewed, 54 (34.2%) had both parents alive, 39 (24.7%) were total orphans, while the rest were either paternal or maternal orphans. Of all the adolescents 53 (33.5%) reported that at least one of the parents had used ARVs whether the parent was alive or deceased. Of those orphaned, 90.7% were under the care of relatives while the rest were either in children's' home or adoptive parents.

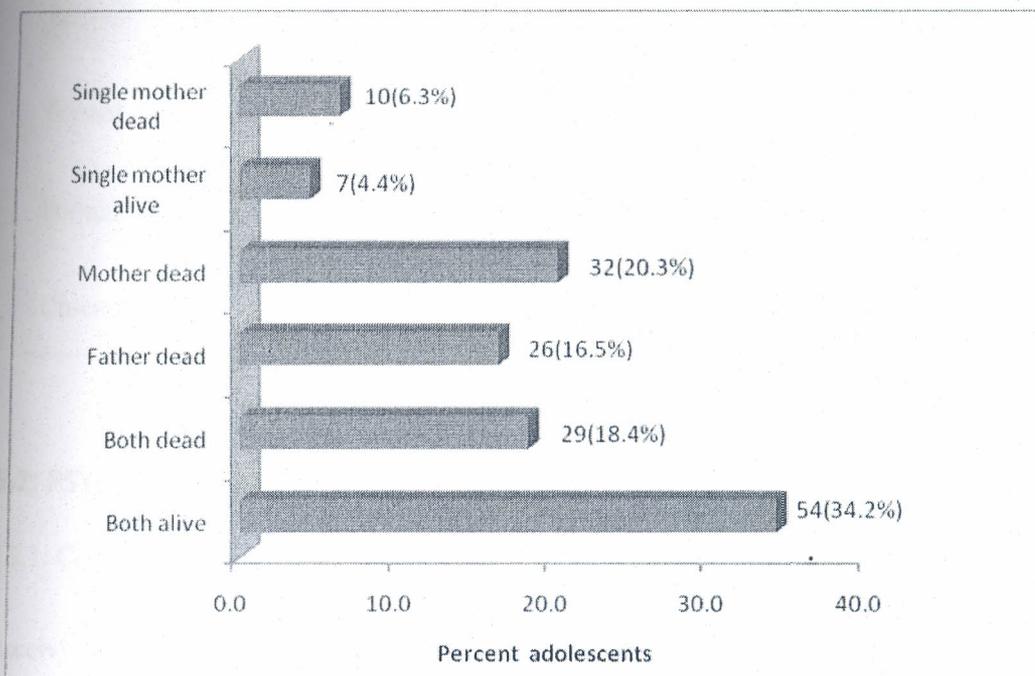


Figure 5.1: Adolescents parental status (n=158)

Parents and caregivers were mainly in formal employment either in the public sector or private sector followed by business and self-employment in the jua kali sector (table 5.3).

Table 5.3: Occupation of the caretaker as reported by the adolescents

Occupation	Mother (n=72)	Father (n=81)	Caretaker (n=44)
Farmer	3 (4.2%)	6 (7.4%)	5 (11.4%)
Business	20 (27.8%)	25 (30.9%)	12 (27.3%)
Self-employed (jua kali)	16 (22.2%)	12 (14.8%)	4 (9.1%)
Formal employment (public)	9 (12.5%)	18 (22.2%)	20 (45.4%)
Formal employment (private)	21 (29.1%)	5 (6.2%)	
Un-employed	3 (4.2%)	15 (18.5%)	3 (6.8%)

5.2: PSYCHOSOCIAL FACTORS

5.2.1: Counseling

Receiving counseling before treatment was started was reported by 141 (89.2%) of the adolescents, while 115 (72.8%) reported having received counseling at each visit and 145 (91.8%) reported receiving specific adherence counseling. When questioned about the extent to which they trusted their healthcare provider, 147 (93%) reported that they trusted their care provider enough to share their personal problems with them. Asked to rate the quality of care that they received at CCC, 116 (73.4%) thought it was excellent, 37 (23.4%) thought it was acceptable while 5 (3.2%) had no comment.

5.2.2: Stigma

To assess stigma and social support, the adolescents were questioned on whether their family or friends avoided them because of their HIV status; they avoided their friends or family

because of their status; family members helped them remember to take their medication and whether they were satisfied with the overall support they got from their family and friends.

Table 5.4: Reports of stigma and social support, n=77

	YES	NO
Family and friends avoid participant because of your HIV status	3 (3.9%)	74 (94.8%)
Participant avoids family and friends because of his/her HIV status (self-stigma)	6 (7.8%)	71 (92.2%)
Family and friends remind participant to take medication	70 (90.9%)	7 (9.1%)
Participant is satisfied with family and friends support	69 (89.6%)	8 (10.4%)

During focus group discussion, participants were divided on the issue of stigma. Some reported having experienced no stigma, one adolescent said that other people treated them “...as being normal...”, and another one said “...it doesn’t affect the relationship because I am given equal treatment by my colleagues...”. In all three FGDs, participants reported support from close family members but not from non family members as put by one “...It has not affected my family because only those close to me like dad and mum know and encourage me about my HIV status and not outsiders...”.

