

**KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY,  
KUMASI**

**COLLEGE OF HEALTH SCIENCES  
SCHOOL OF PUBLIC HEALTH  
DEPARTMENT OF HEALTH PROMOTION AND EDUCATION**



**ASSESSMENT OF HIV/AIDS PATIENTS' ADHERENCE TO THE SINGLE  
MOLECULAR FIXED-DOSE COMBINATION THERAPY OF HIGH ACTIVE  
ANTI RETROVIRAL THERAPY AT THE SUNTRESO GOVERNMENT  
HOSPITAL, KUMASI, GHANA**

**VIVIAN ACHEAMPOMAA ADU (BSC. NURSING)**

**NOVEMBER, 2015**

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**BY VIVIAN ACHEAMPOMAA ADU (BSC. NURSING)**

**A THESIS SUBMITTED TO THE DEPARTMENT OF HEALTH EDUCATION  
AND PROMOTION, COLLEGE OF HEALTH SCIENCES, SCHOOL OF PUBLIC  
HEALTH IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE  
AWARD OF MASTER OF PUBLIC HEALTH DEGREE IN HEALTH  
PROMOTION AND EDUCATION**

**NOVEMBER, 2015**

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## DECLARATION

I hereby declare that this submission is my own work towards a Master of Public Health Degree (MPH) and that, to the best of my knowledge, it contains no material previously published by another person, nor material which has been accepted for the award of any other degree of the university, except where due acknowledgement has been made in the text.

Vivian Acheampomaa Adu .....  
Signature Date

Dr. (Mrs.) Agatha Bonney .....  
Supervisor Signature Date



Head of Department

Signature

Date

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I dedicate this thesis to my dear parents, Mr. and Mrs. Adu (JOEGANI)



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I owe it a debt of gratitude to Dr. (Mrs.) Agatha Bonney, my supervisor, for her objective criticisms, motivation, invaluable suggestions towards the completeness of this work.

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## LIST OF ABBREVIATIONS

<b>AIDS</b>	:	Acquired Immune Deficiency Syndrome
<b>AMR</b>	:	Antimicrobial Resistance
<b>ART</b>	:	Antiretroviral Therapy
<b>ARV</b>	:	Antiretroviral
<b>cART</b>	:	Combination Antiretroviral Therapy
<b>DNA</b>	:	Deoxyribonucleic Acid
<b>EIA</b>	:	Enzyme Immunoassay
<b>ELISA</b>	:	Enzyme-Linked Immunosorbent Assay
<b>FDC</b>	:	Fixed-Dose Combination
<b>HAART</b>	:	Highly Active Anti-Retroviral Therapy
<b>HBV</b>	:	Hepatitis B Virus
<b>HCP</b>	:	Health Care Professional
<b>HIV</b>	:	Human Immunodeficiency Virus
<b>NNRTI</b>	:	Non-Nucleoside Reverse-Transcriptase Inhibitor
<b>NRTI</b>	:	Nucleoside Reverse Transcriptase Inhibitor
<b>PI</b>	:	Protease Inhibitor
<b>PMTCT</b>	:	Prevention of Mother to Child Transmission (of HIV)
<b>QALY</b>	:	Quality-Adjusted Life Year
<b>RNA</b>	:	Ribonucleic Acid
<b>S/R Test</b>	:	Simple or Rapid HIV antibody test
<b>TB</b>	:	Tuberculosis
<b>TDF</b>	:	Tenofovir Disoproxil Fumarate
<b>UNAIDS</b>	:	Joint United Nations Programme on HIV/AIDS
<b>WHO</b>	:	World Health Organization

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## ABSTRACT

The study assessed the HIV/AIDS patients' adherence to the single molecular fixed-dose combination therapy of High Active Anti-Retroviral Therapy (HAART) at the Suntreso Government Hospital, Kumasi, Ghana. A cross-sectional study design was employed. The study systematically sampled 322 PLWHIV/AIDS from the STI unit of the Suntreso Government Hospital. The respondents were patients attending clinic within the period of the study. The study relied on primary data which were collected with structured questionnaire. The questionnaire for the study was pre-tested in Kwadaso S.D.A Hospital in Kumasi. The study aimed at finding out the influence of condition-related factors, healthcare providers' factors, patient-related factors and therapy-related factors on Fixed Dose Combination (FDC)

ART adherence. It was concluded that HIV/AIDS patients at the Suntreso Government Hospital were anxious, had adequate information on FDC and perceived FDC as good for improvement of health status and they were not forgetful to take FDC as prescribed. HIV/AIDS patients were supported by their families but they were stigmatized. HIV/AIDS patients disagreed that they had guidance and counselling services at homes. The study revealed that HIV/AIDS patients had good interpersonal relationship with healthcare providers and that healthcare providers gave them adequate information on FDC but patients perceived healthcare providers as not trustworthy. HIV/AIDS patients perceived cost of medications as expensive but could afford cost of transport. It was realized that FDC was convenient to take but it had side effects. It was recommended that patients should freely disclose their status and take FDC as prescribed without focusing on the side effects. Healthcare providers should show care, love and respect through friendly relationship to encourage regular hospital attendance by HIV/AIDS patients in order to increase adherence to medications.

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## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background of the study

Human Immunodeficiency Virus (HIV) infection leads to the development of the Acquired Immunodeficiency Syndrome (AIDS). The human immunodeficiency virus (HIV) epidemic continues to be a major public health problem, particularly in subSaharan Africa where 67% of infected people live and where 75% of AIDS deaths occurred in 2007 (Howley et al., 2010). However due to drug toxicities, treatment failure, development of drug resistance and the complexity associated with the selection of a specific treatment, the severity of the related side effects and the necessity of preventing the appearance of resistant viral strains lead to the treatment of HIV-1 with a combination of antiretroviral agents (Duse et al., 2008; Homar et al., 2012). The introduction of a combination of antiretroviral agents in the mid-1990s led to a marked reduction in morbidity and mortality from HIV infection (Freeney & Mallon, 2011).

Over the years several studies have demonstrated significant immunologic recover and suppression of viral replication with Highly Active Antiretroviral Therapy (HAART) (Howley et al., 2010; Luma et al., 2012). Subsequently more compact Antiretroviral Therapy (ART) regimens has been created by taking advantage of Fixed-Dose Combination (FDC) products which consist of two or more antiretroviral drugs in a single tablet. The combination of the three or more active drugs has been known to effectively suppress the variety of resistant HIV that can exist within a viral population (Loutfy et. al.,

2007). The FDC antiretroviral product has become a mainstay in the treatment of HIV. To date, most FDC for HIV treatment have consisted of combinations of Nucleoside Reverse Transcriptase Inhibitor (NRTIs) which form the backbone of the ART regimen. The FDC has been introduced to reducing pill burden, or dosing frequency and/or dosing requirements compared to other drugs in the FDC's therapeutic class.

For HIV-infected patients on Highly Active Antiretroviral Therapy (HAART), adherence is of outmost importance. Poor adherence may lead to treatment failure, selection of viral mutations and development of drug resistance. Bagchi and others (2010) noted that poor adherence and the subsequent development of resistance is a primary cause of regimen failure. This has been confirmed by Naing and others (2001) that patient non-adherence to drug regimens has been identified globally as a major public health problem. Thus, adherence in general has been a well-known problem in medicine, especially in chronic and non-symptomatic diseases and according to Miller, (1997) keeping treatment has proven difficult for patients. Optimal adherence is thought to be difficult even though high levels of adherence are needed in order to maintain therapeutic drug levels in the blood. A high level of regimen adherence is therefore a critical and necessary component of successful treatment of HIV.

Nevertheless, adherence itself can be considered as an ever-changing and adapting process which could be influenced by a number of factors. Kleeberger and others (2001) were of the view that socio-economic, health-related, treatment-related, and behaviorrelated factors are the factors that could influence adherence to ART. For instance, Airoidi and others,



(2010) re-iterated that the complexity of medication regimens is often cited as one of the most important adherence barriers to HAART. Airoldi and others have shown that number of regimen attributes, such as the number of daily pills, frequency and timing of doses, dietary restrictions, adverse events, medication storage requirements are seen by patients as major factors making adherence difficult to the proposed HAART regimen. Several studies have also explored how the reduction of pill burden and/or daily doses could affect adherence to antiretroviral regimens. Although the general conclusion of the various studies conducted have been that simpler regimens such as the newly introduced FDC pill were associated with better adherence rates, yet, at least, the subjective tolerability by PLWHIV/AIDS to this newly introduced FDC pill cannot, therefore, be ruled out. In retrospect, there could be a failure to understand the relationship between the patients' perception and acceptance of the FDC pill, treatment regimen (adverse effect), and social environment to this newly introduced FDC pill, among others. The need therefore to assess the HIV/AIDS patients' perception and acceptance of FDC pill, treatment regimen (adverse effect) of the FDC pill, and the social environment to this newly introduced FDC pill could be in the right direction.

## **1.2 Problem Statement**

HIV/AIDS continue to be one of the most serious health issues facing the world today. The UNAIDS estimates that globally, an estimated 32.2–38.8 million people were living with HIV in 2013. Over 1.8 million people lost their lives due to HIV related complication in 2010 alone and many more continue being infected annually with 2.7 million new cases of



HIV (UNAIDS 2013). HIV prevalence has witnessed marginal changes from a prevalence of 5.9% in 2001 to 5% in 2013.

Sub-Saharan Africa records about 68% of those living with the virus. The region also accounts for 70% of all new infections globally and has resulted to loss of 1.2 million lives as at the end of 2013 (UNAIDS 2013). UNSIDS further remarked that countries in the south continue to shoulder a huge HIV burden with high prevalence rates as high as 23.9% in Botswana, 26.1% in Swaziland and 23.2% in Lesotho. Ghana AIDS Commission report in 2013 showed that 225,478 persons made up of 100,336 males and 125,141 females are living with HIV in Ghana. The report further indicated that there were 12,077 new infections and 15263 AIDS deaths and 30,395 children living with HIV. A total of 1,704 new child infections occurred in almost equal proportions by gender and HIV prevalence rate is now 1.7% in Ghana.

Antiretroviral therapy coverage among people with advanced HIV infection was 15% with Ghana being 38th rank in Africa and 31% of global average (Health Sector Report in Ghana, 2010). Nevertheless, adherence with the treatment regimen of HIV/AIDS disease has been a problem. Poor adherence has led to treatment failure, selection of viral mutations and development of drug resistance (Rodriguez-Rosado et al., 1998) and virological failure in HIV-infected patient (Bangsberg et al., 2012).

The situation in the Kumasi Metropolis might not be different from this factual evidence about the HIV/AIDS patients' adherence to ARVs as been reported in certain parts of the

globe. In the study area (Suntreso Government Hospital- STI UNIT), there are about 3.2 infection rate of HIV/AIDS. Ashanti region recorded 1,737 new cases of HIV/AIDS (Ghana Nsem-Fact Files, 2014). The evolution of HAART over the years from a regimen of high pill burden and frequent dosing (more than 20 pills per day) to the current regimen made up of a combination of three ARVs from at least two drug classes (Buscher et al, 2012; Homar et al, 2012) brought relief to the PLWHIV across the country. However, there has been a poor adherence which has led to treatment failure.

In the study area, there has not been any known appraisal on the impact of the single dose therapy on patients in terms of its acceptability, drug toxicities and adverse drug effects. Besides, most antiretroviral drugs have been validated in developed countries (primarily in white populations) but are now being widely used in developing countries, where the vast majority of HIV-infected people live (Subbaraman et al., 2007). Hence, there has not been any research conducted on the actual stakeholders' view on how these HIV/AIDS patients adhere to the newly FDC pill to assess how they are coping with it.

This study therefore seeks to assess how PLWHIV/AIDS in Ashanti region adhere to this newly FDC pill medication/therapy. Thus, the social and economic factors on adherence of the FDC pill, health care team/system factors on adherence of the FDC pill, therapyrelated factors on adherence of the FDC pill, influence of patient-related factors on adherence of the FDC pill and condition-related factors dimensions of adherence would be assessed. It further seeks to find out if PLWHIV/AIDS adherence to the newly introduced FDC pill differs significantly from that of the old medication regimen.

### **1.3 The Rationale for the Study**

For medicines to be effective it is required that prescribers must prescribe properly, dispensers must dispense correctly and patients must use them as instructed (WHO, 2012). However, the decision to take any medicine ultimately lies with the patient based on some certain adhering factors. Since effective taking of prescribed drugs is a necessary condition for effective therapy, it is imperative that adherence to the newly FDC pill is assessed. Besides, a default in drug uptake may lead to development of viral resistant strains and poor quality of life.

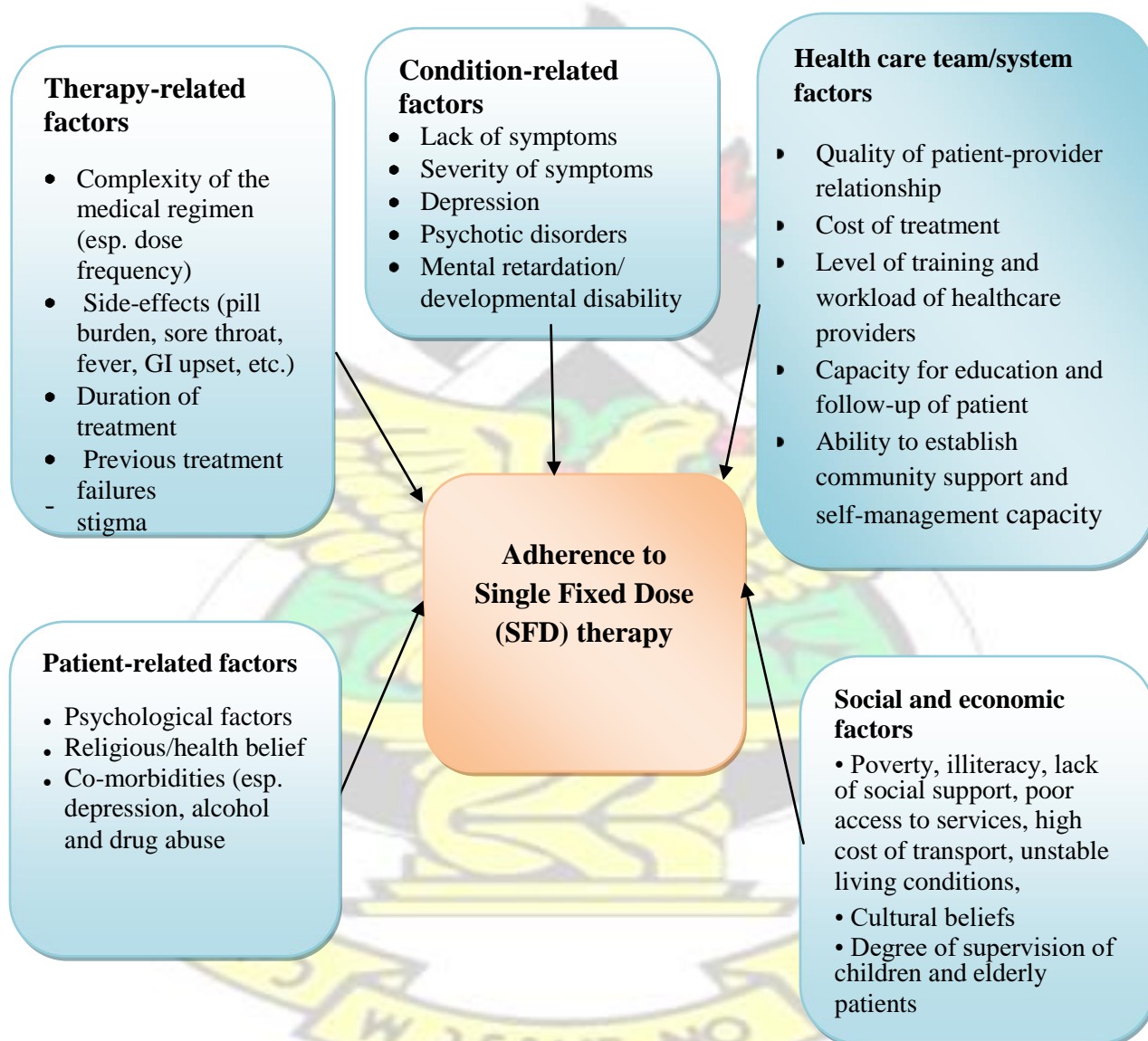
A study of the assessment of the PLWHIV/AIDS adherence to FDC pill is important for several reasons. First, it will underscore the underlying determinants /factors of adherence to the FDC drug, the knowledge of which could help improve healthcare delivery towards PLWHIV/AIDS as well as the health status of PLWHIV/AIDS in the country. Secondly, it is however, unclear how the newly introduced FDCs are accepted by the HIV clients at the Kumasi metropolis. A clearer understanding of how this could help direct policies on further HAART treatment for the country. In addition, policy makers like the Ministry of Health (MOH) / Ghana Health Service (GHS) and other Non – Governmental Organization (NGO) [such as United Nations Population Fund (UNFPA), UNAIDS], concerned with the welfare of PLWHIV/AIDS, and getting a clearer understanding of the major reasons for acceptance/rejection of the newly introduced FDCs among PLWHIV/AIDS, will help them know the exact situations on the ground and how best to deal with it. Moreover, the study will contribute to the existing body of knowledge on the subject of FDC and can stimulate further research in

HIV/AIDS and adherence by providing areas for future research.

#### 1.4 Conceptual Framework

The conceptual framework of this study is shown in Figure 1.1

**Figure 1.1: Conceptual Framework**



**Source:** Modification of —**Dimensions of Adherence** (WHO, 2003)

The conceptual framework as shown in Figure 1.1 is about the factors associated with the adherence to the single fixed dosage therapy regime. It shows for instance, how pill burden,



adverse drug reactions, dosage frequency, among others, influences the acceptance of the single fixed-dose therapy regime. This conceptual framework has been designed to correspond with the objectives of this study. In this study, adherence to FDC by PLWHIV were identified as the dependent variables while Therapy-related factors, Healthcare teams/systems, Patient-related factors, Social and economic factors, Condition-related factors on adherence of the FDC pill were identified as the independent variables.

