

**FACTORS AFFECTING COMPLIANCE WITH THE USE OF  
ANTI-RETROVIRAL DRUGS AMONG PERSONS LIVING WITH  
HIV/AIDS AT THE UNIVERSITY OF NIGERIA TEACHING HOSPITAL  
ENUGU, NIGERIA.**

**BY**

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## DEDICATION

THIS WORK IS DEDICATED TO THE ALMIGHTY GOD FOR HIS DIRECTION,  
PROTECTION, WISDOM AND SUSTENANCE.

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## ABSTRACT

Anti-Retroviral (ARV) drugs are effective in reducing the incidence of death due to AIDS. The drugs are administered free of charge to People Living with HIV/AIDS (PLWHA) in designated clinics throughout Nigeria. Despite their availability compliance with ARV drug treatment remains a major challenge. The factors which influence compliance to ARV drugs among PLWHA in Nigeria have not been adequately studied. This research was therefore targeted at assessing the factors which affect compliance to ARV treatment among PLWHA at the University of Nigeria Teaching Hospital Enugu.

A total of 341 consenting respondents out of the 1,200 patients who attended the weekly HIV clinic over a period of one month were selected for the study. A validated questionnaire which included questions on demographic characteristics, health related information, compliance with ARV, social support, counseling services, side effects, perceived benefits and inhibiting factors to ARV medication was used for data collection. Data were analyzed using descriptive statistics, Chi-square and logistic regression.

Participants' mean age was  $36.8 \pm 9.8$  years, 60.7% were females, 50.7% were married and 57.8% were traders/artisans. Respondents' level of education was as follows: tertiary (31.1%), secondary (42.2%), primary (21.4%) and no formal education (5.3%). Many (48.4%) respondents had been on ARV treatment for 6 to 18 months preceding the study. Eighty three percent of the participants received counseling before they were placed on ARV drugs. An improvement in health was reported by 89.1% of those that took ARV drugs as prescribed. Seventy nine percent of the respondents fully complied with their ARV medication as prescribed. The reasons for failure to take the drugs as prescribed include traveling (19.1%), forgetfulness (17.3%), lack of access to food (7.9%). Forty percent of the respondents experienced side-effects after using the drugs, as a result of which 5.0% stopped using their drugs. The side-effects included rashes (56.2%), diarrhea (30.7%), and abdominal pain (30.7%), vomiting (27.7%) and dizziness (24.8%). More males (82.0%) than females (77.3%) took their drugs as prescribed. Most (82.2%) of the married respondents took their drugs as prescribed compared to the singles (75.3%). Seventy nine point seven percent of the respondents within the age bracket 30 to 40

years complied with their ARV drug therapy whereas, 79.2% of those younger than 30 years and 78% of those older than 40 years took their ARV drugs as prescribed. Respondents who experienced improvements in their health status were more likely to comply with their treatment regimen than those who did not (OR= 15.2, 95% CI=1.6-140.1). The PLWHA who received social/ financial support were also more likely to comply with treatment regimen than those who did not receive social support (OR=1.8, 95% CI=1.1-3.1).

Compliance to anti retroviral drugs was high among the respondents in spite of the attendant side effect. This positive health seeking behavior should be reinforced through effective health education strategy such as daily counseling and patient education.

**Keywords:** Compliance, Anti-retroviral, People living with HIV/AIDS

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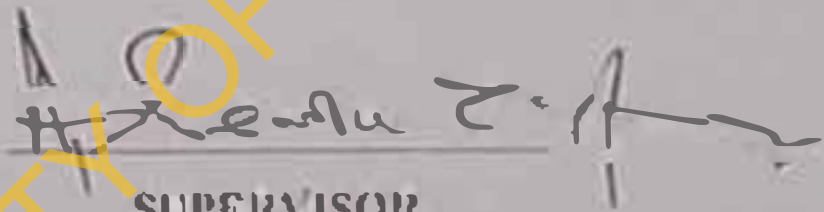
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## CERTIFICATION

I certify that this work was carried out by Pharm. Laurelin Ifeyinwa Onyekwere in the Department of Health Promotion and Education, Faculty of Public Health, College of Medicine, University of Ibadan, Ibadan, Nigeria