It was apparent during FGDs that stigma and lack of social support was also common as narrated by different participants across the three groups: “...I see my mum and dad arguing. They don’t live like husband and wife. Sometimes when I come over (to the CCC) my dad feels like he is spending a lot of money. My mum asked me to keep it a secret but my sister dislikes me and my dad does not take me as a daughter anymore...”

Another participant said “...When I ask for anything my mum can’t buy for me but she likes my brother more. My dad likes me but not my mum...”

One girl also reported that “...*They see me as a short girl and at school they run away from me. Our house girl looks down upon me...*”

While yet another one said “...*Most of them won't be positive about it. Like my cousin told me our family friends are aware of her status and when they visit they ask questions that make her feel intimidated...*”

In the quantitative study, self stigma was reported by 6 (7.8%) of the adolescents. This was also evident in FGD as observed through one adolescent who said, “...*At school, teacher Ben said out of every 12 people in class one was HIV positive, I suspected he was talking about me...*”

5.2.3: Substance use

With respect to substance use, 2 (1.3%) adolescents reported using alcohol. There was no other substance use reported by the other adolescents.

5.2.4: Disclosure:

More than half of the adolescents 81(51.3%), surveyed did not know their HIV status with the median age of disclosure being 12 years and a range of 9 years as the youngest and 18 years the oldest age of disclosure as shown in fig 5.2.

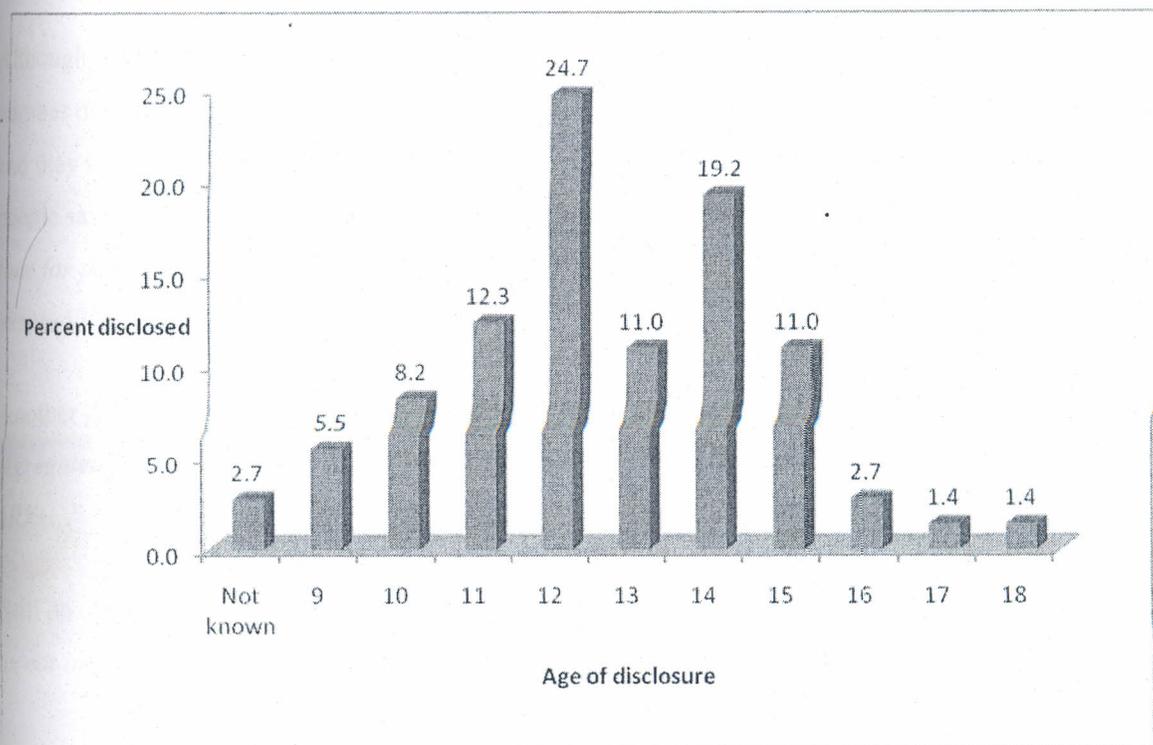


Figure 5.2: Age at which adolescents were disclosed to their HIV status, n=81

5.3: KNOWLEDGE AND ATTITUDES REGARDING HAART AND ADHERENCE

5.3.1: Knowledge

Knowledge regarding HAART and the importance of adherence was adequate with 66 (85.7%) of the adolescents stating that HAART reduces the virus in the body, 69 (89.6%) it prevents one from getting sick and 67 (87%) that it prolongs life. However, there were still some 4 (5.2%) who reported knowing nothing about HAART, 7 (9.1%) thinking HAART cures HIV and 9 (11.7%) reporting that taking HAART is difficult. During FGDs, strong sentiments about the positive effects of HAART were expressed by most adolescents who noted that their health improved markedly on using HAART as exemplified by the following comment “...I used to get sick but when I started using ARVs I’ am now strong I don’t miss school, even at school I’ am asked how I manage now than before...”.

5.3.2: Attitude

Although respondents had a good attitude towards HAART (table 5.6), FGDs revealed that a number of them felt that people who are HIV negative are not convinced that ARVs are good and they have a negative attitude towards them and those using them. Asked what other people say about ARVs, some gave the following answers: “...They say that it’s a waste of time for people infected with HIV to use them because they will never be cured and will die eventually...”