Therapy-related factors were conceptualized as a construct with five interrelated factors; complexity of the medical regimen (esp. dose frequency), side-effects, duration of treatment, previous treatment failures, and medications with social stigma attached to use, among others, could determine whether PLWHIV could adapt or adhere to the use of the FDC. The single fixed dose therapy (SFDT) like all medication has adverse effects like fatigue, headache, sore throat, fever, GI upset etc. and these unpleasantly could influence patient adoption and acceptance of the SFDT.

Patient-related factors were conceptualized as a construct with psychological factors, religious/health belief and co-morbidities (esp. depression, alcohol and drug abuse). Human behavior or action is often backed by reason. Patients will accept or adapt to the single fixed dose therapy based on their perception or belief about the therapy. Their perception and ultimate acceptance of the single fixed dose therapy (SFDT) hinges on perception that the SFDT might (not) be a pill burden on them, the efficacy of the SFDT, the dosage frequency of the SFDT and its resultant impact on their health statuses as obvious in Figure 1.1.



Provider - Patient factors were conceptualized as a construct with its interrelated factors such as the quality of patient-provider relationship, reliability of medication distribution systems, lack of positive reinforcement from the health care provider, long wait times, weak capacity of the system to educate patients and provide follow-up, provider communication skills (contributing to lack of patient knowledge or understanding of the treatment regimen), patient information materials written at too high literacy level, could all determine patients adherence to FDC drug. For instance, awareness or knowledge by patients on the side effects and dosage of the single fixed-dose therapy could also be critical in stimulating HIV victims receipt and adaptability of the single fixed-dose therapy regime.

Condition-related factors were conceptualized as a construct with interrelated factors such as the lack of symptoms, severity of symptoms, chronic conditions and psychotic disorders. Condition-related factors are factors that refer to the symptoms or infections that an individual may acquire or experience because of a weakening immune system response caused by HIV on the body's defense cells (Naicker, 2011). For instance, previous opportunistic infections and time period of disease could be influencing factors towards the acceptance of the single fixed-dose therapy by patients as represented in Figure 1.1. Thus, patients who have had serious opportunistic infections may perceive their illness to be severed and adhere better to their treatment.

Social and economic factors were conceptualized as a construct with its interrelated factors; lack of family or social support network, unstable living conditions, medication cost,

poverty, illiteracy, high cost of transport, degree of supervision of children and elderly patients. The patient's social circumstances and their interpretations of them could lead to adherence level of PLWHIV. For instance, social isolation could increase the risk of decreased compliance with medication among PLWHIV. Social supports towards such things as reminder to take FDC, encouragement to visit the clinic and being accompanied to visit the health could depend on the patient's social environment. Patients with supportive family and friends could tend to adhere better to ART than those lacking this type of support.

These factors of adherence as presented in Figure 1.1 are consistent with the classification done by Reisner and others (2009) and WHO (2003) who arrived at the categories after conducting a content analysis on all factors studied by several studies on factors associated with adherence to ART. These classifications are similar to that arrived at by Naar- King and others (2006) and Mehta and others (1997). All the theories previously reviewed predicted a relationship between the independent and the dependent variables, with regards to HIV drug adherence.

### **1.5 Research Questions**

This study seeks to find answers to the following questions;

1. What specific healthcare providers and the health care system factors influence adherence to FDCART in the Suntreso Government Hospital- STI Unit?
2. What specific patient-related factors influence adherence on the FDC ART in the Suntreso Government Hospital-STI Unit?

3. What specific social and economic factors influence adherence to FDC ART in the Suntreso Government Hospital- STI Unit?
4. What specific therapy related factors influence adherence to FDC ART in the Suntreso Government Hospital-STI Unit?

### **1.6 Objectives of the Study**

The main objective is to assess the HIV/AIDS patients' adherence to the Fixed Dose Combination antiretroviral drugs at the Suntreso Government Hospital-STI Unit.

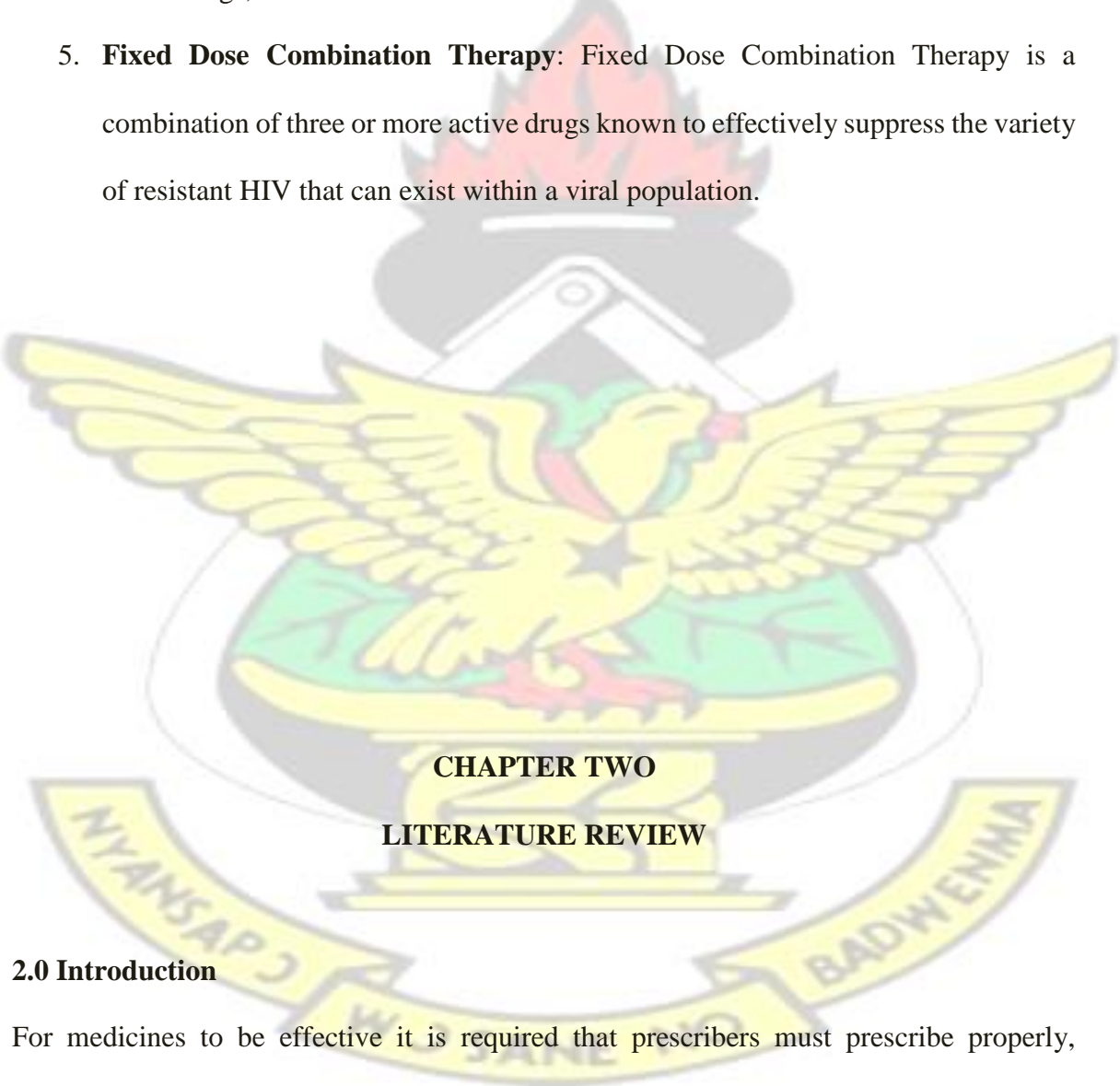
This research is guided by the following specific objectives:

1. To determine the healthcare providers and the health care system that contribute to PLWHIV/AIDS non - adherence of the FDC pill in the Suntreso Government Hospital-STI Unit.
2. To identify the influence of patient-related factors on adherence of the FDC pill
3. To assess the perceived social and economic factors on adherence of the FDC pill.
4. To assess the therapy-related factors on adherence of the FDC pill among PLWHIV/AIDS who visit Suntreso Government Hospital-STI Unit.

### **1.7 Definition of Terms**

1. **Adherence** - Patients ability to follow a treatment plan, take medications at the prescribed time and frequencies and follow restrictions regarding food and other medications. In this study, adherence is defined as taking 95% of the prescribed doses in the week before the survey.

2. **PLWHIV/AIDS:** - All people living with HIV/AIDS -Although the World Health Organization (WHO) considers young people as those aged 10-24 years this study has looked at all people as those aged from infancy to adulthood.
3. **Antiretroviral adherence** - Compliance in taking prescribed ARV medications.
4. **Combination therapy:** Combination therapy refers to treatment with two or more active drugs, administered at one time in their individual formulations.
5. **Fixed Dose Combination Therapy:** Fixed Dose Combination Therapy is a combination of three or more active drugs known to effectively suppress the variety of resistant HIV that can exist within a viral population.



## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.0 Introduction**

For medicines to be effective it is required that prescribers must prescribe properly, dispensers must dispense correctly and patients must use them as instructed (WHO, 2012).

However, the decision to take any medicines ultimately lies with the patient. This chapter



discusses the review of related literature on adherence to Single Fixed Dose Combination therapy by PLWHIV/AIDS and how that could affect their health conditions. It also discusses the review of HIV/AIDS, adherence, and Fixed Dose Combination.

## **2.1 HIV/AIDS and HAART**

Human Immune-deficiency Virus (HIV) is a virus that attacks the human immune system. It destroys the body's natural ability to fight off disease and other infections, causes people to be more susceptible to diseases and leads to Acquired Immune Deficiency Syndrome (AIDS) with its resultant peripheral illnesses such as malaria, tuberculosis, or various STDs. WHO (2007) was however of the view that HIV should be defined in line with a public health approach and to facilitate the reporting of HIV infection, it is recommended that a case of HIV infection is defined according to an individual's infection irrespective of clinical stage (including AIDS) and confirmed by laboratory criteria according to country definitions and requirements. What is therefore not clear is how countries develop and regularly review their testing algorithms for diagnostic and surveillance purposes. A simplified HIV case definition designed for reporting and surveillance would be in right direction.

There has been a rapid evolution of the HIV disease exhibiting Antimicrobial Resistance (AMR) and in particular, Multiple Drug Resistance (MDR) (Gupta et al, 2001). To delay or even prevent the disease, combining drugs with different targets as so-called —free combinations or —fixed\_dose combinations therapy has been the subject of continuing



interest in recent times. The Fixed Dose Combination therapy is combination of three or more active drugs known to effectively suppress the variety of resistant HIV that can exist within a viral population. Nucleoside Reverse Transcriptase Inhibitor (NRTI) zidovudine (AZT) was among the first and early effective Anti-Retroviral Therapy (ART) against HIV introduced in 1987 (New York Times. 1987-03-21) and subsequently several more NRTIs were developed in combination with other drugs but were unable to suppress the virus for long periods of time and patients still inevitably died (New York Times. 1987-03-21). The term Highly Active Anti-Retroviral Therapy (HAART) was introduced to the fact that viral dynamics data showed that the average person with HIV infection produced 10 billion virions/day, bringing into sharp focus the fact that more potent treatment was necessary to completely suppress viral replication. Thus the term Highly Active Anti-Retroviral Therapy (HAART) was distinguished from this early AntiRetroviral Therapy (ART). Therefore, 2 NRTIs with a new class of anti-retroviral, protease inhibitors, namely Indinavir were combined. This concept of 3-drug therapy was quickly incorporated into clinical practice and rapidly showed impressive benefit with a 60% to 80% decline in rates of AIDS death, and hospitalization. Mortality and morbidity associated with HIV disease have dramatically been reduced.

Currently, the introduction of the FDC antiretroviral product has become a mainstay in the treatment of HIV. Combination antiretroviral therapy (cART) has thus become the standard of care for people living with Human Immunodeficiency Virus (HIV) and has resulted in profound reductions in the incidence of Acquired Immune Deficiency Syndrome (AIDS) and AIDS-related mortality (Loutfy et al, 2007).

## **2.2 Fixed-Dose Combinations (FDCs)**

Combination therapy refers to treatment with two or more active drugs, administered at one time in their individual formulations. Similarly, the Fixed Dose Combination Therapy is combination of three or more active drugs known to effectively suppress the variety of resistant HIV that can exist within a viral population. Combination therapy and fixed-dose combination (FDC) formulations have been used in the management of TB and according to Cohen and others (2001) combination therapy has proven successful in the treatment of cancer, infectious diseases, hypertension and neurological disorders.

Combination therapy in a standardized regimen has been the fundamental strategy of WHO and International Union Against Tuberculosis and Lung Disease (IUATLD) for treatment of diseases such as TB (Blomberg, et al, 2001). They explained that increase in the number of drugs to be taken could rather increase the problem of patient compliance. For instance, —Combo.packs for TB treatment (in which all the pills to be taken at one time are packed together to reduce the chances of a patient missing doses) were an attempt to solve this problem. However, with the use of the combo.packs, patients still failed to take the drugs by choosing some and leaving out others. The concept of FDCs came as a further step in the solution of this problem.

The FDCs have since then been available for treatment of other diseases and have long been regarded as a standardized, simpler and potentially more reliable way of treating

HIV related diseases such as tuberculosis (TB). Currently, guidelines from World Health Organization (WHO) and many other international bodies recommend the use of FDC formulations as a step to facilitate the optimal treatment of TB (Blomberg et al, 2001) and HIV/AIDS. However, unlike TB treatment, HIV therapy (being life-long) is more demanding. Hence, the use of FDCs to treat HIV infection for long periods of time has been crucial.

Connor (2003) was of similar view and indeed argued that the use of the FDC for treatment of HIV/AIDS has a reduced ability to tailor medication to individual needs. Kaplan, (2003) however added that FDCs dosing is inflexible and cannot be regulated to patient's needs. He argued that each patient has unique characteristics such as weight, age, pharmacogenetics, co-morbidity, and this may alter drug metabolism and effect. Besides, to Kaplan, FDCs are even (possibly) more expensive than separate tablets. To him, FDCs have potential quality problems, especially with rifampicin in FDCs for TB, requiring bio-availability testing. Again, reaction of one of the components (e.g., a rash to sulfamethoxazole in cotrimoxazole) may result in patient avoiding the —innocent trimethoprim in the future. Thus, drug interactions may lead to alteration of the therapeutic effect.

A study conducted by Njamnshi and others (2012) on adverse drug reactions of HAART in HIV infected patients at the General Hospital, Douala, Cameroon using a cross sectional study revealed that 19.5% of the 339 patients on HAART reported Adverse Drug effects (ADRs). Their study concluded that HAART - associated ADRs are common and



therefore should be actively looked for by caregivers so as to ameliorate the quality of life of HIV patients on treatment (Namme et. al., 2012).

Even though there could be problems with the use of FDCs, yet FDC to treat HIV/AIDS could be potentially reliable (Kaplan, 2003). Warren Kaplan was of the opinion that FDCs may be better than free combinations in that it could slow or even eliminate Antimicrobial Resistance (AMR). To him, simpler dosage schedule improves compliance and therefore improves treatment outcomes; reduces inadvertent medication errors; prevents and/ or slows attainment of antimicrobial resistance by eliminating monotherapy (i.e., one drug is never by itself in circulation); allows for synergistic combinations (i.e., trimethoprim/sulfamethoxazole combination), allows each drug to selectively interfere with successive steps in bacterial folate metabolisms; eliminates drug shortages by simplifying drug storage and handling, and thus lowers risk of being "out of stock". Side effects are reduced by using one drug and the potential for drug abuse can be minimized (i.e., excessive use of the antidiarrheal narcotic diphenoxylate is discouraged by side effects of atropine in the FDC atropine + diphenoxylate).

Kaplan argued further that there are multiple interruptions when using free dose combinations of pills and this could create the risk of monotherapy on some drugs and not in others. This fact, coupled with the in vivo mutation rates of the genome, rapidly could lead to drug resistance to one or more of the free combination drugs. However, Fixed\_dose combinations make the possibility of monotherapy even more remote.



Kaplan argued that effectiveness of FDCs, however, depends on detailed knowledge of the epidemiology and microbial ecology of the particular pathogen. To him, HIV, malaria, or TB, development of AMR, etc. commonly occurs by rapid genetic alterations, and so if evolution of AMR is occurring within a host during course of therapy (which in the case of HIV or TB is quite long), then FDCs would theoretically be effective if more than one drug is present in therapeutic concentration at any one time. In effect, Connor, (2003) added that FDCs are designed to reduce both the pill burden and the dosing frequency.

Pan (2008) conducted a study on the impact of Fixed-Dose Combination Drugs on adherence to prescription medications. The objective of the study was to compare adherence of a FDC [Glucovance, a FDC of metformin and glyburide] to a 2-pill regimen. Longitudinal data from a large claims database were used to assess adherence from January 1, 2000, to December 31, 2001. Propensity scoring methods were used to mitigate concerns related to non-random assignment of patients to treatments. The subjects of the study were individuals prescribed metformin or sulfonylurea or both before July 2000, who were prescribed both metformin and sulfonylurea concurrently (either separately or FDC) after August 2000. Adherence was measured by medication possession ratio; the proportion of days on which a patient had medication available. The results were that the FDC enhanced adherence rates by approximately 13% when compared to a 2-pill regimen. The study therefore concluded that as compared to 2-pill therapy, a FDC resulted in important increases in patient adherence. Economic analyses could therefore be warranted to determine whether the clinical benefits attributable to the adherence gains are worth the incremental cost of a FDC.

A similar study was conducted by Mosen and others (2010) on the effect of once-daily FDC treatment era on initiation of cART. With the study design of retrospective observational analysis, the study sought to determine whether implementation of oncedaily FDC regimens was associated with changes to cART initiation. Electronic medical records between July1999 to June 2006 were queried to identify incident cases of detectable HIV infection in antiretroviral-naïve adults. Cox regression with timedependent covariates was used to examine the effects of once-daily FDC era, clinical, provider, and treatment regimen characteristics on cART initiation. The results showed that once-daily FDC availability did not change the likelihood of cART initiation, but other characteristics were associated with an increased likelihood. The study therefore concluded that availability of once-daily FDC-based regimens did not affect likelihood of cART initiation. Patient clinical characteristics appear to be more important predictors of cART initiation.