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## CHAPTER ONE

### INTRODUCTION

#### Background to the Study

Human Immune-deficiency Virus (HIV) is the causative agent of Acquired Immune Deficiency Syndrome. The seriousness and severity of HIV has put it as a paramount challenge facing the global public health community. The disease is important from an economic perspective because it alters demographic structures and imposes burden of morbidity and mortality on the society affecting especially those contributing fully to the economy through their productive labour (Barnett, 2005). The fact that HIV is a sexually transmitted disease places a cultural taboo on it in developing countries which gave rise to stigma and placed a big barrier to people voluntarily coming out publicly to test, know and declare their status and be ready to receive therapy and counseling where needed. Despite the various intensive intervention embarked on by various countries all over the world to educate and save the life of people living with HIV/AIDS and to stop further spread of the disease, yet millions are dying from HIV/AIDS and new cases of infections are being reported. Majority of people in developing countries are afraid to go for voluntary counselling and testing, yet a fraction live and have normal sexual life without knowing they are carriers. Some PLWHA who are placed on ARV drugs still miss doses and the timing of each dose is not strictly adhered to. The impact of HIV/AIDS in sub Sahara African region is threatening development in all sectors of the society. The loss of productive workers and increase in healthcare and social service spending require difficult decision about resource allocation across all government sectors (UNAIDS, 2002).

By the end of 2008, 33.4 million people were living with HIV, more than 90 percent of them in the developing world. The number of people living with HIV has been increasing and women now comprise 50 percent of adults living with HIV. 2.1 million children under age 15 are living with HIV and millions more are affected by the epidemic, having lost parents to HIV (Global Health Council, 2000-2011). Also by the end of 2011, out of the estimated 33.3 million adults and children living with HIV about 22.5 million adult and

children were living with HIV/AIDS in sub-Saharan Africa, although an estimated 12% of the total world population lives in sub-Saharan Africa (WHO, 2011).

Everyday more than 7,400 men, women and children are infected with HIV – in 2008 alone, an estimated 2.7 million people were newly infected. After peaking in the late 1990s, the global rate of new infections has slowed and the number of new infections has declined, (Global Health Council, 2000-2011). By the end of 2010 HIV/AIDS has become a manageable chronic disease for many people, particularly those in high-income countries and increasingly so for those in developing countries. Over the past 27 years, nearly 25 million people have died from AIDS. With no or limited medication to treat the infection, AIDS patients may die within a few years. This is especially true in developing countries where antiretroviral drugs reach a limited number of people. Of the two million people who died in 2008, 1.7 million were 15 years of age and older, and 280,000 were under the age of 15 (Global health council, 2000-2011). Despite the large amount of aid made available in addressing the AIDS epidemic, shortfall in both money and number of people being reached are apparent. The coverage of ARV drugs was 37% in Africa as at the end of 2009, at this period only Botswana and Rwanda in African region has achieved universal access of 80% ARV coverage (WHO, 2011).

Nigeria, is the most highly populated African nation with a population of 140 million people, having an adult HIV prevalence of 4.4 per cent, the country has the world's third largest burden of HIV/AIDS after South Africa and India. The population of people living with HIV/AIDS is estimated to be 3.86 million, and AIDS-related deaths average 310,000 per year. Children living with HIV/AIDS are of the order of 290,000 while children with one or both parents killed by AIDS-related conditions are believed to be as many as 1.8 million (NACA/Global fund, 2007)

Limited access to ARV drugs is a major challenge within a comprehensive health sector response to the HIV/AIDS epidemics world over. Despite the fact that access to ARV is a big problem yet the Nigerian national ARV coverage has continued to increase over the years. The increasing trend in ARV drug coverage is as follows: 2% (2004), 6% (2005), 13% (2006), and 26% in 2007. (WHO/UNAIDS/UNICEF, 2008), 2010 (NACA 2011). As at December 2007 about 15,345 children under 15 years were receiving ARV drugs. In 2007 of the 190,000 pregnant mothers needing ARV drugs to prevent mother to child HIV



transmitted, only 12,278 received ARV drugs which represented only 7% coverage, (WHO/UNAIDS/UNICEF, 2008).