Another participant said “...People say it would be better if HIV infected persons were segregated and killed to prevent them from infecting more people rather than being put on ARVs...”

Still on other peoples’ attitude towards ARVs another participant said “...Some people say its not important to take them because even young babies can get it from their mothers...”

A school going adolescent reported that “...Other pupils laugh and make mockery at us whenever they see us take the ARVs...”

Table 5.5: Attitudes and beliefs towards ARVs, n=77

	Number	%
No matter what I do, I will probably die of AIDS	8	10.4
ART will be able to get rid of most of the virus in my body	67	87.0
It is impossible to take all the ARV drugs as directed	11	14.3
The medication makes my health better	74	96.1
If I do not take the ARV medication as instructed, the drugs will become useless to my body as the virus will become resistant	71	92.2

5.4: ADHERENCE TO HAART AND APPOINTMENT KEEPING

5.4.1: Scheduled appointment keeping

Of the adolescents surveyed, only 5 (3.2%) reported having missed a scheduled appointment in the previous 6 months as compared to 153(96.8%) who kept all the appointments. All five who missed appointments reported different reasons for missing namely; being away in school, lack of transport money, caretaker got sick, confused appointment dates and had travelled up-country.

5.4.2: ARV regimen and treatment duration

One hundred and forty three (90.5%) of the adolescents were on first line treatment while the rest, 15 (9.5%), were on second line treatment. One hundred and thirty one (82.9%) took their medication on their own while 27 (17.1%) relied on other people to remind them to take their medication.

The median duration of treatment was 33 months with a mean of 33.6 months. The longest duration of treatment was 53 months and the shortest was 7 months.

5.4.3: Self-reported adherence

The mean self-reported adherence during the 3 days prior to the visit was 97.8% and 99% in the previous month. The overall mean adherence for the whole group was 98.4%. Of the 158 adolescents surveyed, 148 (93.7%) had good adherence above 95% during the three days prior to the visit and 152 (96.2%) had 95% or more during the one month prior. Only one adolescent reported missing all his doses during the period in review.

5.4.4: Reasons for missing doses

Of the adolescents who missed their doses, the commonest reason given for missing a dose was simply forgetting to take the ARVs followed by being away from home, school schedule and drugs getting finished before the next appointment (table 5.8).

Table 5.6: Reasons given by adolescents for missing drug doses, n=24

n=24	Number	%
Forgetfulness	10	41.7
Was away from home	6	25
School schedule	4	16.7
Medicine got finished before appointment date	4	16.7
Wrong prescription (drug not dispensed)	1	4.2
Caregiver was sick	1	4.2
Day of drug refill was a public holiday	1	4.2
Timing (overslept)	1	4.2

Similar reasons for missing doses were given during the FGD where one participant suggested that those who forget to take their medication should “*consult people one lives with to always remind the one on ARVs, or talk to his parents and guardians to buy him a watch or phone for setting a reminder as to when to take them*”

On the issue of being away from home and school schedule, a participant said:

“*...Sometimes for example if you are in school you can take in the morning and in the evening you are unable to reach home on time...*”

Another reason given in FGD for missing drug was stigma. One participant said “*...The name Ukimwi (AIDS) for the disease is so bad, such that people prefer to die instead of taking medication...*” while yet another one said “*...There are those who don't want to take*

ARV medication due to the stigma attached to HIV coupled with the routine of visiting clinics for checkups makes them opt to go to a witch doctor... ”

5.4.5: Challenges encountered while on HAART treatment

When asked about challenges they faced during the course of their treatment, adolescents reported being away in school as the main challenge followed by long waiting time at the clinic, distance to the clinic and drug side effects among others (table 5.9). Some adolescents reported having no challenges at all while taking their medication.

Table 5.7: Challenges encountered, n=158

	NUMBER	%
Being away in school	18	11.4
Long waiting time for care	13	8.2
Long distance to the clinic	9	5.7
Side effects of the medications	9	5.7
High pill burden	5	3.2
Lack of adequate information about drugs	2	1.3
Inadequate psychological support for coping with treatment	3	1.9
Inability to travel freely	2	1.3
Stigma	2	1.3
Timing of medication and special requirements	3	1.9
Interference with other activities	1	0.6

5.4.6: Appointment keeping for drug refill

Pharmacy records were reviewed to ascertain the level of appointment keeping for medication refills and 7 (4.4%) of the adolescents had missed at least one drug refill visit in the six months studied giving a pharmacy refill adherence rate of 95.6%.

5.5: RELATIONSHIP BETWEEN ADHERENCE AND DIFFERENT VARIABLES

The difference between mean adherence at three days and at one month was not found to be statistically significant, **p value >0.05**. We used the three day adherence to analyze the relationship between the various variables and adherence.

5.5.1: Socio-demographic factors and adherence

An assessment of the relationship between socio-demographic factors and adherence to HAART treatment was done. The factors assessed were those specific to adolescents (age, sex, being in school or not, education level and type of school being attended) and factors related to their caregivers (whether alive or deceased and using ARVs or not). Although not statistically significant, the study observed that majority (80%) of those with poor adherence were aged between 10-12 years (**Fisher's Exact test Chi square=4.199, p=0.176**).