### **2.3 ADHERENCE**

Medicines are only effective when prescribers prescribe properly, dispensers dispense correctly and patients use them as instructed (WHO, 2012) However, the decision to take any medicines ultimately lies with the patient. Adherence is therefore the patient's ability to follow a treatment plan, take medications at the prescribed time and frequencies and follow restrictions regarding food and other medications. In support of this definition, Paterson et al, (2004) argued that adherence is the act or quality of sticking to something, steady devotion; and the acceptance of an active role in one's own health care.

Ordinarily, it is the patient requirements to follow instructions. Unlike compliance (the need for a patient to follow medical instructions exactly as directed by Health Care Professional (HCP), adherence is the ability to take into consideration priorities and beliefs about medicine taking, and it regards patients as passive recipients of instructions to which they must comply (Munro et. al., 2007).

The use of the word —adherence has been advocated as it implies greater involvement of the patient in decision-making about their health and it is not as despotic (Munro et al., 2007). According to World Health Organization Adherence Project (2003), adherences to prescribed medicines are regarded as the extent to which a person's medication-taking behaviour, following a diet, and/or executing lifestyle changes, corresponds with the agreed recommendations of the HCP.

Munro and others, (2007) shared the need for adherence and argued that as a result of the rapid replication and mutation of the HI virus, it is extremely necessary that high levels of adherence of more than 95% in order to achieve durable viral load suppression is needed. Sub optimal adherence may rapidly lead to resistance, which is a serious public health issue as the resistant virus can in turn be transmitted to other people (Ayenigbara, 2012).

Studies have found that adherence to ART is associated with improved clinical outcomes (AIDSinfo, 2014). A large clinical cohort study conducted in British Columbia using a multivariate analysis, clearly showed that the development of HIV drug resistance had strong associations with an adherence of between 60% and 90%, drug interactions and/or malabsorption issues as well as a high baseline viral load (Bangsberg, 2006). Similarly,



Paterson et al (2004) measured adherence using plasma viral load as an effectiveness indicator. The study was conducted on 81 HIV-infected patients on a protease inhibitor regimen and adherence was monitored, over a period of 6 months, by the use of electronic monitors attached on the medicines bottles. During the duration of the study, 81% of patients with an adherence of more than 95% maintained undetectable viral load, whereas only 64% of those with 90 - 95%, 50 % of those with 80 - 90%, and 30% of those with less than 80% adherence maintained this. It was shown that for every 10% decrease in adherence, mortality increased by 16%. Adherence at levels less than 95% independently predicted viral resistance, hospital admissions and the occurrence of Opportunistic Infections (OIs).

In a related study conducted by Bangsberg and colleagues (2006), none of the patients with an adherence of more than 90% progressed to AIDS, whereas in those with adherence rates of less than 50% and between 51 - 89%, 38% and 8% respectively progressed to AIDS. The study also emphasized that there is a direct link between adherence and therapy failure resulting in the progression to AIDS (Bangsberg and colleagues, 2006).

Invariably, the above studies and other studies conducted reveal that the large number of medicines involved in HAART, the complicated dosing requirements and the sub-optimal tolerability result in variable adherence. A cross-sectional study on 109 HIV-infected ambulatory patients on HAART that assessed beliefs about therapy and their association with adherence, showed that adherence was related to the necessity-concerns differential (NCD); this implies that low adherence may be a result of an implicit 'risk-benefit' analysis



in which beliefs about the necessity of HAART for maintaining health now and in the future are balanced against the concerns about the perceived adverse effects.

A personalized approach that includes careful drug selection, routine follow-up, the provision of information, and feedback and reminder systems, were some of the recommendations that may optimize patient adherence to HAART (Bangsberg et al. 2006). Ongoing patient education and adherence monitoring has been shown to play a significant role in the success of HAART. Throughout the literature, a number of studies aimed at assessing the effectiveness of adherence interventions concluded that adherence could be successful if educational program and supportive counseling are enhanced.

#### **2.4 ADHERENCE AND HAART**

HAART has been a life-long treatment that has consisted of multiple medications to be taken two to three times a day with varying dietary instructions. However, over the past decade, there has been a rapid change in treatment strategies for HIV infection. Antiretroviral treatment moved from mono-therapy and bi-therapy to triple drug therapy or Highly Active Antiretroviral Therapy (HAART). Thus, ARV programs became one of the foremost concerns and that the standard treatment protocol for PLWHIV/AIDS was to maintain near perfect adherence over the long term. But in order to achieve the goal of antiretroviral therapy (ART) and to maintain near perfect adherence over the long term patients are required to maintain more than 90–95% adherence to HAART (WHO, 2003 and Paterson et al., 2004). Unfortunately, non-adherence has become common among individuals treated with HAART. Consequently, inadequate adherence to treatment to HAART has been associated with detectable viral loads, declining CD4 counts, disease

progression, episodes of opportunistic infections and poorer health outcomes. Besides, HAART medications have been associated with side effects, some of which are temporary while others have been more permanent which would require a change of treatment.

Several studies have shown varying levels of adherence to HAART and its medications. According to Chesney and others (2000) about 10% of patients reported missing one or more medication doses on any given day, and about 33% reported missing doses in the previous two to four weeks. They saw this as a problem and argued that the rates of nonadherence to HIV therapies are comparable to those for other chronic illnesses with the exception of other chronic diseases such as hypertension or diabetes, where lower levels of adherence (around 70–80%), are considered adequate to achieve treatment goals.

## **2.5 ADHERENCE ASSESSMENT AND HAART**

With ART, near perfect adherence levels greater than 95% is required to obtain a successful treatment outcome (Bangsberg et al, 2012). Paterson and others (2004) were of the similar view that in order to achieve the goal of antiretroviral therapy (ART) and to maintain near perfect adherence over the long term patients are required to maintain more than 90–95% adherence to HAART. Missing one dose of a medication to missing a single dose of all three or four medications to missing multiple doses or all doses a day or week and/or not observing instructions regarding dietary or fluid intake or not taking medications at prescribed time intervals all constitutes non-adherence. Assessing adherence therefore is problematic and according to Yeni and others (2002) predictors of adherence significantly differ across populations and settings, and no single factor has been consistently linked

with adherence. As a result, Yeni and others argued that HCPs tend to underestimate patient adherence problems as they are difficult to identify and assess accurately, whereas patients tend to misreport their adherence levels.

Apparently, Yeni and others (2002) argued that direct and indirect methods could be used to assess patient adherence. Direct measurements involve the detection of a chemical in the body fluid while the indirect measurements are either by patient self-reports, pill counts, patient interviews, therapeutic or preventative outcomes and by the use of recording devices. Paterson and others (2004) further added that adherence could be measured by measuring levels, electronic devices and by biological markers. Yeni and others were however of the opinion that all these methods have flaws and are inaccurate, whereas those that could generate more reliable results are tedious, laborious and expensive. To them, the use of more than one method (as been advocated), for example pill counts used with other measures such as patient interviews have been more successful in predicting adherence results. Yeni and others hinted that in using more than one method to predicting adherence results, many HCPs may have to assume that socioeconomic status such as lack of education and poverty are factors associated with non-adherence. Others are of either similar as well as different views. Therefore, the need to assess the factors that could affect adherence to HAART / FDC is paramount and impeccable.

## **2.6 FACTORS AFFECTING ADHERENCE TO HAART**

Adherence has been a well-known problem in medicine especially in chronic diseases (Airoldi et al. 2010). Miller (1997) was of the opinion that with non-symptomatic diseases,



keeping to the prescribed treatment has proven difficult for patients. For HIVinfected patients on HAART or FDC's, adherence is of outmost importance. Poor adherence may lead to treatment failure, selection of viral mutations and development of drug resistance (Rodriguez-Rosado et al., 1998 and Bangsberg, et al. 2012). Vervoort and others (2007) explained that adherence an ever-changing and adapting process which could be influenced by many factors. WHO (2003) identified these factors to include therapy-related factors, patient-related factors, condition-related factors, social and economic factors and healthcare systems factors. Kleeberger and others, (2001), Gordillo, and others (1999) and Vervoort and others (2007) were of similar view and argued that adherence could be influenced by socio-economic, health-related, treatment-related, and behavior-related factors.

In the past, although several studies have shown how treatment simplification strategies could enhance patients' adherence to HAART (Maggiolo et al. 2002; Trotta, et al. 2003; Flandre, et al. 2002; Stone, et al. 2004; Boyle et al. 2008) and that this type of intervention were improving patients' quality of life, a few studies have specifically addressed the challenges and relationship between patients' quality of life and adherence (Kleeberger, et al., 2001). Although HAART significantly increases the quality of life in patients with symptoms, it may have negative effects on the quality of life in asymptomatic patients. The need therefore to assess the therapy-related factors, patientrelated factors, condition-related factors, social and economic factors and health care team/systems factors to FDC pill as propounded by WHO (2003) is in the right direction.



### 2.6.1 Therapy-related factors

Therapy-related factors are factors that bother on the complexity of the medical regimen such as dose frequency, side-effects of drugs (e.g. sore throat, fever, GI upset, pill burden, etc.), duration of treatment, previous treatment failures and availability of medical support. Heiss and others (2011), Hare (2009) and WHO (2007) argued that as the complexity of the medicines regimen increases adherence decreases. These complexities include the number of units per dose, the number of doses per day and the prerequisite to comply with strict and special requirements related to food and fluid intake. Some regimens consist of several doses of medicines per day alongside various requirements or limitations on food intake and other activities and this could result in poor adherence (Airoldi et. al, 2010).

In addition to these complexities are the problems of toxicity and side effects that may greatly influence an individual's readiness and willingness to adhere to the therapy. Heiss et al., (2011); Hare, (2009); WHO, (2007) were however of view that regimens with a lower pill burden, a maximum dosing of twice a day, fewer alterations in lifestyle patterns (eg dietary restrictions) and with minimal side effects are likely to be better adhered to.

Indeed, Agyarko-Poku and others (2014) were of opinion that pill burden could be a factor for non-adherence to antiretroviral drugs (ARVs) and that the introduction of Fixed Dose Combination ARVs regime could be seen as an antidote to pill burden among HIV patients on treatment. However, other authors argued that even though the already introduced FDC medicines has reduced the number of units a patient has to take and has shown to improve adherence, however, FDCs are associated with problems such as the need for a lead-in dose

required for Nevirapine, and the occurrence of adverse effects from one of the components (Hare, 2009; WHO, 2007).

With the advent of FDCs, Agyarko-Poku and others (2014) therefore conducted a study on the topic *“Too bad! Fixed Dose Combination antiretroviral drugs.”* The study hypothesized that not all HIV patients will accept this new regime, and was conducted to determine their perception on the new treatment regime. 1681 HIV positive patients accessing care at Suntreso STI/HIV Clinic in Kumasi, who had been on treatment for more than 12 months and consented to participate were recruited for this cross sectional study. They were interviewed using semi-structured pre-texted questionnaire prior to the commencement of the new Fixed Dose Combination ARVs treatment regime. The results showed that whereas, 60.9% (1023/1681) found the present dose regime cumbersome, 39.1% (657/1681) of the patients preferred the multiple dose regime. 42.2% (709) of the respondents had some reservations about fixed dose combination regime whilst 24.6% (413) preferred it, with 33.3 % (559) been indifferent. Reasons for the reservation included; *‘Side effect may be too serious’* (48.3%, 342/709), *‘Virus too powerful for a single molecule’* (30.2%, 214/709), *‘Attempt to deprive us of drugs and facilitate our death’* (13.8%, 92/ 709) and *‘Cost of drugs will be expensive in future for a combined drugs therapy’* (7.7%, 55/709). The study therefore concluded that although, majority of patients find the multiple dose regimes cumbersome, they are skeptical about the use of the fixed dose combination treatment regime. The new regime may result in overdosing if they find it inadequate to provide the needed protection. The fear of serious adverse reaction from combination of ARVs compared with separate drugs may scare them from taking the

treatment. Intensive adherence counseling and taking care of the above concerns is essential before patients are switched onto the fixed dose ARV regime.

Heiss and others (2011) however reiterated that optimal adherence should occur. They argued that even though ART regimens usually have temporary side effects including transient reactions like diarrhea and nausea as well as longer lasting effects like lipodystrophy and neuropathy, optimal adherence could occur. They further indicated that interventions such as education on the use of medicines and on the importance of adherence, regimen simplification and tailoring of the prescription to fit into the patient's lifestyle could minimize the side effects to improve adherence. The use of reminder devices has also been advocated to improve adherence to FDC. Agyarko-Poku and others (2014) also proposed intensive adherence counseling as a way of dealing with negative perception of FDC to improve its adherence.

#### **2.6.2 Patient – Related Factors**

When medicines are prescribed and dispensed, it is up to the patients to use them as directed. However, this might not always be the case. Thus, patients could be a contributory factor to non-adherence to drugs. Patient factors that have been studied include psychological issues (such as active drug or alcohol use, degree of social support and depression), the patient knowledge and religious or health belief about their illness, confusion, forgetfulness, co-morbidities (esp. depression, alcohol and drug abuse, among others).



Psychological factors on adherence of a drug are one of the patient related factors that enable patients take prescribed medication. Psychological factors to drug adherence are factors that relate to the mental being of the patient. This could comprise of depressive symptoms, aggravated levels of depression, anxiety, distress, despair, among others and this according to Reisner and others (2001) could influence adherence to drugs. They further argued that patient's depressive symptoms and other psychological issues which could affect adherence could be attributed to, for instance, previous sexual abuse. Naar-King and others (2006) affirmed this assertion and argued that previous abuse could affect adherence. Reisner and others supported this view and reiterated that young people who experienced sexual abuse under age 12 and are living with HIV have had a prior suicide attempt and have poor adherence levels. This history of abuse has a higher likelihood of engaging in drug abuse (Anaya et al, 2005). Therefore, Anaya and others advised that familiarity with the patient history could thus prove useful in predicting adherence behavior.

While depressive symptoms and previous abuse could be some of the psychological factors associated with adherence, confusion and forgetfulness could equally constitute major obstacles to adherence to HAART as confusion may arise from requirements and/or restrictions on food or water intake and misunderstandings of complex regimens and/or poor instructions from the HCP. Forgetfulness has been cited as the most common reason for non-adherence, with the middle dose in a three times daily regimen being the most commonly forgotten one. Magura and others (2012) were however of the opinion that low



adherence is not attributable to simply forgetting to take medication. They argued that forgetting to take medication was one of the less frequently endorsed items (31%).

A study was conducted by Habtamu and others (2013) on factors affecting adherence to antiretroviral treatment in Harari National Regional State, Eastern Ethiopia. A crosssectional study was conducted on HIV patients and attending the ART service at Hiwot Fana and Jugal hospital. Adherence was defined as taking 95% of the prescribed doses in the week before the survey. The result of the study indicated that among the 239 study participants, the magnitude of adherence to ART in the week before interview was 87%. The main reasons for non-adherence were forgetting (47.2%), traveling (18.9%), and being busy doing other things (15.1%). There was not any independent predictor identified for adherence to ART. The study therefore concluded that forgetfulness was the most common reason for the non-adherence. Therefore, the ART counseling needs to give emphasis to using memory aids. In addition, a further study on adherence rate and its determinants with multiple adherence measurements was recommended.

Perhaps forgetfulness could be attributed to alcoholism. Garvie and others (2011) argued that young people who are living with HIV are not averse to alcohol and substance abuse. Garvie and others (2011) and Reisner and others (2009) reported that frequent use of alcohol and substance abuse by HIV patients results in impaired decision making and is a critical predictor of adherence. Wanjohi (2009) equally affirmed that alcohol and substance abuse by HIV patients are usually non-adhering patients who usually miss taking their doses.

Wanjohi and others explained that increases in alcohol consumption which go beyond usual drinking levels are more likely to cause non-adherence than nonhazardous drinking which is not associated with brain functioning impairment.

A study conducted by Rao and others (2007) with youth in a focused group admitted to stopping medication when experiencing depressive symptoms due to alcohol. In their studies among young people, Naar-King and (2006) found a significant correlation (CI95%) between adherence and psychological distress further strengthening this preposition.

Reisner and others (2009) were of the view that adherence could be on the increase if a patient's accepting attitude towards medication is positive and belief that medication will improve health status. A patient's accepting attitude towards medication and belief that medication will improve health status is associated with increased adherence (Reisner et al, 2009). Castro (2005) reports on clients in Senegal who increased adherence as a result of positive attitude to ARVs which they associated with weight gain which is highly valued in that society. Belzer and others (1999) found that youth who believed that HIV medication would improve the quality of their life were more likely to have >90% adherence rate ( $p=.01$ ). Mehta (1997) reported on study where 50% of the non-adherent group reported skipping the prescribed drugs because they did not believe they needed it. The reverse of this is true since negative attitudes towards medication may interfere with patient adherence. In one focused group discussion (Rao, et al, 2007) some youth reported

throwing away their medication because of the feeling that the medication will change their lifestyle.

Interventions that have been proposed to minimize these psychological-related factors that result in poor adherence include the Health Belief Model (HBM). This is a social psychological model, developed to explain preventative health behaviour, and being used in conjunction with other models explain, describes and predicts non-adherence behaviours according to the three factors of susceptibility, severity and benefit. It suggests that patients are more likely to adhere to instructions from the HCP when they feel susceptible to illness, believe the illness to have potentially serious consequences to health or daily functioning and do not anticipate major obstacles like side effects (WHO, 2007).

While psychological factors have proved to be more stable predictors of adherence behavior, the varying rates of tests significance call for more studies to establish how well the factors relate to adherence.