As the worldwide HIV/AIDS pandemic continues to gather momentum, millions of people infected with HIV definitely will face early death unless they receive appropriate life extending medical care. There have been tremendous gains in survival and quality of life following introduction of highly active antiretroviral therapy. Countries that have broad access to effective antiretroviral therapy (ART) have been experiencing dramatic clinical benefits from ARV drug therapy. Very few people are progressing to AIDS. Hospital AIDS wards have practically emptied and the age adjusted death rate from HIV/AIDS has declined by more than 70%. Compliance with ART has emerged as both the major determinant of this success (Machilinger et al, 2005). The success of the current ARV drug in the treatment of HIV has transformed the global view of HIV as a lethal killer to a chronic disease. The advent of ARV drugs have faced many challenges such as limited access to ARV drugs by those infected with HIV, lack of compliance with ARV prescription, drug side effect, and emergence of resistant strain of HIV which are not responsive to the current ARV drugs in use.

Low compliance with medication could lead to the emergence of resistant strains of HIV virus. Adherence is the degree to which a patient conforms to treatment as prescribed by a healthcare provider (Illiya, Kabir, Abubakar, Babashum, Zubair, 2005). Quantitatively, adherence is expressed as percentage of prescribed doses that have been taken by the patient. In Anti retroviral drug therapy, adherence of less than 95% has been linked with treatment failure and emergence of virus mutation that are resistant to current ARV drugs (Illiya et al, 2005).

ARV drugs act by reducing the replication of the HIV, thereby reducing the viral load while increasing body immunity by increasing the CD4 lymphocytes as a result of the above strict compliance with ARV medication is needed to achieve optimal result. Consequently non adherence results into drug resistance which is a concern with HIV treatment, because once it occurs, future treatment options become limited (Mohamed et al, 2003). Once resistant to a drug, a patient can no longer benefit either from the particular drug or from other antiretroviral drug from its class. Cases like this if not kept in check might lead to the development of multiple drug resistance in the population which will be of alarming public health concern.



Human Immunodeficiency virus (HIV) mutates rapidly in the absence of drug or in sub-therapeutic treatment. Hence taking the antiretroviral drugs rigidly as prescribed without missing or reducing dose becomes extremely important (Leslie et al, 1998). Drug resistance may occur regardless of whether a person adheres to his/her treatment regime or not. The most common reason for drug resistance is people missing doses or taking low doses or not following food restriction (Leslie et al, 1998). Thus the emergence of drug resistance strains of HIV and failure of ART is worrisome for two reasons: first resistance to ARV drugs have been reported in patient in Nigeria (Mohammed, 2002). Secondly in a developing country such as Nigeria the option of second line drugs are limited in case of a person that develops resistance to the 1<sup>st</sup> line ARV drugs (Mohammed, 2002). This increases the probability of at risk population becoming infected with multi-resistant HIV, thereby producing a potential public health consequence. Plasma HIV-RNA levels have shown to quickly rebound in those with undetectable viral loads after stopping therapy, in some cases even exceeding pre-therapy levels within 21 days. Recently it has been shown that PLWHA on long term anti retroviral drugs with undetectable levels of plasma viremia can harbor replication competent HIV –1 DNA in resting memory CD4+ T cells. This throws more light on the need for indefinite lifetime use of ARV drugs even when undetectable levels of plasma viremia have been met, at best with current medications.

#### Problem statement

Since the evolution of highly active anti-retroviral drugs like protease inhibitors in treatment of people living with HIV (PLWHA), the quality of life of these group of people have greatly increased (Machilinger et al, 2005) and antiretroviral adherence is known to be the second strongest predictor of progression to AIDS after CD lymphocyte count (Machilinger et al, 2005). In one study, self reported, no compliance with ART drugs was associated with low likelihood of suppressing plasma viral load below 50 copies/ml at 52 weeks follow up (Mohamed and Sarki, 2002). Also no adherence has been indicated in development of resistant strain of HIV leading to untreatable form of the disease (Leslie et al 1998, Adair, Mallett- Tyndale and Cohen 2003).

Adherence clearly is associated with CD4 lymphocytes count. In a cohort study involving 1,095 participants, those who reported adherence level of 100%, 80-99% and 0 to 79% had CD4 count increases of 179, 159, and 53 cells/ $\mu$ l respectively from the baseline to month 12 ( $p < 0.001$ ). In the same study those with 95% adherence had mean increase in CD4

count of 83 cells/ $\mu$ l while those with adherence of  $\geq 95\%$  had a mean increase of 6 cells/ $\mu$ l. In the same study a 10% decrease in adherence was found to result in doubling of viral load (Machtinger et al 2005). These findings suggest that very high level of adherence is required for full and durable virology suppression in ART.