Table 5.8: Adherence by age in years

n=158	n	Adherence level		P value
		<95%	>/=95%	
Age groups in years				
10-12	77	8 (5.0%)	69 (43.7%)	0.176
13-15	47	1 (0.6%)	46 (29.1%)	
16-19	34	1 (0.6%)	33 (20.9%)	
Total		10 (6.3%)	148 (93.7%)	

There was also no statistically significant relationship between any of the other assessed variables including sex, being in school, type of school, alcohol use, being orphaned or parents being on ARVs and adherence as shown in table 5.10.

Similarly, there was no statistically significant relationship between duration of treatment and adherence or being either on first line or second line treatment and adherence.

Table 5.9: Adolescents and parents socio-demographic factors and adherence

		Poor Adherence <95%	Good Adherence ≥95%	Fisher's Exact Test P value
Sex n=158	Male	7	66	0.189
	Female	3	82	
	Total	10	148	
Attending school n=158	Yes	9	143	0.329
	No	1	5	
	Total	10	148	
Type of school n= 152	Primary	9	100	0.160
	Secondary	0	38	
	College	0	5	
	Total	9	143	
Alcohol use n= 158	Yes	0	2	1.000
	No	10	146	
	Total	10	148	
Parents alive n= 158	Both alive	1	53	0.150
	Both dead	1	28	
	Father dead	2	24	
	Mother dead	5	27	
	Single mother alive	0	7	
	Single mother dead	1	9	
	Total	10	148	
	Parents on ARVS n= 158	Yes	4	
No/Unknown		6	99	
Total		10	148	

5.5.2: Psychosocial factors and adherence

There was no significant relationship between adherence and disclosure status (**Fisher's Exact test Chi=0.326, p=0.747**) or age of disclosure (**Fisher's Exact test Chi=0.912, p=.702**).

There was a significant relationship between stigma and adherence (**Fisher's Exact test Chi= 23.617, p=0.006**) as well as a tendency towards significance between social support and adherence (**Fisher's Exact test Chi =7.110, p=0.051**) as shown in table 5.11 below.

Table 5.10: Stigma/social support and adherence, n=77

		Adherence level		Fisher's Exact Test	
		Poor <95%	Good >=95%	Chi square	P value
Participant avoids family and friends because of his/her illness (self stigma)	Yes	1	5	1.739	0.282
	No	3	68		
Family and friends avoid participant because of his/her illness (stigma)	Yes	2	1	23.617	0.006
	No	2	71		
Family and friends remind participant to take his/her medication	Yes	4	66	0.422	1.000
	No	0	7		
Participant is satisfied with the support of family and friends	Yes	2	67	7.110	0.051
	No	2	6		

Stigma was also strongly cited in FGDs as a hindrance to taking ARVs while social support was reported as encouraging. Regarding stigma a participant said, "...*They see me as a short girl and at school they run away from me...*", while another said "...*our house girl looks down upon me and my mum asked me to keep my HIV status a secret but my sister discovered, she dislikes me and my dad does not take me as a daughter anymore...*".

Another one said, "...*Community thinks that people living with HIV are immoral because they believe people are infected through sexual intercourse...*" while yet another reported self stigma thus "...*Before I knew my status I used to perceive everything as being fine, when I knew my status I felt people look down upon me. I even panic...*"

Regarding social support one adolescent said “... *When one is positive the family has love towards such a person because we had a close person who suffered so we have accepted. Even my cousin we are close. It has brought us real close...*”

5.5.3: Knowledge/attitude and adherence

Majority of the adolescents had adequate knowledge with 69 (89.6%) scoring above 5, on a scale of 1-10 in which adequate knowledge was defined as scoring above 5, and only 8 (10.4%) scoring below 5. There was no significant relationship between level of knowledge and adherence (**Fisher's Exact test Chi square= 0.967, p= 0.361**). There was similarly no significant relationship between adolescent attitude towards HAART treatment and adherence.

CHAPTER 6: DISCUSSION:

This study examined adherence in adolescents aged 10-19 years. To our knowledge, this was the first study on adolescent adherence to HAART in Kenya. Majority (93.7%) of the adolescents reported good adherence which is significantly higher than what has been reported in both regional and international studies(37) (38) (39). A more recent study reported better adherence with a mean adherence of 94 % (40).

In this study, a high level of appointment keeping to both scheduled clinic visits and pharmacy refill was also observed. Of all the adolescents surveyed, 96.8% reported keeping scheduled clinic appointments and 95.6% were found to have refilled their drugs on time from reviewed pharmacy records. Both appointment keeping and drug refill have been found in other studies to correlate to adherence (41). Although self-reported adherence has been found in some studies to overestimate adherence (42) (43) the associated high adherence to pharmacy refill and appointment keeping in this population gives credence to the high self reported drug adherence.

The good adherence can possibly be explained by the extensive adherence counseling provided before initiation of treatment and during follow-up as well as the positive attitude towards the health care providers and the quality of care. While conducting the study, participants were asked whether they had received counseling and 89.2% reported receiving counseling before treatment was started, 72.8% reported receiving counseling at each visit while 91.8% reported receiving specific adherence counseling in the course of treatment. The participants also reported having a good relationship with the care providers with 93% reporting that they trusted their care provider enough to share their personal problems with them, a factor that has been found to have a positive effect on treatment outcome (41). Many of the participants reported being satisfied with the quality of care given at CCC with 73.4% terming it excellent and 23.4% saying they thought it was acceptable.