### **2.6.3 Social and economic factors and adherence**

The social and economic context is a crucial element that plays a big role in ensuring adherence (Zuurmond, 2008). According to Hare (2009) lack of social support, poverty, illiteracy, poor access to services, high cost of transport, unstable living conditions, among others are social and economic factors that contribute to adherence to drugs. Ickovics and Meade (2002) were of the view that social support helps patients adhere better. Social



support towards such things as reminder to take medication, encouragement to visit the clinic and being accompanied to visit the clinic are dependent on the patient's social environment. Naicker (2011) argued that social support is a great motivator of adherence behaviour. The social and emotional support received from close family, friends, and colleagues positively influenced adherence behaviour. In her study, responses such as: *"you need a support system... you can't be on your own ...you need people"*; *"my family, my kids make me take my meds, they help me"*, among others, were predominant. She further argued that persons who accessed workplace, private and semiprivate healthcare were particularly expressive about the supportive relationship they shared with their health care providers. *"I can open up to him [doctor] ...talk man to man... if he is not there I can go talk to her [occupational health nurse]."*

Cardinal to receiving social support is disclosure to the members within social cycle since support cannot be achieved unless one discloses. Zuurmond (2008) found that patients who disclose their status to family members seem to do much better on adherence, a fact that is supported by Hardon and others (2007) who found most ARV users interviewed in Tanzania as a result of disclosure had received various forms of help such as food, reminder to take medicine and transport from family members and friends. Thus social support increases adherence and according to Mehta and others (1997) social isolation increases the risk of decreased compliance with medication among PLWHIV. In support of this assertion, Belzer and others (1999) argued that youth (living with HIV) who disclosed their status to at least one person were more likely to begin taking medication and remain on treatment longer. They were however of the view that this did not lead to observed



relationship between disclosure and adherence. Despite the documented benefits of disclosure, it still remains a challenge among the PLWHIV. Non-disclosure may lead to patients taking medication secretly (Hardon et al, 2007, Reisner et al, 2009) to avoid family members and friends get to knowing their status or altogether miss doses (Zuurmond, 2008).

Naicker (2011) was also of preposition that poverty, transport cost (to and from clinics) and long travel distances emerged as stumbling blocks to adherence behavior are all some of the socio-economic factors. In her study, participants shared that unemployment lead to depression and this causes persons to miss doses. Needing someone to take care of children negatively impacted on adherence and dependence on the social grant cause persons to default to keep their CD4 <200 (to qualify for the grant).

Nevertheless, a study conducted in Rwanda to analyze the impact of socio-economic factors on adherence to HAART found no significant differences between adherent and non-adherent patients when considering criteria like profession, level of education and distance from the hospital. These findings are similar to others obtained in South African studies. The main reasons given by patients were ‘forgetfulness’ and ‘lack of understanding of the instructions’. Counselling and the provision of appropriate, understandable information on the disease and treatment seemed to be the key elements to enhance adherence (Hare, 2009).

#### **2.6.4 Condition-related factors**

Condition-related factors are factors that refer to the symptoms or infections that an individual may acquire or experience because of a weakening immune system response caused by HIV on the body's defense cells (Naicker, 2011). These are Factors that relate to the disease or condition of the patient such as the rate of progression of the disease, the level of disability, the severity of symptoms and the availability of effective treatment may influence adherence. Bart and others (2013) was of the view that there are number of condition-related risk factors, such as morning stiffness, disease activity, erythrocyte sedimentation rates, overall (perceived) health functioning, disease duration and quality of life. However, Bart and others reiterated that none of these factors were consistently related to non-adherence. Only perceived effect was poorly associated with nonadherence and adherence. In other chronic diseases, however, co morbidities such as depression (in diabetes or HIV/AIDS), and drug and alcohol abuse are important modifiers of adherence behavior (Bart et al, 2013).

A study conducted to investigate the relationship between disease severity and medicines adherence among HIV patients showed that asymptomatic patients tended to be less adherent compared to symptomatic patients (Heiss et al., 2011; Hare, 2009; WHO, 2005). Similarly, Naicker (2011) conducted on factors that influence adherence to Highly Active Antiretroviral Therapy (HAART). Using a qualitative descriptive study to explore the factors that influence adherence to HAART among persons who accessed treatment in the greater Durban area with Eligible participants over 21, revealed that Most of the participants felt sick, weak, tired and feverish more often than not or they experienced

weight loss or had rash which could not be explained. Some of the participants were diagnosed with opportunistic infections. The symptoms and opportunistic infections were all indicative of a weak immune system response.

#### **2.6.5 Healthcare system factors / HealthCare Provider Factors**

The patient-provider relationship plays an important role in improving adherence to prescribed medications in chronic disease. It serves as a motivating factor for adherence to HAART. Significant barriers to adherence may stem from the relationship between the patient and the provider or the health care provider. Quality of patient-provider relationship, cost of treatment, reliability of medication distribution systems, level of training and workload of healthcare providers, capacity for education and follow-up of patients, monitoring of performance of system, among others, are some of the important factors that improve adherence.

Hare (2009) and WHO (2005) expressed that if the medicine distribution system are reliable and the cost of treatment are low adherence would be improved. Adherence may also be affected by the monitoring of performance systems and the ability of the healthcare system to establish community support and self management capacity (Hare, 2009; WHO, 2005). Poor implementation of educational interventions by the healthcare system and lack of clear instructions from the HCPs who are not trained on adherence issues could result in poor adherence.

Altice and others (2001) were of the view that trusts and confidence in providers has been found to influence adherence positively. Although existing data is limited, they further argued that, aspects of the clinical setting may be associated with improved adherence. A friendly, supportive and nonjudgmental attitude of healthcare providers, convenient appointment scheduling and confidentiality could contribute to better adherence.

A study conducted by Naicker (2011) revealed that HIV patients who accessed private and semi-private health care facilities were full of praise for the quality of service experienced –spoke highly of the encouragement and support received, and the open and trusting relationship they shared with their service provider's. These healthcare providers were described as good listeners who involved the persons in treatment decision making:

- *“Passionate doctor takes longer and shows he is concerned” “doctor talks to me, he explains things to me, he has an open door policy”*. An area of grave concern mentioned by participants accessing care at public clinics and hospitals was the lack of confidentiality and privacy regarding their HIV treatment [which violates their right to confidentiality and privacy – Patients' Rights Charter]: - *“if you are waiting in that queue then you are waiting for ART”*. Persons in need of treatment were therefore reluctant to access treatment at their local clinic or hospital because the community would get to know their HIV positive status. Persons would therefore access treatment in another town or clinic far from their home to ensure that no one recognizes them.

Significant barriers to adherence may be overcome in the presence of a meaningful and supportive relationship between the patient and their HCP. Factors that may establish and



strengthen such a relationship include the quality and clarity of communication, patient perception of HCP competence, compassion, patient-active participation in treatment decisions, and regimen convenience.

In order to address these issues, patient-oriented interventions to improve adherence have been proposed which include providing accessible education and information, e.g. leaflets in the appropriate language, and actively involving a patient in his or her treatment through encouraging the patient to talk about the symptoms, how they respond to them and how their medicines are taken. To supplement this, a number of aids like pill organizers and cap alarms may be recommended to help establish a daily routine (Heiss, 2011; Hare, 2009; WHO, 2005).

On the other hand, HCPs and care givers-oriented interventions to improve adherence have also been proposed which include providing the proper training of HCPs and care givers on adherence education, which should proceed hand in hand with the identification of treatment goals and the development of treatment strategies to meet them. Readily available information with unlimited access by the patient is also important (WHO, 2005).

In all, WHO, (2005) reiterated that the education of both HCPs and patients about the disease, the taking of medicines and the management of side effects improves adherence and that —the use of clear written instructions is synergistic with the use of FDC or unit-of-use packing. Enhanced patient understanding of the relationship between adherence, viral load and disease progression could result in improved adherence. WHO, (2005) proposed

that for adherence to be improved there should be education on the use of medicines, supportive medical consultation and screening for co-morbidities (WHO, 2005).

## **2.7 Summary of Literature Review**

The fight against HIV/AIDS continues and many here have been rapid evolution of the HIV disease exhibiting Antimicrobial Resistance (AMR) and in particular, Multiple Drug Resistance (MDR) (Gupta et al, 2001) and fixed dose combinations therapy. The introduction of the FDC antiretroviral product has become a mainstay in the treatment of HIV. Combination antiretroviral therapy (cART) has thus become the standard of care for people living with Human Immunodeficiency Virus (HIV) and has resulted in profound reductions in the incidence of Acquired Immune Deficiency Syndrome (AIDS) and AIDS-related mortality (Loutfy et al, 2007).

Scholars such as Rodriguez-Rosado and others (1998) and Bangsberg and others (2003) have noted that adherence to FDC is outmost important to treatment improvement. WHO (2003) indicated the adherence to FDC could be influenced by factors such as therapyrelated factors, patient-related factors, condition-related factors, social and economic factors and healthcare systems factors. Therapy-related factors include factors like side effects of FDC, frequency of dose and duration of treatment whilst patient-related factors include factors such as psychological factors (example alcohol intake), religious or health believe and forgetfulness. Socio-economic factors included cost of transport, access

to healthcare, social support whilst condition-related factors included factors like severity of symptoms, mental retardation and psychotic disorders.

# KNUST

## **CHAPTER THREE**

### **METHODOLOGY**

#### **3.0 Introduction**

This chapter deals with the general research design. It covers the population, study variables, data collection techniques and tools, study type, sampling techniques and sample size, pre-testing, plan for the data handling, ethical consideration, field work preparation, data entry, limitations and assumptions of the study.

#### **3.1 Study methods and Design**

The research work employed the cross-sectional study design to assess HIV/AIDS patients' adherence to the single molecular fixed-dose combination therapy of High Active Anti-Retroviral Therapy (HAART) at the STI unit at the Suntreso Government Hospital, Kumasi, Ghana. The study employed quantitative method. This approach was adopted because it offered the best means of obtaining valid data for the study.

### **3.2 Profile of the Study Area**

The study was carried out in Kumasi Metropolis of the Ashanti Region of Ghana. Kwabre, Bosomtwe and Antwima Kwanwoma districts bounded the metropolis in the north and to the south: on the east is Ejisu Municipal and Atwima District on the west of the metropolis. The metropolis has an estimated population of 143,000,241 and annual growth rate of 3.4% (GSS, 2012). Specifically, the study was carried out at the Suntreso Government Hospital located to the west of Kumasi Metropolis. HIV/AIDS continues to be a major challenge to health professionals. Antiretroviral treatment is offered in nine centers and these centres are KATH, Kumasi South Hospital, Suntreso Government Hospital, Aninwaa Medical Center, Asafoagyei Clinic, Atasomanso Hospital, KNUST Hospital, SDA Hospital and Bomso Clinic. Suntreso Government Hospital was selected because Suntreso Hospital's catchment area was densely populated with 423,008 inhabitants and it took 24.20% of the Kumasi Metropolitan population (GSS, 2012).

Suntreso Government Hospital, STI unit is a specialist clinic. It was built in 1998 and is one of its kind in the Ashanti Region. Clients living with HIV/AIDS and who visited the Sexual Transmitted Infection Unit of the hospital for their medications constituted the population for the study.

### **3.3 Study Population**

The study population was made up of PLWHIV/AIDS who attended STI Unit in the Suntreso Government Hospital in the Kumasi metropolis, at the period of conducting the study. The population of PLWHIV/AIDS at the period of the study was 3220 (HAART



Centre, Suntreso Government Hospital, June, 2014).

### 3.3.1 Inclusion criteria

People living with HIV/AIDS and above 18 years and on treatment were included in the study.

### 3.3.2 Exclusive criteria

People living with HIV/AIDS and less than 18 years were not included in the study.

### 3.4 Sample size calculation

The sample size was calculated based on the following: 95% confidence interval with 5% desired or the required size of standard error that was allowed. The proportion of PLWHIV/AIDS in the Kumasi Metropolis was estimated as 25.70%. Sample size was calculated with the formula

$N = z^2 (p q) / d^2$  (Wayne 2012) Where N = sample size z = Reliability Coefficient with 95 percent confidence certainty p= Proportion of PLWHIV/AIDS in the Kumasi Metropolis Where  $q = 1 - p = 1 - 0.2570 = 0.743$  d = the desired of the required size of standard error allowed. If the value of p is 0.2570 (which gives the largest sample size) and the desired standard error chosen to be 0.05 with reliability coefficient of 95 % certainty ( $z = 1.96$ ).

Then,  $n = [(1.96)^2 (0.2570 * 0.7430)] / (0.05)^2$

$N = [(3.84) (0.190951)] / 0.0025$

$N = [(0.73325184)] / 0.0025$

$N = 293$

**Adjusting with 10% non-respondent rate:**

$$(0.1 * 293) + 293$$

$$N = 322.3 = 322$$

**3.5 Sampling Techniques**

The sampling was done in two phases. The first was to select the HAART centre where the study was to be carried out. The study conveniently selected HAART centre at the Suntreso Government Hospital. This is because Suntreso Hospital's catchment area was densely populated with 423,008 inhabitants and it took 24.20% of the Kumasi Metropolitan population (GSS, 2012).

The second phase was to sample the respondents who were PLWHIV/AIDS, attending HAART centre at the Suntreso Government Hospital at the period of the study. For the study period a total of 3220 clients were listed in the unit. The study systematically sampled the respondents. The sample size of 322 at an interval of  $k=10$  was obtained. All the PLWHIV/AIDS at the centre were ranked numerically using Suntreso Government Hospital, HAART centre identification number as a guide. Simple random sampling was employed to select the first index by balloting.

The researcher wrote numbers 1-10 separately on pieces of paper, folded them and put them in a box. An independent person who was a nurse at the Centre was asked to pick one of the folded papers. The paper coded number 3 was picked and the third person on the list was chosen as the first respondent for the study. With an interval of 10, the 13<sup>th</sup> person on the list was chosen as second respondent. This was carried out until the entire sample size of 322 was obtained.

### **3.6 Data collection tools and techniques**

The study relied on primary data. Primary data were collected using structured questionnaire administered to respondents who were PLWHIV/AIDS, attending HAART centre at the Suntreso Government Hospital in the Kumasi Metropolis.

Before the administration of questionnaire, the researcher sought permission from authorities of HAART Centre at the Suntreso Government Hospital and appointments were made between the researcher and the HAART authorities. Questionnaires were administered between 4<sup>th</sup> August, 2014 and 18<sup>th</sup> August, 2014. The questionnaire was divided into six parts. Part A covered background characteristics of respondents, Part B dealt with history of HIV/AIDS infection of respondents, Part C covered patient-related factors and FDC adherence. Part D dealt with socio-economic factors and FDC adherence, Part E covered healthcare or providers factors and FDC adherence whilst the last part (Part F) dealt with therapy-related factors and FDC adherence.

The researcher was personally at the HAART Centre with three trained research assistants in the Suntreso Government Hospital from morning, about 9am to the evening, about 4.30pm every day from 4<sup>th</sup> August, 2014 to 18<sup>th</sup> August, 2014 in order to get access to respondents for an interview. The respondents willingly participated and each respondent took at most 30 minutes to fill in the questionnaire. The respondents who could not write or read were assisted by the researcher to write or read for smooth fill in of the questionnaire.

#### **3.6.1 Pre-testing of Research Tools**

The questionnaire for the study was pre-tested at the SDA Hospital, also in Kumasi

Metropolis. This facility has similar characteristics with the Suntreso Government Hospital. This was done to check for clarity, consistency and acceptability of the questions to respondents. Following this, the necessary corrections were made and the questionnaires were finalized for the actual field work.

### 3.7 Study Variables

Quantitative method was used in measuring both the dependent and independent variables. The dependent variable was PLWHIV/AIDS' FDC ART adherence (Taking all the prescribed drugs / strictly following drug schedules).The independent variables were basically the circumstances or conditions that determined adherence to FDC ART including therapy-related issues, social and economic factors, condition-related factors, healthcare system as well as patient-related factors. A table of the conceptual definitions and scales of measurement of the variables are presented in Table 3.1.

**Table 3.1: Measurement of Key Variables in the Study**

Study	Operational	Study Indicators	Scale of	Statistical
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<b>Variables</b>	<b>Definitions</b>		<b>Measurement</b>	<b>Analysis</b>
Sex	Being male or female	Male, female	Ordinal	Frequency/percentages
Age	Age in years	Above 18 years	Interval	Frequency/percentages
Education	Highest level of educational attainment	No formal education, basic education, secondary education and tertiary education	Ordinal	Frequency/percentages
Religion	Being Christian or Muslim	Christianity and Islamic	Ordinal	Frequency/percentages
Social and economic factors and FDC adherence	Influence of socioeconomic factors on FDC adherence among PLWHIV/AIDS	Family support, guidance at home, poverty	Ordinal/nominal	Frequency/percentages, Chi-sq. and P-value
Healthcare system factors and FDC adherence	Influence of healthcare systems' influence on adherence to FDC ART among PLWHIV/AIDS	Patient-provider relation, time spent at healthcare center, etc	Ordinal/nominal	Frequency/percentages, Chi-sq. and P-value
Patient – related factors and FDC adherence	Influence of patientrelated factors on FDC ART among PLWHIV/AIDS	Forgetfulness, depression, time schedule etc.	Ordinal/nominal	Frequency/percentages, Chi-sq. and P-value
Therapy-related factors and FDC adherence	Influence of therapy-related issues that influence adherence to FDC ART among PLWHIV/AIDS	Side effects, cost of treatment, quality of drugs etc	Ordinal/nominal	Frequency/percentages, Chi-sq. and P-value

**Source: Author's Own Construct, 2014**

### **3.8 Data Handling and Processing**

At the end of each day, questionnaires were checked for completeness. Questionnaires were sorted, numbered and kept in files labeled per unit from which the participants were recruited. Data were then coded before entered into SPSS, version 16.0.

### **3.9 Data Analysis and Statistical Method**

The data were analyzed and discussed according to arrangement of research objectives. However, the background characteristics of respondents were first analyzed and presented to form the basis of the study. Descriptive analyses were done using frequencies and percentages and results were presented using bar charts, pie charts and tables. Associations were tested using Pearson Chi-square test.

A scale of 1-4 was used for some of the analysis, whereby

1 = Rarely

2 = Sometimes

3 = Most times

4 = All times.

### **3.10 Ethical Considerations**

Ethical clearance for the study was obtained from the Committee on Human Research, Publications and Ethics (CHPRE) of the Kwame Nkrumah University of Science and Technology (KNUST), School of Medical Sciences, KNUST. In addition to this, clearance was also obtained from the Suntreso Government Hospital and the STIs Unit.

All the necessary permissions were sought from the relevant persons and authorities.

Privacy and confidentiality of respondents were placed at the highest premium.

### **3.11 Assumptions of the Study**

The study was based on the following assumptions that:

- The sample size adequately represented the study population.
- The respondents were honest and frank with their responses.
- The researcher followed all the laid down rules governing the research.