In industrialized countries where treatment are usually provided free of charge measures adopted to improve compliance with treatment include counseling, patients education program and telephone hot line. Studies are therefore needed to determine level of adherence and to identify the determinants of high adherence in Nigerian Context. These research findings will help to define efficient and acceptable adherence measure for patients within the Nigerian health system.

To the best of knowledge of the researcher few studies in Nigeria have explored the factors that determine compliance amongst PLWHA especially in the Eastern region of Nigeria. There is therefore need to research into the factors that determine outcome of Compliance to ARV drugs amongst PLWHA in Nigeria as the success of the current ARV drug therapy revolves around PLWHA compliance with their ARV therapy.

### Justification

The primary goal of ARV therapy is to prevent HIV related morbidity and mortality and development of resistance to ART drug therapy. Many studies have shown a strong correlation between adherence and clinical outcomes and or laboratory markers (notably CD4 count). Non adherence has been shown to diminish the immunological benefit of ART and increase AIDS related morbidity, mortality and hospitalizations, (Machtinger et al 2005, Adam et al 2003). Antiretroviral drugs treatment may be a lifelong process. As a result of this there is crucial need for scientific research into the importance of compliance with ARV drug and factors that motivate and restrain compliance with ARV drugs. The findings of such research will be integrated in counseling and interventions targeted at educating PLWHA to help them improve their adherence which will in turn improve the outcome of ARV drugs and improve quality of life, life expectancy and productivity of PLWHA while reducing the frequency of premature death and opportunistic infections. Also such research findings will go a long way to help clinician/health care workers, public health personnel, the pharmaceutical industry and other ancillary services to create meaningful answers to the myriad of questions surrounding antiretroviral drug adherence.



This research is therefore justified for three reasons, first to identify factors that will motivate compliance with ARV therapy by PLWHA, which is of benefits not only for the health of the individual but also for the health of the public as a whole. Identifying factors that will determine compliance with antiretroviral drugs both in timing and in dosing, will help to bring down the incidence of ARV drug failure. Also identifying restraining/constraining factors to this practice will ensure adequate intervention to weaken such negative forces with the ultimate goal being to ensure regular and consistent compliance to the ARV medication so that PLWHA could attain greater than 95% adherence.

Secondly a sound knowledge of these factors will increase clinicians and other health workers attention to adherence when working with people living with HIV and can help in the development of intervention to improve adherence. This will in turn improve the quality of life and longevity for those infected with HIV while abolishing the incidence of drug resistance and spread of the HIV virus.

Thirdly this study strives to identify sources of support that play important role in facilitating PLWHA's compliance with ARV and get them to integrate the finding of this research into the patient ART counseling.

#### **Research questions**

1. What is the relationship between demographic characteristics and compliance?
2. How many tablets have you missed in the last seven days?
3. What factors motivate PLWHA to take their ARV drugs?
4. What factors restrain PLWHA from taking their ARV drugs?

#### **Broad objective**

The main objective of this study was to determine factors that affect compliance with the use of anti-retroviral drug regimen.

#### **Specific objectives**

The specific objectives were to;

1. Determine reported compliance with ARV medication by people living with HIV/AIDS.

2. Identify motivation factors of compliance with ARV medication regimens
3. Determine restraining factors to ARV medication regimen.
4. Determine reported perceived benefits of compliance with ARV medication regimens by PLWHA.
5. Determine relationship between demographic characteristics and compliance to ARV drugs.

### Hypothesis

Based on the variables measured, the following null hypothesis were formulated.

1. There is no association between respondent's demographic characteristics and compliance with ARV drugs.
2. There is no association between side effects and compliance with ARV drugs.
3. There is no association between receipt of social support and compliance.
4. There is no association between reported effects of drugs on respondents' health and compliance to ARV drugs.

## CHAPTER TWO

### LITERATURE REVIEW

#### Global HIV Situation

In 2007, there were estimated to be 30-36 million people living with HIV/AIDS globally and nearly 3 million incident cases, including 400,000 newly infected children under the age of 15 years, 90% of whom resided in Africa. Among newborns who contracted the virus through maternal transmission, approximately half did not survive more than 2 years. While the pandemic has stabilized in Africa since 2001, the number of reported cases increased in other regions of the world during the same period (Global Health, 2010).