These sentiments were further reinforced during focus group discussion where different participants expressed satisfaction with different aspects of care such as availability of drugs, support groups and friendly staff. One adolescent said “...*the health care process is good since it accords the children a chance to interact with their peers of the same status to share their experiences in a group...*”. However, most were unhappy with the waiting time and

reported during the group discussion that getting files from records took too long suggesting they should be retrieved the day before; some doctors came in late and the number of doctors and nurses should be increased to reduce the waiting time. One thirteen year old girl put it thus “...*Its not good because you can come at 8 am and leave at 4 pm, you get bored, hungry...*”

Reasons given for failing to take medication were varied but the most common was forgetting 41.7% followed by being away from home 25% and school schedule 16.7%. These factors mentioned are consistent with findings from other studies and can be resolved by for example providing reminder devices or cue-dosing and adjusting treatment time to fit in with daily activities such as school or providing means of carrying the drugs conveniently to school. Healthcare providers related reasons for failing to take drugs included medicine getting finished before next appointment date (16.7%), wrong prescription (4.2%) and day of drug refill being a public holiday (4.2%). Combined, these reasons constitute a considerable 25% cause of failing to take drugs.

Although majority (80%) of those who reported adherence less than 95% were 12 years and below, age was not found to be significantly associated with adherence. Age has been found to play a role in adherence especially at infancy and adolescence. Other studies have reported that in adolescents, issues such as denial and fear of HIV status, misinformation about HIV, administration of complex regimens when adolescents do not want to be different from their peers can all act as significant barriers to adherence. This effect of age-related issues on adherence was not observed in this study.

Other socio-demographic variables such as sex, level of schooling as well as type of school attended were also not found to affect adherence. This is in contrast to studies that have shown a higher level of adherence in adults with post-primary education. This could probably be explained by the fact that although the study population was at different levels of education, majority were still in primary school at the time of the interview. This is unlike in adult populations who have been out of school for some years implying that perhaps some certain behavioural characteristics acquired in post-primary education persist among adults leading them to be more adherent than those who dropped out in primary school.

Caregiver socio-demographic characteristics which were examined such as being on ARVs and occupation were not significantly associated with adherence in adolescents.

The study found a significant statistical association ($p=0.006$) between adherence and stigma as measured by patients' perception of whether friends and family avoided them because of their illness. This finding of stigma as a predictor of adherence is similar to studies done in adults. In a study done in a large cohort of adults in five countries in Africa, it was noted that part of the reason for poor adherence to ARV medications can be linked to the stigma experienced by people living with HIV (44). Although self stigmatization was evident in both the qualitative and quantitative part of the current study, it was not found to be significantly associated with adherence.

There was also a trend towards significance ($p= 0.051$) between adherence and social support as measured by whether they were satisfied with the support they got from family and friends. Most adolescents reported that they were satisfied with the support they got from family and friends in taking their drugs.

The study found that only 48.7% of the adolescents knew their HIV status with the median age of disclosure being 12 years. The disclosure age ranged from as early as 9 years to as late as 18 years. Like similar studies among adolescents, disclosure status was not found to be associated with adherence. This does not however mean that the issue of disclosure is not important in this population especially because studies in chronic diseases such as cancer have shown positive effects such as decreased anxiety, improved family functioning and long term gains in psychosocial functioning (45). It is possible that long term adherence will be impacted by the disclosure status. With the wide age range observed when disclosure occurred, the question of when it is most appropriate to disclose the status to the child arises. This implies that in developing appropriate models for disclosure, other factors such as cognitive development are perhaps more important in making this decision rather than just the chronological age. Caregivers and health care workers need to work together to determine the readiness of an adolescent to be told his/her status. Studies have reported a reluctance by caregivers to disclose fearing the "negative" impact this might have on the adolescent but this was not observed in this study.

Adolescents who indulged in substance abuse were under represented in this study with only 1.3% reporting alcohol use and those who reported using alcohol had good adherence. This is probably due to the fact that majority of our subjects were in school and therefore this issue needs to be examined more in out of school adolescents.

There was no statistically significant association between adherence and knowledge and attitude observed in this study. The level of knowledge regarding HAART and adherence was high in this population with 89.6% scored as having adequate knowledge. The attributes of good knowledge included positive responses such as HAART reduces the virus level in the body, prolongs life and prevents one from getting sick. However, there was still a small number who had inadequate knowledge. Negative attributes included belief that HAART can cure HIV, makes one die faster and makes one sicker. A few adolescents (5.2%) knew nothing about HAART. Given that health literacy has been shown to have an impact on adherence in adults (46), and that it improves receiving medical care in adolescents (47), the inadequate knowledge among a few adolescents is of concern and should be addressed through counseling and providing appropriate information.

Adolescents surveyed displayed a positive attitude towards HAART both during interviews and focus group discussions. Regarding HAART, one adolescent said; “...*medicines help a lot, before people knew they used to die a lot but nowadays with ARVs, people do not die a lot...*”. However, a small percentage (10.4%) still thought they would die of AIDS regardless of what they did and 14.3% scored low on self-efficacy stating that they believed it was impossible to take ARVs as directed.