### **3.12 Study Limitations**

The anticipated limitations of the study were that:

- The cross-sectional study design did not permit an investigation of the causeeffect relationships.
- Adherence to FDC ART as a study has never been undertaken in Ghana.

Therefore it was very difficult to lay hands on previous data on the same subject.

## CHAPTER FOUR

### RESULTS

#### 4.1 Introduction

This chapter presents results of the study. Data were collected from HIV/AIDS patients at STI unit in the Suntreso Government Hospital in the Kumasi Metropolis. A total number of 322 PLWHIV/AIDS were covered. The study used SPSS (version 16.0) to analyze the data. The data analyses were into three parts: characteristics of respondents, HIV/AIDS history of respondents and factors that influence adherence to FDC.

#### 4.2 Background characteristics of Respondents

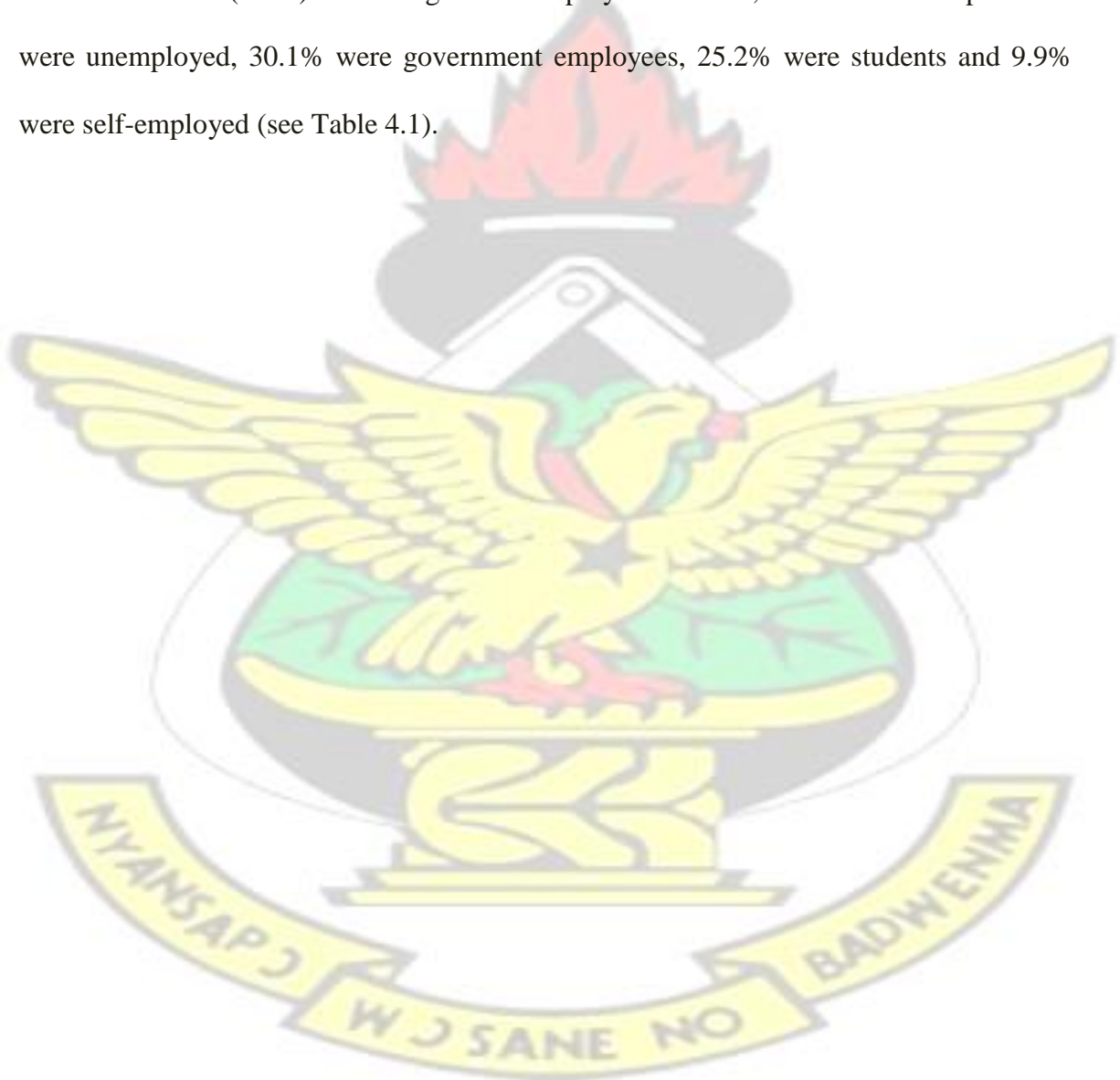
Table 4.1 presents results of the background characteristics of the respondents involved in the study and the characteristics were sex, age, educational attainment, marital status, religion, employment status and living arrangement. Out of 322 respondents, 43.8% were males whilst 56.2% were females. The mean age of the respondents was 33 years and 39.8% of the respondents were between 26 years and 35 years. This was followed by respondents between 18 years and 24 years (25.5%), respondents between 36 years and 45 years (24.8%) and respondents between 46 years and 55 years (9.9%).

From Table 4.1, 80.1% of the respondents were Christians with the remaining 19.9% as Muslims. Among the respondents, 55.0% were single, 25.2% were married, 10.6% were divorced and 9.3% were widowed. In relation with living arrangement, 34.8% lived alone,



25.2% lived with spouses, 24.9% lived with other relatives, 10.2% lived with biological parents and 5.0% lived with foster parents.

Second cycle education was the highest academic qualification for the respondents with 37.6%. This was followed by basic education (35.1%), tertiary education (17.4%) and no formal education (9.9%). With regards to employment status, 34.8% of the respondents were unemployed, 30.1% were government employees, 25.2% were students and 9.9% were self-employed (see Table 4.1).



**Table 4.1: Background Characteristics of Respondents (n=322)**

<b>Variables</b>	<b>Frequency (F)</b>	<b>Percentage (%)</b>
<b>Sex</b>		
Male	141	43.8
Female	181	56.2
<b>Age</b>		
Between 18years and 25 years	82	25.5 39.8
Between 26years and 35 years	128	24.8
Between 36years and 45 years	80	9.9
Between 46years and 55 years	32	
<b>Religion</b>		
Christianity	258	80.1
Islamic	64	19.9
<b>Highest Academic Qualification</b>		
No formal education	32	9.9
Basic education	113	35.1 37.6
Second cycle education	121	17.4
Tertiary education	56	
<b>Marital Status</b>		
Married	81	25.2 55.0
Single	177	10.6
Divorced	34	9.3
Widowed	30	
<b>Living Arrangement</b>		
Living alone	112	34.8
Living with biological parents	33	10.2 5.0
Living with foster parents	16	25.2
Living with spouse	81	24.9
Living with other relatives	80	
<b>Employment Status</b>		
Government employee	97	30.1 9.9
Self-employed	32	34.8
Unemployed	112	25.2
Student	81	

**Source: Field Data, 2014****4.3 History of HIV Infection of Respondents**

History of HIV infection of the respondents is key to the understanding of the analysis of the study and this is shown in Table 4.2. From Table 4.2, 40.1% had lived with

HIV/AIDS between three years and six years. This was followed by respondents with HIV/AIDS below one year (35.1%) and those with HIV/AIDS between one year and three years (24.8%).

With regards to family awareness of HIV/AIDS status of respondents, 84.8% indicated that their families knew that they were HIV/AIDS patients whilst 5.0% indicated that their families were not aware of their HIV/AIDS status. Table 4.2 further shows that 10.2% of the respondents were not aware whether or not their families knew that they were HIV/AIDS patients.

Another aspect was the number of years that the respondents had been on HAART, 305 out of 322 responded. Table 4.2 indicates that 52.5% of the respondents had been on HAART between one year and three years whilst 48.5% had been on HAART for below one year. Again, 84.8% had been on Fixed Dose Therapy whilst 15.2% had never been on Fixed Dose Therapy. Out of 273 respondents on Fixed Dose Therapy, 64.8% had been on the therapy below one year whilst 35.2% had been on the therapy between one year and three years (see Table 4.2). Table 4.2 shows that out of 273 HIV/AIDS patients on Fixed Dose Therapy, 55.0% took their drugs at all times, 14.9% took their drugs most of the times, 9.9% sometimes took their drugs whilst 5.0% rarely took their drugs.

**Table 4.2: History of HIV Infection of Respondents**

Variables	Frequency (F)	Percentage (%)

<b>Years HIV Infection (n=322)</b>		
Below 1 year	113	35.1
Between 1 year and 3 years	80	24.8
Between 3 years and 6 years	129	40.1
<b>MY HIV status is known by my family (n=322)</b>		
Yes	273	84.8
No	16	5.0
I do not know	33	10.2
<b>No. of Years HIV patients have on HAART (n=305)</b>		
Below 1 year		
Between 1 year and 3 years	148	48.5
	157	52.5
<b>FDC and MD HAART Patients (n=322)</b>		
Fixed Dose	273	84.8
Multi Dose	49	15.2
<b>No of years on Fixed Dose Therapy (n=273)</b>		
Below 1 year	117	64.8
Between 1 year and 3 years	96	35.2
<b>Fixed dose Therapy are taken as prescribed (n=273)</b>		
Rarely	16	5.0
Sometimes	32	9.9
Most of the time	48	14.9
All the time	117	55.0

**Source: Field Data, 2014**

#### **4.3.1 Socio-demographic Characteristics and the Choice of Therapy**

This subsection explores whether or not the choice of FDC by PLWHIV/AIDS depended on socio-demographic characteristics such as sex, age, religion, academic attainment, marital status, living arrangement and employment status.



Table 4.3 shows that sex (Chi-sq. =58.909: P-value= 0.000), age (Chi-sq. = 64.825: Pvalue=0.000), academic qualification (Chi-sq. =180.279: P-value= 0.000) and employment status (Chi-sq. =78. 371: P-value= 0.000) of the respondents who were PLWHIV/ AIDS significantly influenced choice of therapy. Female, younger, educated and employed HVI/AIDS patients significantly preferred FDC therapy to multi dose therapy. From Table 4.3, out of the 181 female respondents, 98.3% preferred FDC therapy whilst 1.7% were on multi dose therapy. Also, out of 141 male respondents, 67.4% were on FDC therapy whilst 32.6% were on multi dose. Among 82 respondents between 18 years and 25 years, 98.8% were on FDC dose whilst 1.2% were on the multi dose. Out of 128 respondents between 26 years and 35 years, 92.3% were on FDC whilst 7.7% were on multi dose. Moreover, between the age group of 36 years and 45 years, 76.3% were on FDC whilst 23.7% were on multi dose. Out of 32 respondents between 46 years and 55 years, 43.7% were on FDC whilst 56.3% were on multi dose.

Table 4.3 reveals that among 32 respondents who had no formal education, 6.3% were on FDC whilst 93.7% were on multi dose. Also, out of 113 respondents who had basic education, 85% were on FDC whilst 15.0% were on multi dose. Furthermore, 98.3% and 1.7% of respondents who had secondary education were on FDC and multi dose respectively whilst all the respondents who had tertiary education were on FDC. Again from Table 4.3, all the respondents who were government employees and self- employed were on FDC. However, 67.9% and 32.1% of respondents who were unemployed were on

FDC and multi dose respectively; 84.0% and 16.0% of respondents who were students were on FDC and multi dose respectively.

However, religion (Chi-sq. = 0.0830; P-value=0.848), marital status (Chi-sq. =1.959; Pvalue= 0.588) and living arrangement (Chi-sq. =2.904; P-value= 0.069) of respondents did not significantly influence choice of therapy. From Table 4.3, 84.5% respondents who were Christians were on FDC whilst 15.5% were on multi dose and 85.9% and 14.1% of Muslims were FDC and multi dose respectively. With regard to marital status, 84.0% and 16.0% of married were on FDC and multi dose respectively; 86.4% and 13.6% of single were on FDC and multi dose respectively; 85.3% and 14.7% of divorced were on FDC and multi dose respectively and 76.7% and 23.3% of widowed were on FDC and multi dose respectively. Data on Living arrangement of respondents in relation to choice of therapy revealed that respondents who were living alone, 86.6% were on FDC whilst 13.4% were on multi dose; for respondents living with biological parents, 63.6% and 36.4% were on FDC and multi dose respectively, for respondents living with foster parents, 68.8% were on FDC whilst 31.2% were on multi dose; for respondents living with spouse, 95.1% and 4.9% were on FDC and multi dose respectively and for respondents living with other relatives, 83.8% were on FDC whilst 16.2% were on multi dose therapy.

**Table 4.3: Socio-demographic of Characteristics and the Choice of Therapy by**

<b>Respondents</b>					
<b>Characteristics</b>	<b>Total F (%)</b>	<b>Fixed Dose F (%)</b>	<b>Multi Dose F (%)</b>	<b>Chi-sq.</b>	<b>P-value</b>
<b>Sex</b>					
Male	141 (100.0)	95 (67.4)	46 (32.6)	58.909	0.000
Female	181 (100.0)	178 (98.3)	3 (1.7)		

<b>Age</b>					
Between 18years and 25 years	82 (100.0)	81 (98.8)	1 (1.2)	64.825	0.000
Between 26years and 35 years	128 (100.0)	117 (92.3)	11(7.7)		
Between 36years and 45 years	80 (100.0)	61 (76.3)	19 (23.7)		
Between 46years and 55years	32 (100.0)	14 (43.7)	18 (56.3)		
<b>Religion</b>					
Christianity	258 (100.0)	218 (84.5)	40 (15.5)	0.083	0.848
Islamic	64 (100.0)	55 (85.9)	9 (14.1)		
<b>Highest Academic Qualification</b>					
No formal education	32 (100.0)	2 (6.3)	30 (93.7)	180.279	0.000
Basic education	113 (100.0)	96 (85.0)	17 (15.0)		
Secondary education	121 (100.0)	119 (98.3)	2 (1.7)		
Tertiary education	56 (100.0)	56 (100.0)	0 (0.0)		
<b>Marital Status</b>					
Married	81 (100.0)	68 (84.0)	13 (16.0)	1.959	0.588
Single	177 (100.0)	153 (86.4)	24 (13.6)		
Divorced	34 (100.0)	29 (85.3)	5 (14.7)		
Widowed	30 (100.0)	23 (76.7)	7 (23.3)		
<b>Living Arrangement</b>					
Living alone	112 (10.0)	97 (86.6)	15 (13.4)	2.904	0.069
Living with biological parents	33 (100.0)	21 (63.6)	12 (36.4)		
Living with foster parents	16 (100.0)	11 (68.8)	5 (31.2)		
Living with spouse	81 (100.0)	77 (95.1)	4 (4.9)		
Living with other relatives	80 (100.0)	67 (83.8)	13 (16.2)		
<b>Employment Status</b>					
Government employee	97 (100.0)	97 (100.0)	0 (0.0)	78.371	0.000
Self-employed Unemployed	32 (100.0)	32 (100.0)	0 (0.0)		
Student	112 (100.0)	76 (67.9)	36 (32.1)		
	81 (100.0)	68 (84.0)	13 (16.0)		

**Source: Field Data, 2014**

#### **4.4 Factors Influencing FDC Therapy Adherence**

This study explored patient-related factors, social factors, therapy-related factors and health care providers' factors influencing adherence to Fixed Dose Therapy in the Suntreso Government Hospital.



#### 4.4.1 Patient-related Factors and Adherence to FDC Therapy

The study selected key patient-related factors and asked the respondents to indicate how these applied to them (see Table 4.4). A scale of 1 – 4 was used to analyse these factors.

Whereby 1 = —Rarely, 2 = —Sometimes, 3 = —Most times and 4 = —All times.

Table 4.4 indicates that out of 273 respondents on FDC, 129 (47.3%) had been drinking alcohol whilst 144 (52.7%) had not been drinking alcohol. From Table 4.4, respondents who indicated they had been drinking alcohol, 12.5%, 24.8%, 30.1% and 32.6% —rarely, —sometimes, —most at times and —all the time respectively adhered to FDC as prescribed. However, among the respondents who did not resort to drinking alcohol, 6.3% —most times and 93.7% —all the time adhered to FDC as prescribed. However, the Chi-square test result (Chi-square=134.33: P-value= 0.000) shows respondents' forgetfulness significantly influenced adherence to FDC as prescribed by physician.

It is revealed in Table 4.4 that 128 (46.9%) of the respondents ran out of medication whilst 145 (53.1%) did not. Out of respondents who ran out of medication, 12.5%, 18.0%, 33.6% and 35.9% —rarely, —sometimes, —most at times and —all the time respectively adhered to FDC as prescribed. However, 6.2%, 3.4% and 90.4% of respondents who did not run out of medication, —sometimes, —most at times and —all the time —respectively adhered to FDC as prescribed. The Chi-square test (Chi-square =92.33: P-value= 0.000) showed that availability of medicine significantly influenced respondents adherence to FDC as prescribed.



Aggression is another important variables considered in patient –related factors. 193 (70.7%) of the respondents were aggressive whilst the remaining 80 (29.3%) were not (see Table 4.4). The table further revealed that 11 (5.7%), 22 (11.4%), 31(16.1%) and 129 (88.8%) of the respondents who were aggressive —rarely, —sometimes, —most times and —all time respectively adhered to FDC as prescribed. Out of respondents who were not aggressive, 5(6.3%)—rarely, 10 (12.5%) —sometimes, 17 (21.3%)—most times and 48 (59.9%)—all times adhered to FDC as prescribed. The Chi-square test (Chi-square =0.494: P-value= 0.920) shows that aggression did not significantly influence adherence to FDC by respondents.

From Table 4.4, out of 273 respondents on FDC, 201 (73.6%) indicated that they had enough information on FDC whilst 72 (26.4%) indicated otherwise. Out of 201 respondents who had enough information on FDC, 7 (3.5%), 12(6.0%), 35 (17.4%) and 147(73.1%)—rarely, sometimes, —most times and —all time adhered to FDC as prescribed. However, among the respondents who indicated that they did not have enough information on FDC, 9 (12.5%) —rarely, 20 (27.8%) —sometimes, 13 (18.1%) —most times and 30 (41.6%) —all the time adhered to FDC as prescribed by their physicians. The Chi-square test (Chi-square= 36.971: P-value=0.004) on dependence of respondents' adherence to FDC on information on FDC as shown in Table 4.4 indicated that provision of information on FDC significantly influenced adherence to FDC as prescribed by physicians.