CONCLUSION:

Overall there was good adherence in adolescents in KNH hospital with 93.7% of all the adolescents reporting $\geq 95\%$ adherence. This illustrates that it is possible for adolescents in our setting to achieve and maintain optimal adherence levels for viral suppression to avoid treatment failure and emergence of viral resistance.

The commonest causes of failing to take medication were forgetting to take drugs, being away from home and school schedule.

Stigma and lack of social support were significant barriers to adherence. Few staff at the clinic and also staff coming late, pharmacy issuing mistakes such as drugs getting finished before the next appointment as well as long waiting periods were challenges that adolescents often faced during treatment.

Extensive adherence counseling provided before initiation of treatment and during follow-up were identified as factors that promote adherence. Similarly a positive attitude towards the health care providers and the quality of care provided were identified as factors that promote adherence in adolescents.

RECOMMENDATIONS

Good adherence in adolescents can be achieved as demonstrated by the study. This can be enhanced by developing interventions that will help to promote and maintain adherence over time which are recommended below.

1. In KNH, forgetting to take medication and being away from home were identified as the main cause of failing to take drugs and these should be addressed by healthcare providers during counseling. Interventions to address these should include reminder devices and pill organizers where feasible as well as helping identify activities that adolescents can use as cues to remind them to take their drugs. The healthcare providers should help adolescents tailor their treatment to their school schedule. They should help them identify a time to take drugs before they leave for school and when they get back home from school or carry the drugs with them to school.
2. Healthcare workers in pharmacy contributed to over 25% of the failure to take drugs and the chief pharmacist should ensure that issuing of drugs in the pharmacy is improved so that the drugs do not get finished before the next appointment. Where scheduled refill appointments coincide with important school dates such as exam periods, arrangements should be made to either refill earlier or give extra pills to cover that period.
3. The current extensive adherence counseling should be maintained and strengthened to also address issues related to stigma and social support in adolescents. There is need for the CCC manager to increase the number of counselors in CCC for them to be able to cope with the number of clients and maintain quality. Currently, there are only four qualified counselors in the CCC attending to all the clients including adults and pediatrics. Two of the counselors are specially trained for pediatric counseling. The CCC manager needs to identify and train counselors dedicated to handle the special needs of adolescents. These counselors should also be trained in adherence counseling.
4. The CCC manager should also aim to identify a space dedicated to adolescents where they can interact with their peers and access information relevant to them.

Long term, KNH should aim to establish a fully fledged adolescent CCC with staff trained to deal with adolescent issues as it has done with the adolescent reproductive health and VCT centre.

5. Long waiting period was identified during the quantitative study and also strongly identified as a major challenge that adolescents faced in accessing treatment. Delay in retrieving records should be addressed by streamlining the process of retrieving files. In the short term, the filing clerks should retrieve patients files on the day before the visit but long term, the KNH management should aim at implementing electronic record-keeping which will make the patient records easily accessible to the care provider.
6. Further research on adherence in late adolescence and out of school adolescents who were under-represented in this study should be undertaken.

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APPENDIX 1: CONSENT

My name is Dr Ann Gatuguta (or assistants' name) a postgraduate student in the Department of Community Health, University of Nairobi. We are conducting a study to find out how easy or difficult it is to take medication regularly. We would like to request you to take part in this study. This will assist us to understand some of the difficulties you experience while taking these medicines. With the information obtained we will be able to give recommendations on overcoming these challenges.

If you consent to participate in this study, we will then ask you questions related to you and your health. We will also ask you how you have been taking medicines and some of the difficulties you have experienced while taking them. There is no foreseeable risk or harm that will come to you when you take part in this study. The potential benefit is that in case you are experiencing any problems we will offer suggestions of how to overcome them and if you so wish we will refer you to a counselor.

You are not under any obligation to answer any of the questions you may feel uncomfortable with. Failure to answer any of the questions will not in any way affect your treatment. You are also free to decide not to take part in this study or to withdraw at any time during the interview.

The information you give during the interview and the results of the study will be held in the strictest confidence.

If you understand your rights in this study and freely agree to take part in it, please sign below.

I confirm that the purpose of this study has been explained to me and I hereby consent/not consent to participate in it.

Signature/thumb print.....Date.....

Witness:NameSignature.....Date.....

APPENDIX 2: ASSENT

We would like to talk with you (and your parent) about how you take your drugs. We would like to help you learn ways to take good care of yourself. Taking your drugs at the right time and in the right way is important so that you stay healthy. If you agree we will ask you questions about how you take your drugs and the difficulties you find in taking them. We will ask you questions such as your age, whether you go to school and where you go to school. We will find out if you know why you come to this clinic or why you take medicine every day. We will ask you how you feel about taking your drugs and your illness. We will also ask you about who takes care of you.

You do not have to answer any questions you feel uncomfortable about. We will not tell anyone that you took part in this study. You do not have to take part in this study if you do not want to. No one will be unhappy with you if you do not want to be in the study.

Subjects' statement:

This study has been explained to me. I agree to take part in the study. I have had a chance to ask questions and if I have more questions I can ask.

Name.....

Signature of subject..... Date.....

Witness:

Name.....

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

APPENDIX 3: QUESTIONNAIRE

Questionnaire ID No.....

Date of interview.....

Name of hospital.....

Name of interviewer.....

INSTRUCTIONS TO THE INTERVIEWER:

Introduce yourself to the respondent and make the respondent comfortable in a private room/space.

Explain the purpose of the study and read the contents of the consent form to them. Have the respondent sign the consent.

PART 1: SOCIAL – DEMOGRAPHIC CHARACTERISTIC

1. How old are you (in complete years).....

2. Sex of the respondent: Male (...) Female (...)

3. Are you currently attending school: Yes (...) No (...) (Go to 5)

4. If yes, what type of school

Primary(...) Secondary (...) College (...)

Private school (...) Public (...) Mission (...)

Boarding Yes (...) No (...)

Others (specify).....(Go to no. 8)

5. If not, Highest level of schooling achieved

None (..)

Primary in-complete (..)

Primary complete (..)

Secondary in-complete (..)

Secondary complete (..)

6. Are you employed? Yes (..) No (..)

What do you do?

Farmer (..)

Business (..)

Self employed (Jua kali) (..)

Formal employment (..)

Other (specify).....

7. What is the range of your income per month?

Below Ksh 5, 000 (..)

5, 001–10, 000 (..)

10, 001–15, 000 (..)

15, 001–20, 000 (..)

Above 20, 000 (..)

8. Are your parents alive?

Both alive (…)

Both dead (…)(go to 11)

Father dead (…)

Mother dead (…)

9. Are your parents on any treatment (if deceased, were they on treatment)?

Yes (…) No (…)

Which treatment ARVs (…) Others (specify).....

10. What is the occupation of your father mother

Farmer (…)

Business (…)

Self employed (Jua kali) (…)

Formal employment (civil service job) (…)

Formal employment (private sector job) (…)

Un-employed (…)

Other (specify).....

11. If orphaned who is taking care of you

Relative (…)

(Specify eg maternal grandmother etc).....

Spouse (…)

Self (...) (Go to 13)

Other (...) (Specify).....

12. What is the occupation of your caretaker above

Farmer (...) (..)

Business (...) (..)

Self employed (Jua kali) (...) (..)

Formal employment (...) (..)

Un-employed (...) (..)

Other (specify).....

13. If self, do you take care of others Yes (...) how many (...) No
(...)

14. What is your marital status?(where applicable)

Married- monogamous (...) (..)

Married-polygamous (...) (..)

Single (...) (..)

Divorced/separated (...) (..)

Widowed (...) (..)

Other (specify).....

15. Do you have children? Yes (...) how many (...) No (...)

APPOINTMENT KEEPING

16. Do you use money for transport to come to this hospital? Yes (...) No (...)

17. Who provides you with this money?

Self (...)

Friends (...)

Relatives (...)

NGO/research project (...)

18. Have you missed an appointment or drug refill in the (not filled within one week of appointment date)

Last month? (..)

Three months?(..) How many (...)

Six months? (..) How many (...)

When was the missed appointment due: Date (.....)

When did you come for the missed appointment: Date (.....)

19. If missed any appointment, why?

Forgot (...)

Was in school (...)

No transport money (...)

Was sick (...)

Others (specify).....

PART 2

DISCLOSURE

20. Please tell me what is the nature of your illness

HIV (...) Don't know (...) (Go to 23)

Other (specify).....

If HIV continue below

21. When did you know about your HIV status? (Age).....

Who told you?

Do you know how you got infected?

Sexual contact (...) perinatal (...) don't know (...) Others (...)

(specify).....

22. Who else knows about your status apart from your health care provider?

No one (...)

Parent (...)

Spouse/sexual partner (...)

Close relative (...)

Close (non sexual) friend (...)

Other (Specify).....

23. How long have you been on these drugs?

24. Who reminds you to take the drugs? Self (...) Other
(specify).....

It is difficult for most people to take their medications everyday without failure. The reason I want to know is to help identify these difficulties and try to make it easier for you to take medications.

Please tell me which drugs you are currently taking? (If patient does not know the name of the drugs, refer to the patient's prescription or look at the dispensed drugs).

Drug	How often do you take it	Any special instructions
1	Once (...) twice (...)	
2.	Once (...) twice (...)	
3	Once (...) twice (...)	

Please tell me if you have missed any doses in the last 3 days?

Drug 1 Yes (...) No (...) No. of doses missed (...)

Drug 2 Yes (...) No (...) No. of doses missed (...)

Drug 3 Yes (...) No (...) No. of doses missed (...)

Did you miss any dose over the last one month?

Drug 1 Yes (...) No (...)No. of doses missed (...)

Drug 2 Yes (...) No (...)No. of doses missed (...)

Drug 3 Yes (...) No (...)No. of doses missed (...)

If any of the doses were missed, what was the reason for missing the drugs

Forgetfulness (...)

Too frequent dosing (...)

School schedule (...)

Financial constraints (...)

Shortage of specific medicine (...)

Discouraged by friend or family (...)

Was on herbal medication. (...)

Were away from home (...)

Had too many pills to take (...)

Wanted to avoid side effects (...)

Did not want others to notice you taking medication (...)

Felt like the drug was toxic/harmful/ not effective (...)

My health condition improved (...)

Had problem taking pills at specified times(With meals,on empty stomach)(...)