Moreover, 101 (37.0%) liked taking drugs but 172 (63.0%) did not. Respondents who indicated that they liked taking drugs, 1(1.0%), 4 (4.0%), 12 (11.9%) and 84 (83.1%) of them —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by their physicians. However, respondents who did not like taking drugs, 15 (8.7%), 28 (16.3%), 36 (20.9%) and 93 (54.1%) of them —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by their physicians. The Chi-square test results (Chi-square=26.001: P-value=0.000) shows that respondents who liked taking drugs adhered better to FDC than those who did not.

Table 4.4 shows that 180(65.9%) perceived FDC as good for them whilst 93 (34.1%) perceived FDC not good for them. Table 4.4 further revealed that among respondents who perceived FDC as good, 6 (3.3%), 13 (7.2%), 31 (17.2%) and 130 (72.3%) —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by their physicians. However, out of the respondents who perceived FDC as not good for them, 10 (10.7%) —rarely, 19 (20.4%) —sometimes, 17 (18.3%) —most times and 47 (50.6%) —all the time adhered FDC as prescribed. The Chi-square test result (Chisquare=19.371: P-value= 0.000) shows that respondents' perception of quality of FDC significantly influenced their adherence to FDC as prescribed by their physicians.

**Table 4.4: Patient-related Factors and FDC Therapy Adherence of Respondents**

Variables	Fixed dose Therapy are taken as prescribed (n=273)						ChiSq.	Pvalue
	Total	1	2	3	4			
	F (%)	Rarely F (%)	Sometimes F (%)	Mosttimes F (%)	All times F (%)			

Do you drink alcohol?						134.33	0.000
Yes							
No	129(100.0)	16(12.5)	32(24.8)	39(30.1)	42(32.6)		
	144(100.0)	0(0.0)	0(0.0)	9(6.3)	135(93.7)		
Do you ran out of medication?						92.33	0.000
Yes	128(100.0)	16(12.5)	23(18.0)	43(33.6)	46(35.9)		
No	145(100.0)	0(0.0)	9(6.2)	5(3.4)	131(90.4)		
Are you aggressive?						0.494	0.920
Yes	193(100.0)	11(5.7)	22(11.4)	31(16.1)	129(88.8)		
No	80(100.0)	5(6.3)	10(12.5)	17(21.3)	48(59.9)		
Do you have enough information on FDC						36.971	0.004
Yes	201(100.0)	7(3.5)	12(6.0)	35(17.4)	147(73.1)		
No	72(100.0)	9(12.5)	20 (27.8)	13(18.1)	30(41.6)		
Do you like taking drugs?						26.001	0.000
Yes	101(100.0)	1(1.0)	4(4.0)	12(11.9)	84(83.1)		
No	172(100.0)	15(8.7)	28(16.3)	36(20.9)	93(54.1)		
Is FDC good for you						19.371	0.000
Yes	180(100.0)	6(3.3)	13(7.2)	31(17.2)	130(72.3)		
No	93(100.0)	10(10.7)	19(20.4)	17(18.3)	47(50.6)		

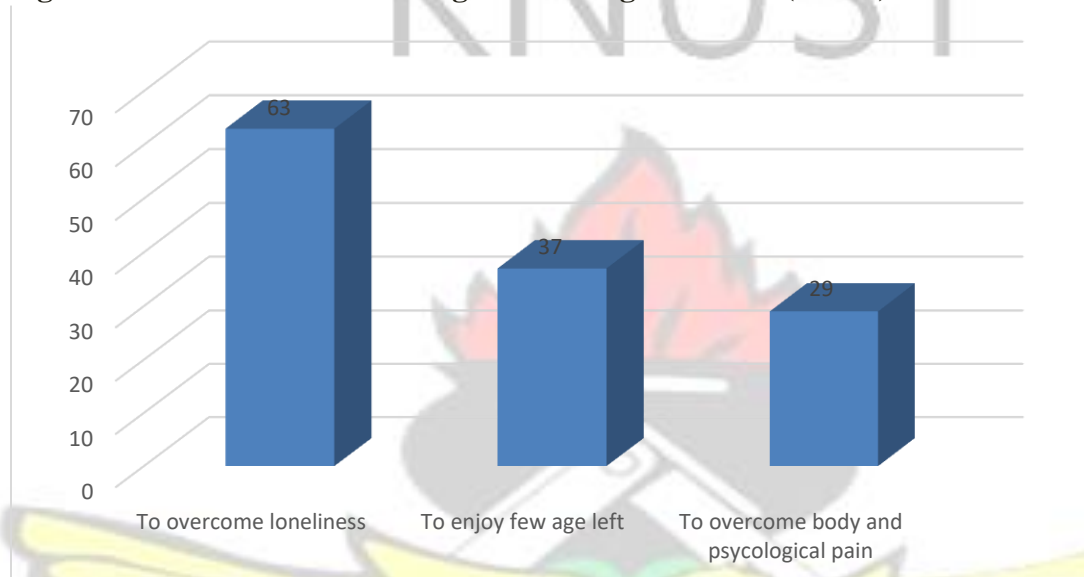
**Source: Field Data, 2014**

#### **4.4.1.1 Reasons for Resorting to Drinking Alcohol**

The study further sought for reasons why PLWHIV/AIDS forgot to take the prescribed FDC and only 129 respondents who forgot to take FDC as prescribed by their physicians responded to this question. The responses are summarized in Figure 4.1. Figure 4.1 shows that 63 (48.8%) had resorted to drinking alcohol to overcome loneliness.

Moreover, 37 (28.7%) had resorted to drinking alcohol to enjoy life and the remaining 29 (22.5%) had been drinking alcohol to overcome body and psychological pains.

**Figure 4.1: Reasons for Resorting to Drinking to alcohol (n=129)**



**Source: Field Data, 2014**

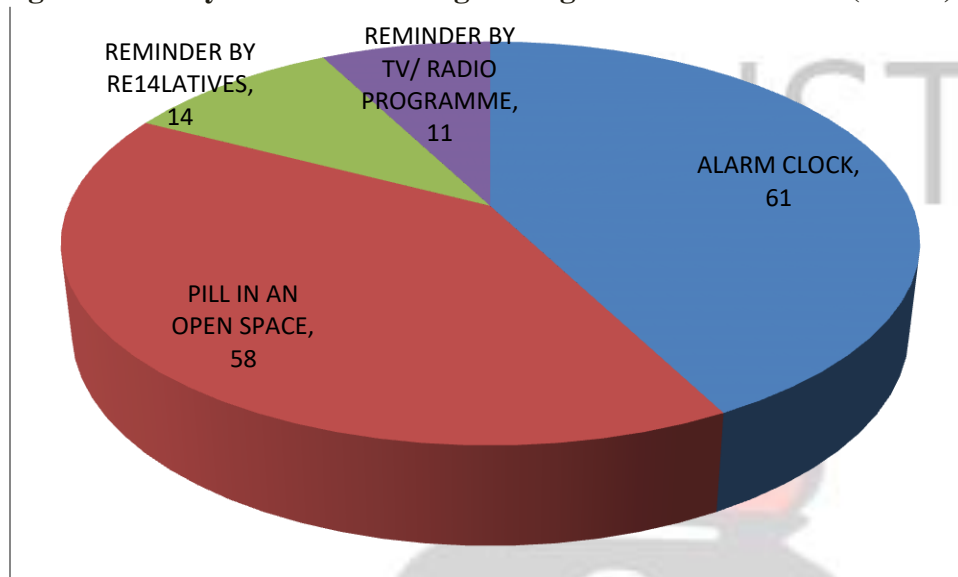
#### **4.4.1.2 Strategies to Remember Taking FDC as Prescribed**

Another important aspect was personal strategies that would help PLWHIV/AIDS remember to take FDC as prescribed. The study asked the respondents to indicate the strategy that had been useful to them in order to remember taking their prescribed FDC medication and 144 respondents responded to this question and the responses are given in Figure 4.2.

From Figure 4.2, 42.4% attested that they used alarm clock to remind themselves to take their pills. This was followed by putting pills in an open space (40.3%), reminder by relatives (9.7%) and reminder by TV/radio programme (7.6%).



**Figure 4.2: Ways of Remembering Taking FDC as Prescribed (n=144)**



**Source: Field Data, 2014**

#### **4.4.2 Socio-economic Factors and Adherence to FDC Therapy**

The study selected key social factors (such as family support, support in times of emergency, loneliness, affiliations and guidance) and asked the respondents to indicate how these applied to them by responding —Yes| or —No| or — I do not know| to selected items (see Figure 4.5).

Figure 4.5 shows that 144 (52.7%) of respondents who were PLWHIV/AIDS had assistance from family members whilst 129 (47.3%) did not receive any assistance from their families.

The scale of 1 - 4 was used for the analysis among the respondents who attested that they had assistance from their families, 3 (2.1%), 12 (8.3%) and 129 (89.6%) —sometimes|, —most times| and —all the time| respectively adhered to FDC as prescribed. However, out of 129 respondents who indicated that they had no assistance from family, 16 (12.4%)

—rarely, 29 (22.5%) —sometimes, 36 (27.9%) —most times and 48 (37.2%) —all the times adhered to FDC as prescribed by their families. The Chi-square test result (Chisquare=85.627: P-value= 0.000) shows that family support or assistance influenced PLWHIV/AIDS adherence to FDC as prescribed by physicians. Respondents who had assistance from family adhered more to FDC than those who had no assistance from family.

From Table 4.5, out of 273 respondents, 48 (17.6%) had counselling at home but 225 (82.4%) had no counselling services at home. Out of 48 respondents who received counselling at home, 7 (14.6%) and 41 (85.4%) —most times and —all the time respectively adhered to FDC as prescribed. However, out of 225 respondents who did not receive counselling at home, 16 (7.1%) —rarely, 32 (14.2%) —sometimes, 41 (18.2%) —most times and 136 (60.5%) —all the time adhered to FDC as prescribed. Counselling at home significantly influence PLWHIV/AIDS adherence to FDC (The Chi-square test (Chi-square =14.343: P-value= 0.003) and respondents who counselling at home adhered more to FDC than respondents who had counselling at home.

Another socio-economic factor the study considered was sharing of ideas with others and 220 (80.6%) of the respondents shared idea with others but the remaining 53 (19.4%) did not share ideas with others. Respondents who shared idea with others significantly adhered more to FDC as prescribed by their physicians (Chi- square= 7.765: Pvalue=0.049). Out of 220 respondents who shared idea with others, 16 (7.3%), 28 (12.7%), 34 (15.5%) and 142 (64.5%) —rarely, —sometimes, —most times and —all the time adhered to FDC as prescribed by their physicians. However, among respondents who did not share ideas with

others, 4 (7.5%), 14 (26.4%), 35 (66.1%) —sometimes, —most times and —all the times respectively adhered to FDC as prescribed by physicians.

Figure 4.5 indicates that 16 (5.9%) out of 273 respondents belonged to other social groups, aside religion whilst 257 (94.1%) did not belong to any social group, apart from religion. Out of respondents who belonged to other social groups, 3 (18.8%) and 13 (81.2%) —most at time and —all the time respectively took their FDC as prescribed. However, 16 (6.2%), 32 (12.5%), 45 (17.5%) and 164 (63.8%) of the respondents who did not belong to any social group —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by their physician. The Chi-square test (Chisquare= 3.708: P-value=0.303) shows that PLWHIV/AIDS adherence to FDC did not depend on their affiliation to social groups.

Figure 4.5 revealed that 87 (31.9%) of respondents perceived HIV/AIDS as a curse whilst the remaining 186 (68.1%) did not perceived HIV/AIDS as a curse. It was further shown in the table that 7 (8.0%), 12 (13.8%), 22 (25.3%) and 46 (52.9%) of the respondents who perceived HIV/AIDS as a curse —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by their physicians. However, out of respondents who did not perceived HIV/AIDS as a curse, 9 (4.8%) —rarely, 20 (7.3%) —sometimes, 26 (9.5%) —most times and 131 (48.0%) —all the time adhered to FDC as prescribed by their physicians. The Chi-square test result (Chi-square= 8.637: P-value=

0.033) as shown in Figure 4.5 indicates that PLWHIV/AIDS perception on HIV/AIDS as curse or not significantly influenced adherence to FDC.

Figure 4.5 shows that 49 (17.9%) of the respondents perceived FDC as expensive whilst the remaining 224 (82.1%) did not perceive FDC therapy as expensive. The perception on cost of medication significantly influenced adherence to FDC. Out of 49 respondents who perceived FDC as expensive, 6 (12.2%) —rarely, 3 (6.1%) —sometimes, 11 (22.2%) —most times and 29 (59.2%) —all the time adhered to FDC as prescribed. However, among 224 respondents who perceived FDC as not expensive, 10 (4.5%), 29 (12.9%), 37 (16.5%) and 148 (66.1%) —rarely, —sometimes, —most times and —all the time respectively adhered to FDC as prescribed by physicians.

**Table 4.5: Social Factors and FDC Therapy Adherence of Respondents (n=273)**

Variables	Fixed dose Therapy are taken as prescribed (n=273)					ChiSq.	Pvalue
	Total F (%)	1 Rarely F (%)	2 Sometimes F (%)	3 Most times F (%)	4 All times F (%)		
Assistance from family							
Yes	144(100.0)	0(0.0)	3(2.1)	12(8.3)	129(89.6)	85.627	0.000
No	129(100.0)	16(12.4)	29(22.5)	36(27.9)	48(37.2)		



Counselling at home Yes No	48(100.0) 225(100.0)	0(0.0) 16(7.1)	0(0.0) 32(14.2)	7(14.6) 41(18.2)	41(85.4) 136(60.5)	14.343	0.003
Sharing idea with others Yes No	220(100.0) 53(100.0)	16(7.3) 0(0.0)	28(12.7) 4(7.5)	34(15.5) 14(26.4)	142(64.5) 35(66.1)	7.765	0.049
Membership of social groups Yes No	16(100.0) 257(100.0)	0(0.0) 16(6.2)	0(0.0) 32(12.5)	3(18.8) 45(17.5)	13(81.2) 164(63.8)	3.708	0.303
HIV/AIDS is a cure Yes No	87(100.0) 186(100.0)	7(8.0) 9(4.8)	12(13.8) 20(7.3)	22(25.3) 26(9.5)	46(52.9) 131(48.0)	8.637	0.033
FDC is expensive Yes No	49(100.0) 224(100.0)	6(12.2) 10(4.5)	3(6.1) 29(12.9)	11(22.4) 37 (16.5)	29(59.2) 148(66.1)	6.849	0.036

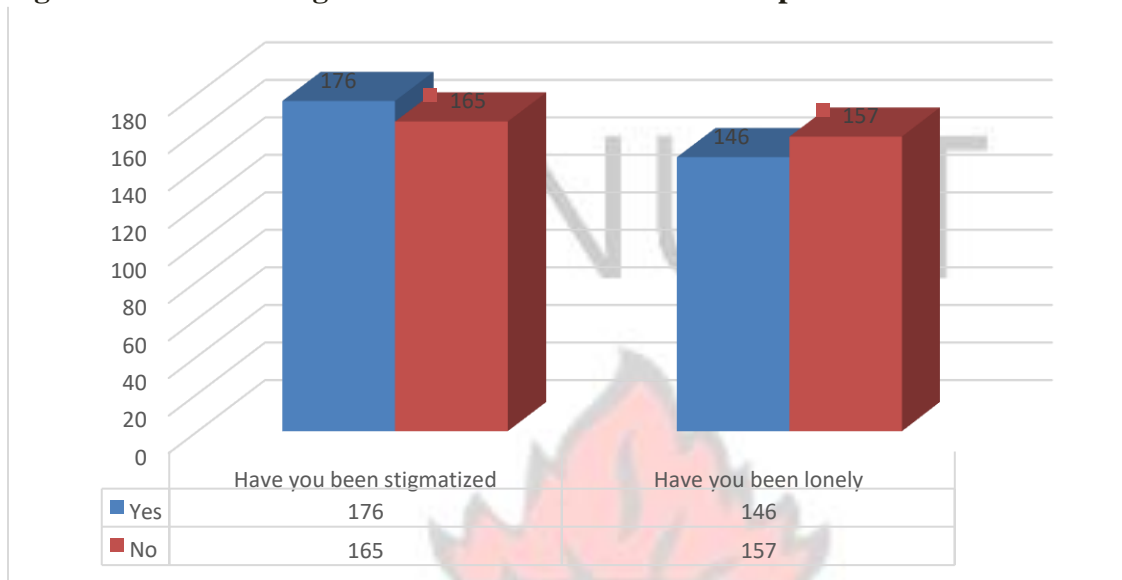
**Source: Field Data, 2014**

#### **4.4.2.1 Loneliness and Stigmatization of PLWHIV/AIDS**

The studies further found out from the respondents whether or not they were stigmatized and lonely and the responses are given in Figure 4.3. All the respondents (322) responded to these questions.

Figure 4.3, 146 (45.3%) respondents indicated they had not been stigmatized whilst the remaining 176 (54.7%) attested that they had been stigmatized. Moreover, the same figure showed that 165 (51.2%) respondents were lonely but the remaining 157 (48.8%) indicated that they were not lonely

**Figure 4.3: State of Stigmatization and Loneliness of Respondents**



**Source: Field Data, 2014**

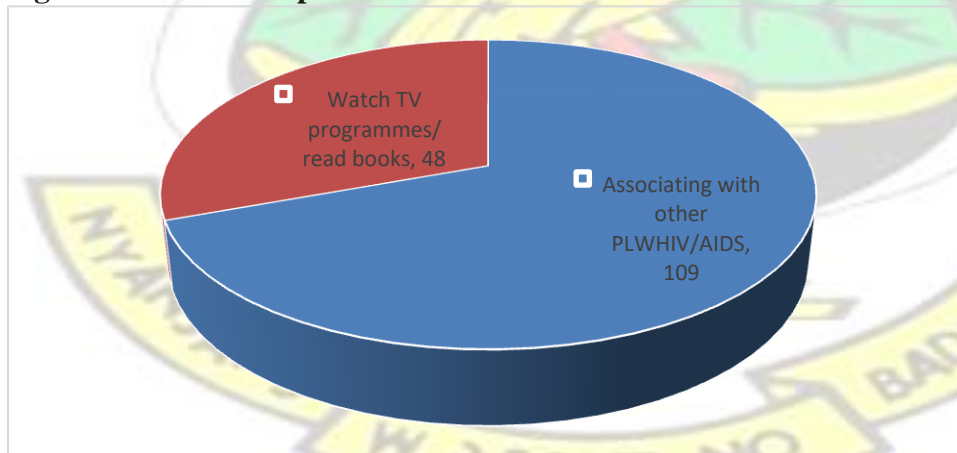
The study further asked the respondents who were stigmatized to indicate whether or not they were stigmatized by the family, spouse, friends, social group members and church members (see Table 4.6). Out of 176 respondents who were stigmatized, 127 (72.2%) attested that they had been stigmatized by family whilst 49 (27.8%) indicated otherwise. Table 4.6 shows that 131 (74.4%) respondents indicated that they had been stigmatized by their spouse whilst 45 (25.6%) indicated otherwise. Out of 167 respondents who responded to this item, 71 (40.3%) attested that they had been stigmatized by their friends whilst 105 (59.7%) had not been stigmatized by their friends. Moreover, 68 (38.6%) and 59 (33.5%) indicated they had been stigmatized by their club members and church members respectively whilst 108 (61.4%) and 117 (66.5%) had not been stigmatized by club members and church members respectively.

**Table 4.6: Sources of Stigmatization from Various Groups (N=176)**

Sources of stigmatization	Responses			
	Yes		No	
	F	%	F	%
Family	127	72.2	49	27.8
Spouse	131	74.4	45	25.6
Friends	71	40.3	105	59.7
Club groups members	68	38.6	108	61.4
Church members	59	33.5	117	66.5

**Source: Field Data, 2014**

The study moreover asked the respondents who attested that they had not been lonely to indicate others things that had kept them busy. In this section 157 respondents responded to this item as shown in Figure 4.4. Out of 157 respondents, 109 (69.4%) attested that they kept themselves busy by associating with other PLWHIV/AIDS whilst the remaining 48 (30.6%) read book and watched TV programmes to avoid loneliness.

**Figure 4.4: What Respondents do to Overcome Loneliness**

**Source: Field Data, 2014**

### 4.3.3 Healthcare Provision Factors and Adherence to FDC

This aspect of the study considered how healthcare factors and adherence to FDC were related. The study focused on friendliness of providers, information provided by providers on FDC, follow-ups by healthcare providers, confidentiality of information and trust. The responses are summarized in Table 4.7.

Table 4.7 shows that 247 (90.5%) of respondents who were PLWHIV/AIDS perceived healthcare providers to be friendly whilst the remaining 26 (9.5%) perceived their healthcare providers to be unfriendly. Among the respondents who perceived their healthcare providers to be friendly, 1(0.4%), 21 (8.5%), 48 (19.4%) and 177 (71.7%) —rarely, sometimes, —most times and —all the time respectively adhered to FDC. However from Table 4.7, respondents who perceived healthcare providers as unfriendly —rarely (57.7%) and —sometimes (42.3%) adhered to FDC as prescribed by their physicians using the scale of 1 – 4. The Chi-square test result (Chi-square= 178.35: P-value=0.000) revealed that adherence to FDC depends on friendliness of healthcare providers.

Another variable considered under this sub-section was provision of adequate information on FDC and 216 (79.1%) attested that they received adequate information on FDC whilst 57 (20.9%) of the respondents indicated otherwise. Provision of information on FDC significantly influenced adherence to FDC (Chi-square= 151.11: P-value= 0.000). From Table 4.7, out of 216 respondents who received adequate information on FDC, 4 (1.9%) —rarely, 7 (3.3%) —sometimes, 28 (13.0%) —most times and 177



(79.5%) —all the time adhered to FDC. However, 12 (21.1%), 25 (43.9%) and 20 (35.0%) of the respondents who received little information on FDC —rarely, —sometimes and —most times respectively adhered to FDC.

From Table 4.7, out of 273 respondents, 89 (32.6%) attested that they had follow ups from their healthcare providers whilst 184 (67.4%) did not receive follow ups from their providers. All those who received follow ups adhered to FDC at —at all times.

Using the scale of 1 – 4 whereby 1 = —rarely, 2 = —sometimes, 3 = —most times and 4 = —all times, 16 (8.7%), 32 (17.4%), 48 (26.1%) and 88 (47.8%) of respondents who did not receive follow ups —rarely, —sometimes, —most times and —all the time respectively adhered to FDC. The Chi-square test result (Chi-square= 72.620: P-value= 0.000) as shown in Table 4.7 suggests that follow ups on PLWHIV/AIDS and PLWHIV/AIDS' adherence to FDC were significantly associated.

Table 4.7 shows that 110 (40.3%) of the respondents perceived healthcare providers keeping information on PLWHIV/ AIDS confidential whilst the remaining 164 (59.7%) attested otherwise. However Table 4.7 shows that PLWHIV/AIDS' adherence to FDC was significantly influenced by keeping PLWHIV/AIDS' information confidential (Chisquare=49.286: P-value= 0.000). Out of 110 respondents who perceived healthcare providers as keeping clients information confidential, 15 (13.6%) and 95 (86.4%) —most times and —all the time adhered to FDC. Also, 16 (9.8%), 32 (19.6%), 33 (20.2%) and 82 (50.4%) of respondents who perceived healthcare providers as not keeping information on clients confidential, —rarely, —sometimes, —most times and —all the time respectively adhered to FDC.

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**Table 4.7: Healthcare Providers Factors and FDC Therapy Adherence of Respondents (n=273)**

	Fixed dose Therapy are taken as prescribed (n=273)					ChiSq.	Pvalue
	Total F (%)	1 Rarely F (%)	2 Sometimes F (%)	3 Most at times F (%)	4 All the times F (%)		
Do you see healthcare providers as friendly?							
Yes	247 (100.0)	1(0.4)	21(8.5)	48 (19.4)	177 (71.7)	178.35	0.000
No	26 (100.0)	15 (57.7)	11(42.3)	0 (0.0)	0 (0.0)		
Do healthcare providers provide adequate information?							
Yes	216(100.0)	4(1.9)	7(3.3)	28(13.0)	177(79.5)	151.11	0.000
No	57(100.0)	12(21.1)	25(43.9)	20(35.0)	0(0.0)		
Do healthcare providers do follow-up							
Yes	89(100.0)	0(0.0)	0(0.0)	0(0.0)	89(100.0)	72.620	0.000
No	184(100.0)	16(8.7)	32(17.4)	48(26.1)	88(47.8)		
Do healthcare providers keep clients' information confidential							
Yes	110 (100.0)	0(0.0)	0(0.0)	15(13.6)	95(86.4)	49.286	0.000
No	163(100.0)	16(9.8)	32(19.6)	33(20.2)	82(50.4)		

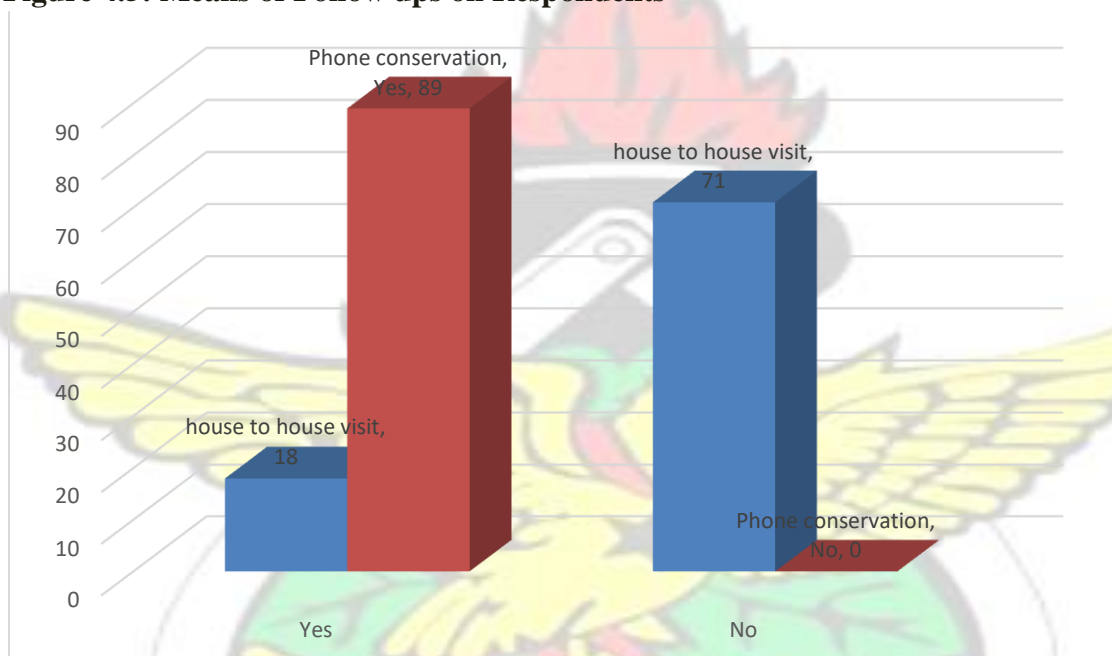
**Source: Field Data, 2014**

#### 4.3.3.2 Mode of Follow ups on Clients

The study further asked the respondents to indicate how healthcare providers followed up on them and 89 respondents responded to this question and their responses is shown as

Figure 4.5. From the figure 4.5, the means of follow-up on respondents were phone call conversation and house to house visit. All the 89 respondents received phone calls from their providers as a means of follow-up on them. However, 18 (20.2%) of the respondents had been visited in their various homes whilst the remaining 71 (79.8%) had not been visited in their homes.

**Figure 4.5: Means of Follow ups on Respondents**



**Source: Field Data, 2014**

#### **4.3.4 Therapy –related and Conditions and Adherence to FDC**

Therapy –related and conditions variables considered in this study were side effects of FDC and convenience of use of FDC.

Side effects as shown in Table 4.9 significantly influenced adherence to the FDC drugs (Chi-square test =45.489: P-value =0.000). The table also shows that, out of 140



respondents who had experienced side effects of FDC, 119 (85.0%) had experienced tiredness as side effect whilst the remaining 21 (15.0%) had not experienced any form of tiredness as a result of taking FDC therapy. Moreover, 37 (26.4%) of them had fever as a result of taking FDC whilst 103 (73.6%) had not experienced any fever as side effect of FDC. Table 4.9 further shows that all (140) the respondents attested that they had lost weight due to FDC therapy. Also, out of 140 respondents who responded to this item, 24 (17.1%) indicated that they had experienced body rashes as side effect whilst 116 (82.9%) indicated otherwise. Again, 18 (12.9%) had headache as side effect of FDC whilst 122 (87.1%) had not experienced any headache due to FDC therapy.

From Table 4.9, 221 (80.9%) of the respondents attested that FDC therapy was convenient for them whilst 52 (19.1%) indicated that FDC therapy was not convenient for them. Convenience of taking FDC significantly influenced adherence to FDC drugs and respondents who perceived FDC convenient adhered more to taking FDC than those who did not (Chi-square=207.066: p-value=0.000).

**Table 4.9: Therapy- related Factors and FDC Therapy Adherence of Respondents**

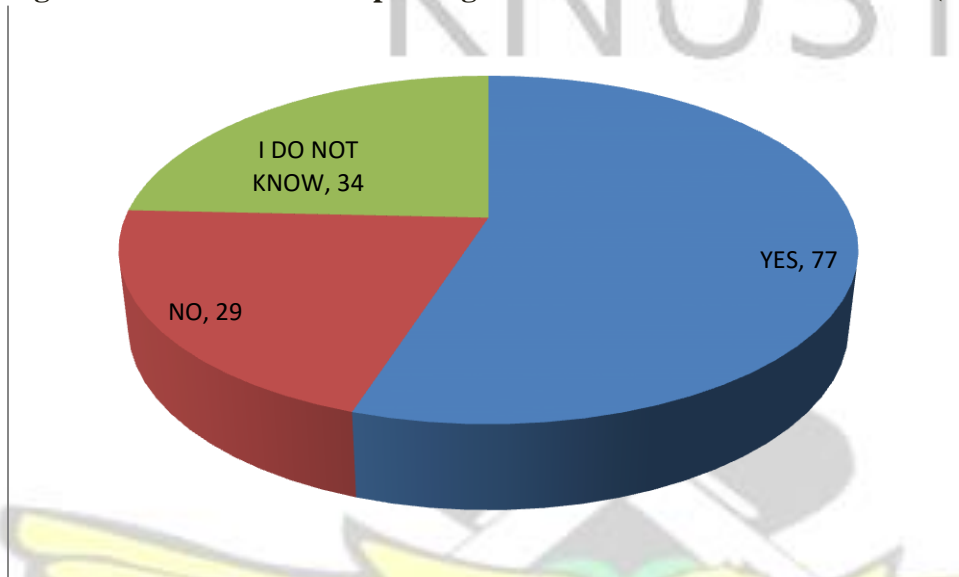
Variables	Fixed dose Therapy are taken as prescribed (n=273)
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	Total F (%)	1 Rarely F (%)	2 Sometimes F (%)	3 Most at times F(%)	4 All the times F(%)	Chi-Sq.	Pvalue
Have you experienced any side effect of FDC							
Yes	140(100.0)	16(11.4)	27(19.3)	31(22.1)	66(47.2)	45.489	0.000
No	133(100.0)	0(0.0)	5(3.8)	17(12.8)	111(83.4)		
Do you think FDC therapy is convenient							
Yes	221(100.0)	0(0.0)	4(1.8)	40(18.1)	177(80.1)	207.066	0.000
No	52(100.0)	16(30.8)	28(53.8)	8(15.4)	0(0.0)		
<b>Some selected Side Effects of FDC</b>				<b>Responses (N=140)</b>			
				<b>YES</b>		<b>NO</b>	
				<b>F</b>	<b>%</b>	<b>F</b>	<b>%</b>
Do you feel tired when you take FDC				119	85.0	21	15.0
Do you feel feverish when you take FDC				37	26.4	103	73.6
Do you lose weight when you take FDC				0	0.0	140	100.0
Do you have body rashes when you take FDC				24	17.1	116	82.9
Do you have headache when you take FDC				18	12.9	122	87.1

**Source: Field Data, 2014**

The study further asked these respondents whether or not they would stop using FDC pills due to its side effects and the responses are given in Figure 4.6.

**Figure 4.6: Would You Stop Using FDC Pills Due to its Side Effects (n=140)**



**Source: Field Data, 2014**

From Figure 4.6, out of 140 respondents, 29 (20.7%) indicated that they would stop using FDC pills, 34 (24.3%) were not sure whether or not they would stop using FDC pills whilst 77 (55.0%) indicated they would continue to use FDC pills, despite its side effects.

## **CHAPTER FIVE**

## **DISCUSSION**

### **5.1 Introductions**

This chapter discusses the results presented in Chapter Four of the study. The findings were compared to literature reviewed on each factor influencing adherence to FDC pills.

### **5.2 History of HIV/AIDS Infection**

HIV/AIDS continue to be one of the most serious health issues facing the world today. In Ghana, current HIV/ AIDS epidemic estimates show that 225,478 persons made up of 100,336 males and 125,141 females are living with HIV (Ghana AIDS Commission, 2013). The study showed that majority (40.1%) of the respondents had lived with HIV/AIDS between three years and six years. This was followed by respondents with HIV/AIDS below one year (35.1%) and those with HIV/AIDS between one year and three years (24.8%). This clearly indicates that HIV/AIDS is not a new disease in Ghana and many Ghanaian have lived with the disease for many years. The study confirmed that more females were living with HIV/AIDS than males as 56.2% of the respondents were females whilst 43.8% were males. This is not surprising since in Ghana and Ashanti Region in particular female outnumbered the male (2012 Population and Housing Census). This also confirmed several reports such as World Health Organization (2010) and Ghana AIDS Commission (2009) that prevalence of HIV/AIDS among female is higher than male. The HIV/AIDS patients' awareness of Highly Active Anti-Retroviral Therapy (HAART) was high since all the respondents were on HAART. The study showed that majority (52.5%) of HIV/AIDS patients had been on HAART between one year and three years



whilst 48.5% had been on HAART for less than one year. However, not all HIV/AIDS patients on HAART were on Fixed Dose Combination Therapy as 84.8% of the respondents had been on Fixed Dose Combination Therapy whereas 15.2% had never been on the Fixed Dose Combination Therapy. This is clear indication that most HIV/AIDS patients have accepted the Fixed Dose Combination Therapy in the study area. Moreover, the high acceptance of the Fixed Dose Combination Therapy among the HIV/AIDS patients suggests the drug is relatively good with probably little side effects. However, the sensitization on the Fixed Dose Combination Therapy should continue to ensure that all patients are on it.

Another key issue on Fixed Dose Combination Therapy is adherence to it. Paterson et al, (2004) argued that adherence is the act or quality of sticking to something, steady devotion; and the acceptance of an active role in one's own health care. According to WHO (2003) adherences to prescribed medicines are regarded as the extent to which a person's medication-taking behaviour, following a diet, and/or executing lifestyle changes, corresponds with the agreed recommendations of the HCP. The study revealed that 55.0% of HIV/AIDS patients took their medications at all times, 14.9% took their medications most of the times, 9.9% sometimes took their medications whilst 5.0% rarely took their medications.

The FDC Therapy has been introduced to reduce pill burden, or dosing frequency and/or dose requirements compared to other drugs. These factors have worked together to increasing the likelihood of adherence.

### **5.3 Patient-related Factors and Adherence to FDC Therapy**

When medicines are prescribed and dispensed, it is up to the patients to use them as directed. However, this might not always be the case. Thus, patients could be a contributory factor to non-adherence to drugs. Patient factors that have been studied include psychological issues (such as active drug or alcohol use, degree of social support and depression), the patient knowledge and religious / health belief about their illness, confusion, forgetfulness, co-morbidities (esp. depression, alcohol and drug abuse, among others).