Felt depressed /overwhelmed (…)

Sharing ART with other family members and friends (…)

Religious beliefs (…)

Not fully understanding the regime and its requirements.(…)

Transportation problems getting to the clinics. (…)

Lost pills (…)

Others specify.....

25.What challenges do you encounter in taking these drugs? (Tick appropriately).

Being away in school (…)

Inability to continually afford medicine (…)

Unco-operative/ unfriendly health workers (…)

High pill burden (…)

Long waiting time for care (…)

Lack of adequate information about drugs (…)

Frequent shortages of drugs at the clinic (…)

Side effects of the medications (…)

Expensive Laboratory monitoring tests (…)

In adequate Psychological support for coping with treatment (…)

Long distance to the clinic (..)

Others specify.....

(Instructions to interviewer: reassure patient and offer suggestions to overcome specific obstacles the patient has raised.)

PART 4 KNOWLEDGE/ATTITUDE/PSYCHOLOGICAL FACTORS

(Skip to question 28 for adolescents who have not been disclosed to their status)

26. Please tell me what you know about the drugs you are taking?

Nothing (..)

They cure HIV (..)

They prolong life of HIV positive persons (..)

They make a HIV positive person sicker due to side effects (..)

They make a HIV positive person die faster (..)

They are expensive (..)

They are difficult to take (..)

They prevent one from getting sick (..)

Reduce virus in the body (..)

Other specify.....

27. What is the importance of taking your drugs at the right time and in the right way as directed by your health care provider?

None (..)

- Cure HIV (…)
- Reduce the virus (…)
- Prolong life (…)
- Don't know (…)
- Other (specify).....

ATTITUDES AND BELIEFS ABOUT ART

	True	False	Don't know
No matter what I do, I will probably die of AIDS.	(..)	(..)	(..)
ART will be able to get rid of most of the virus in my body.(..)		(..)	(..)
It is impossible to take all the ARV drugs as directed.	(..)	(..)	(..)
The medication makes my health better		(..)	(..)
If I do not take the ARV medication as instructed, the drugs will become useless to my body as the virus will become resistant			(..) (..)
(..)			

SOCIAL SUPPORT AND STIGMA

- Do you avoid your friends or relatives because of your illness? Yes (…)
- No (…)
- Do your friends or relatives avoid you because of your illness? Yes (…)
- No (…)
- Do your friends or family members help you remember to take your medication? Yes
- (…) No (…)

In general, are you satisfied with the overall support you get from your friends and family members? Yes (...) No (...)

COUNSELING / ATTITUDE TOWARDS CARE PROVIDER

28. Did you receive counseling (did someone talk to you about your condition, treatment and answer your questions about your condition)

Before you started your treatment? Yes (...) No (...)

Do you receive adherence counseling (information on how to take your drugs and why its very necessary to do so) during your treatment? Yes (...) No (...)

Do you receive counseling on every day you come to the clinic? Yes (...) No (...)

Do your ART providers spend enough time with you? Yes (...) No (...)

Do you trust your care provider enough to share personal problems with him/her? Yes (...) No (...)

Would you say the care you receive from your care providers is Excellent (...) Acceptable(...)poor (...)?

MENTAL STATUS

29. Do you have any of the following

Not currently able to sleep well? Yes (...) No (...)

Do not feel relaxed after sleeping? Yes (...) No (...)

Do not have good appetite for food? Yes (...) No (...)

Constantly feel tired? Yes (...) No (...)

Find it difficult to concentrate on your school/work? Yes (...) No (...)

Frequently feel sad or hopeless? Yes (...) No (...)

Blame others for your illness? Yes (...) No (...)

SUBSTANCE USE

30. Do you take alcohol Yes (...) No (...)

31. Do you use any of the following substances?

Cigarettes Yes (...) No (...)

Bhang Yes (...) No (...)

Miraa Yes (...) No (...)

Cocaine (Powder, crack, injections) Yes (...) No (...)

Sniffing glue Yes (...) No (...)

Other (specify).....

APPENDIX 4: CLINICAL RECORDS

CD4 COUNTS

CD4 COUNT	BASELINE DATE	MONTH 6 DATE	OTHER DATE
ABSOLUTE COUNT			
PERCENTAGE			
VIRAL LOAD			

PHARMACY REFILL

Visit	Expected date of refill	Date of refill	Expected no. of pills remaining	Pills counted
1				
2				
3				

HOSPITALIZATION/OUTPATIENT TREATMENT

In-patient	Date/ Duration				
	Diagnosis				
Out-patient	Date				
	Diagnosis				

APPENDIX 5: GUIDE QUESTIONS FOR FGDS

(Exclude adolescents who have not been disclosed to their HIV status)

Instructions to the facilitator: introduce yourself and make the participants feel comfortable. Have the participants introduce themselves. Thank them for agreeing to participate and reassure them of confidentiality. Request permission to tape record the session.

We would like to talk about HIV and how it affects you.

How has HIV affected you?

How has your status affected your family?

How has your status affected your relationship with friends and colleagues?

Let us talk about ART, what do you know about ART?

What do you feel about ART?

What do other people say about ART?

Are other people convinced that ART is necessary? If no, why not?

Many people are not able to take their ARV drugs the way they are supposed to, what do you think are the reasons for this?

What do you think can be done to help people on ART take their medication better?

Instructions to facilitator: Thank the participants for their time and participation.