Alcoholism was among other factors considered under patients-related factors. The study showed that 47.3% of respondents were alcoholic whilst 52.7% were not. Alcoholism significantly influenced adherence to FDC as those who were alcoholic adhered less to FDC than those who were not. Those who had resorted to alcohol indicated that they drank alcohol to overcome loneliness (48.8%) and feel happy in life (28.7%) and to overcome body and psychological pains (22.5%). The findings contradict the conclusion of Garvie et al, (2011) that young people who are living with HIV are not averse to alcohol and substance abuse. Garvie et al, (2011); Reisner et al, (2009); Braithwaite, et al, (2008); Murphy et al, (2005) all reported that frequent use of alcohol and substance abuse by HIV patients results in impaired decision making and is a critical predictor of adherence. Wanjohi (2009) equally affirmed that patients who are alcoholic are usually non-adhering patients who usually miss taking their doses. This suggests that HIV/AIDS patients in the STI Unit of the Sunreso Government Hospital would have a little higher rate of adherence to Fixed Dose Therapy since some (47.3%) of them had resorted to alcohol as a means of overcoming loneliness and social and psychological pains.

Aggression or anxiety is a critical psychological factors on adherence of a drug (Reisner et al, 2009). The study showed that HIV/AIDS patients were aggressive or anxious or distress as 70.7% indicated that they were anxious whilst 29.3% indicated otherwise. Aggression however did not significantly influenced adherence to Fixed Dose Therapy (F-Stats=0.494; P-value=0.920). The finding of this study contradicts the finding of Reisner and others that patient's depressive symptoms could affect adherence. The differences in the results is attributable to historical background of respondents. In the Reisner and others' study the respondents had been abused sexually and had attempted suicide at tender ages but in the current study none of the respondents had been sexually abused or attempted suicide. Anaya and others (2005) advised that familiarity with the patients' history could thus prove useful in predicting adherence behavior. This suggests that adherence to FDC Therapy could improve if healthcare providers at the STI Unit of the Suntreso Government Hospital probe into history of patients and effectively guide and counsel patients on the basis of their past histories.

Information on drugs and perception on the drug play important role in adherence to Fixed Dose Combination Therapy. Majority (73.6%) of the respondents attested that they had adequate information on FDC pills. The study further showed that 65.9% believed FDC pill could improve their health status. The study revealed that drug information and perception on quality of drug significantly influenced adherence to Fixed Dose Combination Therapy. This is consistent with findings of studies by Reisner and others (2009) and Simoni and others (2012) that adherence could be on the increase if a patient's accepting attitude towards medication is positive and belief that medication will improve



health status. Belzer and others (1999) found that youth who believed that HIV medication would improve the quality of their life were more likely to have >90% adherence rate ( $p=.01$ ). The reverse of this is true since negative attitudes towards medication may interfere with patient adherence.

#### **5.4 Socio-economic Factors and Adherence to Fixed Dose Therapy**

Family support, lack of social support, poor access to services, poverty, illiteracy and cultural beliefs are important predicting factors of adherence to Fixed Dose Therapy (Zuurmond, 2008).

The study revealed that family members helped HIV/AIDS patients to take medications as 52.7% attested that family members supported them. The respondents noted family members reminded them to take medication and encouraged them to visit the clinic. Patients with supportive family and friends significantly adhered better to ART than those lacking this type of support. However, HIV/AIDS patients disclosed that they did not have special guidance and counselling at home. This presupposes that family members and associates did not spend enough time with them; either due to fear of infection or busy schedules. Importantly, guidance and counseling which was crucial to adherence (HIV/AIDS Information from AVERT. Org, 2013) was missing in the support provided by family members to PLWHIV/AIDS at the STI Unit of the Suntreso Government Hospital.



Cardinal to receiving social support is disclosure to the members within social cycle since support cannot be achieved unless one discloses. The HIV/ AIDS patients confirmed that family members, relatives and associates were aware of their HIV/AIDS status and majority (84.8%) of the respondents had disclosed their HIV/AIDS status to people around them. Zuurmond (2008) argued that patients who disclose their status to family members seemed to do much better on adherence.

On the economic factors, the study considered cost of medications. The respondents attested that cost of medication was expensive and perception on cost of medication significantly influenced adherence to FDC Therapy (Chi-square =6.849: P-value=0.036). This connotes the findings of Naicker (2011) that high cost of medication emerged as stumbling blocks to adherence behavior of PLWHIVE/AIDS. It was revealed from the study that most of the respondents were not actively employed due to their HIV/AIDS infection and therefore had low incomes. This had imposed challenges on them to visit the healthcare center as expected and buy medications, hence their adherence rate was expected to be low.

### **5.5 Healthcare Provision Factors and Adherence to FDC**

The study under this section focused on patient-provider relationship, follow-up on patients, time spent at the facility and quality of information provided on drugs at the facility.

The relationship between patients and healthcare providers was among the variables of consideration under healthcare system factors. The respondents indicated that they had good relationship with healthcare providers and patients-providers relationship

significantly influenced adherence to FDC Therapy at the STI Unit of the Suntos Government Hospital. According to the respondents, the healthcare providers cared for them and listened to their concerns and had time to explain issues bothering them. This finding is in line with a study conducted by Naicker (2011) which revealed that HIV patients who accessed healthcare facilities were full of praise for the quality of service experienced –spoke highly of the encouragement and support received, and the open and trusting relationship they shared with their service providers. These healthcare providers were described as good listeners who involved the persons in treatment decision making.

Follow –up on patients after receiving treatments and prescriptions significantly influenced adherence to FDC Therapy. The respondents (67.4%) however detested that healthcare providers followed up on them. The reasons given were varied. According to the respondents, they (HIV/AIDS patients) did not want to be seen with healthcare providers since it would draw attraction on them. Due to this perception, it was revealed that some HIV/AIDS patients were not attending HAART at their own communities but travelled to other towns for treatment.

Patients trust for healthcare providers was considered. Altice and others (2001) were of the view that trust and confidence in providers have been found to influence adherence positively. In the study, it was realized that respondents (59.1%) indicated healthcare providers did not keep their information (HIV/AIDs status) confidential. According to the patients, the health facility was frequently changing health personnel since the facility was accepting national service personnel on yearly basis. The national service personnel were

seen as breaching the patients' information confidentiality oath. This perception negatively influenced the disclosure of important information to healthcare providers and negatively influenced the willingness of patients to visit healthcare facility regularly. This undermined effective adherence to FDC among PLWHIV/AIDS at the STI Unit of the Suntreso Government Hospital.

### **5.6. Therapy –related Factors and Adherence to FDC**

Therapy-related factors considered in the study were dose frequency, side-effects of drugs and availability of drugs.

The respondents (81.0%) confirmed that it was convenient to take FDC since it was a single dose taken once per day at any time within the day. The respondents said the FDC Therapy was more convenient to take than other ART. The convenience with which ART drugs are taken significantly influence adherence to prescribed drugs. In the opinion of Heiss and others (2011), Hare (2009) and WHO (2005), complexity of the medicines regimen decreases adherence. These complexities include the number of units per dose, the number of doses per day and the prerequisite to comply with strict and special requirements related to food and fluid intake. The assertion was agreed by Airoidi and others (2010) that several doses and limitations on food intake and other activities could result in poor adherence.

The second item on therapy-related factors was side effects of FDC Therapy. Side effects FDC Therapy may greatly influence an individual's readiness and willingness to adhere to the therapy. The respondents confirmed that FDC Therapy had side effects and the side

effects of FDC Therapy significantly influenced patients' willingness to adhere to treatment. The side effects, according to the respondents included headache, fever and body weakness. This was consistent with study by Agyarko-Poku and others (2014) which concluded that although, majority of patients found the multiple dose regimes cumbersome, they are skeptical about the use of the fixed dose combination treatment regime. The new regime might result in overdosing if patient found it inadequate to provide the needed protection. The fear of serious adverse reaction from combination of ARVs compared with separate drugs might scare patients from taking the treatment. Intensive adherence counseling and taking care of the above concerns is essential before patients are switched onto the fixed dose ARV regime. Heiss and others (2011) reiterated that optimal adherence should occur. They argued that even though FDC Therapy usually has temporary side effects including transient reactions (diarrhea and nausea) as well as longer lasting effects (like lipodystrophy and neuropathy), optimal adherence would occur.

## **CHAPTER SIX**

### **CONCLUSIONS AND RECOMMENDATIONS**

#### **6.1 Introduction**

HIV/AIDS patients are introduced to various forms of ART management and FDC Therapy is one of them. Whether or not HIV/AIDS patients adhere to FDC Therapy depends on factors such as patient-related, socio-economic, therapy-related and healthcare system factors. The study therefore assessed how these factors influenced adherence to FDC Therapy at the STI unit in the Suntreso Government Hospital.



## **6.2 Conclusions**

### **6.2.1 History of HIV/AIDS Patients**

It can be concluded from the study that HIV/AIDS is not new in Ghana and 40.1% of the respondents had lived with HIV/AIDS between three years and six years. HIV/AIDS patients disclosed their HIV/AIDS status to people around them and 84.8% of the respondents indicated that people knew that they were HIV/AIDS patients.

The study found that majority (84.8%) of the respondents had been on Fixed Dose Combination Therapy and 55.0% of them took their drugs at all times.

### **6.2.2 Patient-related Factors and Adherence to FDC Therapy**

The study found that HIV/AIDS patients at the STI Unit of the Suntreso Government Hospital were anxious, had adequate information on FDC Therapy and perceived FDC Therapy as good for improvement of health status. PLWHIV/AIDS had not resorted to drinking alcohol.

Adherence to FDC Therapy at the STI unit in the Suntreso Government Hospital was significantly influenced by alcoholism, drug information and perception of drug quality but was not significant to aggression.

### **6.2.3 Socio-economic Factors and Adherence to FDC**

From the study it was found that even though HIV/AIDS patients were stigmatized, they were not lonely as they had a lot of support from their family members. However, they did

not have guidance and counselling services at homes, though support and guidance/counselling significantly influenced adherence to FDC Therapy at the study area.

#### **6.2.4 HealthCare System Factors and Adherence to FDC**

The study revealed that HIV/AIDS patients had good relationship with healthcare providers and healthcare providers gave them adequate information on FDC. However, the respondents further stated that healthcare providers could not be trusted and providers did not follow-up on them at home.

#### **6.2.5 Therapy-related Factors and Adherence to FDC**

It was revealed in the study that cost of medication was expensive for HIV/AIDS patients. They could however afford cost of transport.

It can be concluded that, though FDC Therapy was convenient to take, it had side effects such as headache, fever and body weakness and convenience of taking FDC Therapy pills and side effect of FDC Therapy significantly influence adherence to FDC Therapy at the STI Unit of the Suntreso Government hospital.

### **6.3 Recommendations**

The following recommendations were made on the basis on the findings and discussions of the study. The recommendations were for patients, family members, healthcare providers and the government.

### **6.3.1 HIV/AIDS Patients**

1. HIV/AIDS patients should disclose their HIV/AIDS status to close family members so that they can provide them with needed assistance to improve their adherence to FDC.
2. HIV/AIDS patients should use reminders specially alarm clock to alert them on the times to take drugs to improve adherence to FDC.
3. HIV/AIDS patients should not focus much on the side effects of FDC but focus on the ‘improvement in health status benefit’ of strictly adhering to FDC.
4. HIV/AIDS patients should be socially active by belonging to social groups to reduce loneliness and promote social supports such as guidance and counseling.

### **6.3.2 Family Members**

HIV/ AIDS patients should be supported by family members all the time for proper utilization of their medications to improve their adherence to FDC.

### **6.3.3 Healthcare Providers**

1. Healthcare providers should show care, love and respect through friendly relationship with PLWHIV/AIDS to encourage regular hospital attendance by HIV/AIDS patients in order to increase adherence to medications.
2. Cost of medication should be tailored to the income level of HIV/AIDS patients to promote regular purchase of medications to increase adherence to medication.
3. Healthcare providers should educate partners of HIV/AIDS patients so that the partners can provide the needed assistance to patients to improved adherence.

4. Healthcare providers should consider past history of HIV/AIDS patients to enable them give appropriate guidance and counseling to patients.

#### **6.3.4 Government**

1. The government should make FDC medications are available all the time to be supplied to various HAART centers.
2. The government should ensure that the cost of FDC medications are free to all PLWHIV / AIDS to increase adherence.

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## **APPENDIX**

**KWAME NKRUMAH UNIVERSITY OF SCIENCE AND  
TECHNOLOGY/DEPARTMENT OF HEALTH EDUCATION**



# ASSESSMENT OF THE SINGLE MOLECULAR FIXED-DOSE COMBINATION THERAPY OF HIGH ACTIVE ANTI RETROVIRAL THERAPY ADHERENCE AT THE KUMASI METROPOLIS QUESTIONNAIRE FOR PLWHIV/AIDS

## Introduction

Good morning/afternoon. I am a student at School of Medical Sciences, KNUST. I will be conducting several meetings with people like you in the Kumasi metropolis to find out your views and ideas about "Assessment of the Single Molecular Fixed-Dose Combination therapy of High Active Anti Retroviral Therapy adherence at the Kumasi metropolis". Your opinions are highly essential at the same time vital as they will help us to improve the kind of service we provide. Whatever you say will be treated confidential, so feel at ease to express your candid opinion. Be assured that your responses will not in any way be linked to your identity. You are kindly requested to answer the questions below by indicating a tick or writing the appropriate answer when needed. **THANK YOU**

**Questionnaire number:**

**Date of Interview:**

## SECTION A: BACKGROUND CHARACTERISTICS

1. Age.....
  2. Gender:      Male [   ]              Female [   ]
  3. Marital status   Married [   ]      Single [   ]      Divorced [   ]      Widowed [   ]
  4. Religion:      Christian [   ]      Moslem [   ]      Traditionalist [   ]  
Other [   ], specify .....
  5. Please indicate your highest level of education?  
No education [   ]                      College/University level [   ]
  6. W Primary school level [   ]                      Post graduate level [   ]  
h J.H.S. / MSLC level[   ]  
iSSSCE level [   ]                      Any other (specify).....
- ch of the following best describes your main work status over the last 12 months?  
Please indicate it.
- Gov't employee [   ]                      National Service [   ]



Self-employed [ ]

In school/college [ ]

Any other .....

**7. Please indicate your current living arrangement?**

Living alone [ ] living with spouse [ ] living with biological parents [ ]

Living with foster parents [ ] living with friends [ ] living in student hostel [ ]

Living with relatives [ ] any other, specify .....

**SECTION B: HISTORY OF HIV INFECTION**

**8. For how long have you known your HIV status?**

Since .....

**9. Does anyone know the HIV diagnosis? (Please tick the one that applies)**

Yes [ ]

Don't know [ ]

No [ ]

Refused [ ]

**10. For how long have you been on HAART? (Please tick the one that applies)**

A week to 3 weeks ago [ ] Month to 3 months ago [ ] Since last 6 months

[ ] Almost a year ago [ ] Over 1 year [ ] Over 2 years [ ]

Other, specify.....

**11. Are you currently on a Fixed Dose Therapy?**

Yes [ ]

No [ ]

No response [ ]

**12. If yes, for how long have you been on the therapy? Please specify**

A week to 3 weeks ago [ ] Month to 3 months ago [ ] Since last 6 months

[ ] Almost a year ago [ ] Over 1 year [ ] Over 2 years [ ]

Other, specify.....

**13. If you are not on FDC, do you wish to be on it ?**

Yes [ ]

No [ ]

I do not know [ ]

**14. How often do you adhere to Fixed dose?**

1= rarely [ ] 2= sometime [ ] 3= most times [ ] 4= all time [ ]

## Factors Influencing Adherence to Fixed Dose Therapy i.

### Patient- related Factors

The following are some of the patient-related factors that influence adherence to fixed dose therapy, tick the response that are applied to you.

Questions	Responses		
15. Do you drink alcohol?	Yes	No	I do not know
16. Do you ran out of medications			
17. Are you aggressive?			
18. Do you receive enough information on fixed dose therapy?			
19. Do you enjoy taking drugs			
20. Do you see fixed dose as good medication for you			

21. I you drink alcohol, why do you do that?

1= to overcome loneliness [ ] 2= to enjoy life [ ]

3= to overcome body and psychological pain

22. If you adhere to fixed do at all time, what helps you to do that?

1= I use of alarm clock [ ] 2= I put the dose in an open place

3= my relatives/ friends remind me daily [ ] 4= I use special TV/ radio programme as reminder [ ]

### ii. Socio-economic Factors

The following are some of the socio-economic factors that influence adherence to fixed dose therapy, tick the response that are applied to you.

Questions	Responses
-----------	-----------

23. Do you receive assistance from your family?	Yes	No	I do not know
24. Do you receive counseling at home?			
25. Do you share ideas with other people?			
26. Do you belong to any social group, apart from religious group?			
27. Do you think HIV/AIDS is curable?			
28. Do you think you, fixed dose therapy is expensive?			
29. Have you been lonely?			
30. Have you been stigmatized?			

The following are groups of people who may be a source of stigmatization, indicate how these are applied to you?

Questions	Responses		
	Yes	No	I do not know
31. Have you been stigmatized by your family?			
32. Have you been stigmatized by friends			
33. Have you been stigmatized by church members?			
34. Have you been stigmatized by club members?			

### iii. Healthcare Providers Factors

The following are some of the socio-economic factors that influence adherence to fixed dose therapy, tick the response that are applied to you

Questions	Responses
-----------	-----------

	Yes	No	I do not know
<b>35.</b> Do you think healthcare providers are friendly?			
<b>36.</b> Do healthcare providers give adequate information?			
<b>37.</b> Do healthcare providers follow-up on you?			
<b>38.</b> Do healthcare providers keep your HIV/AIDS confidential			

The following means through which healthcare providers do follow-up, if they follow up on you, indicate how they do it.

Questions	Responses		
	Yes	No	I do not know
<b>39.</b> Healthcare providers call me through phone?			
<b>40.</b> Healthcare providers come to my house			

#### **iv. Therapy-related factors**

The following are some of the therapy-related factors that influence adherence to FDC, tick the response that are applied to you

Questions	Responses		
	Yes	No	I do not know
Have you experienced any side effects of fixed dose?			
Do think fixed dose therapy is convenient to take?			



The following are some of the side effects of fixed dose therapy, indicate how these are applied to you?

Questions	Responses		
	Yes	No	I do not know
Do you lose weight when you take FDC			
Do you have body rashes when you take FDC			
Do you feel feverish when you take FDC			
Do you have headache when you take FDC			
Do you feel tired when you take FDC			