Antiretroviral therapy (ART) significantly suppresses HIV viral loads in infected individuals, greatly reduces HIV-related mortality and transmission rates, and enables healthcare providers to treat the disease as a manageable chronic condition. Taken daily as a life-long treatment or over a controlled 28-day regimen as a post exposure prophylactic by those who experience a high-risk event such as a sexual encounter with an infected individual or a needle-prick exposure by a healthcare worker, antiretroviral drugs have been responsible for the remarkable declines in post infection morbidity and mortality over the last 20 years. Due to dramatic effect of ART, 'test and treat' methods have been adopted as a potentially important strategy in the fight against HIV. In the test and treat approach, a premium is placed on universal testing, followed by placing individuals who test positive for HIV immediately on ART to minimize their infectiousness to others (Global Health, 2010). By the end of 2008, 33.4 million people were living with HIV, more than 90 percent of them in the developing world. The number of people living with HIV has been increasing and women now comprise 50 percent of adults living with HIV. 2.1 million Children under age 15 are living with HIV and millions more are affected by the epidemic, having lost parents to AIDS (Global Health 2010).

Everyday more than 7,400 men, women and children are infected with HIV. In 2008 alone, an estimated 2.7 million people were newly infected. After peaking in the late 1990s, the global rate of new infections has slowed and the number of new infections has declined (Global health council, 2000-2011). Dealing with HIV/AIDS is not easy, regardless of country a person may face discrimination, problems with access to care and



treatment, and uncertainty about family decisions. However, it is relatively less complicated to cope with the disease in industrialized countries than in developing countries. With ARVs, HIV/AIDS has become a manageable chronic disease for many people, particularly those in high-income countries and increasingly so for those in developing countries. Over the past 27 years, nearly 25 million people have died from AIDS. With no or limited medication to treat the infection, AIDS patients may die within a few years. This is especially true in developing countries where antiretroviral drugs reach a limited number of people. Of the two million people who died in 2008, 1.7 million were 15 years of age and older, and 280,000 were under the age of 15 (Global Health Council, 2000–2010).

### **HIV situation in Sub-Saharan African region**

Sub-Saharan Africa which encompasses 43 of the 46 countries in the WHO African Region continues to be the region worst affected by the HIV epidemic. Based on the most recent UNAIDS/WHO estimates, as of December 2009, the number of people living with HIV in sub-Saharan Africa was 22.5 million (WHO, 2011). This represented two thirds of the global number of 33.3 million people living with AIDS, although only about 12% of the world's population lives in sub-Saharan Africa.

The HIV prevalence among adults aged 15–49 years declined from 5.8% in 2001 to 5.0% in 2009, but the number of people living with HIV has continued to increase, up from 19.7 million in 2001 as a result of the momentum of the epidemic and growing population. In 2009, an estimated 1.8 million people became newly infected with HIV in sub-Saharan Africa (WHO, 2011). The epidemic peaked in the mid 1990s. The rate at which people become newly infected in 2009 was 25% less than the peak rate (WHO, 2011). Countries in the Southern Africa sub region continue to be the epicenter of the HIV epidemic, with higher prevalence rates in the urban centers and women being more affected than males (WHO, 2011). The gender bias is more in Africa and is attributed to low social state of women, risky sexual practice and endemic poverty in Africa. These contribute to the spread of HIV/AIDS. The impact in women is less in Asia (28%). Increase mortality in workforce translates into productivity losses and loss to employers due to staff illness and death.

HIV programmes have helped strengthen national health systems by attracting new funding for health, supporting capacity building and integrating chronic disease management into health care settings. The African Region has begun to see progress in the fight against the HIV epidemic. Of the 10 countries in the Region accounting for 80% of the people living with HIV, the incidence of HIV infection declined by more than 25% in six countries (Ethiopia, Malawi, Mozambique, United Republic of Tanzania, Zambia and Zimbabwe) and stabilized in three countries (Kenya, Nigeria and Uganda) between 2001 and 2009 (WHO, 2011). On the whole, the incidence of new HIV infections is decreasing in 22 countries (Botswana, Burkina Faso, Central African Republic, Congo, Cote d'Ivoire, Eritrea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Malawi, Mali, Mozambique, Namibia, Rwanda, Sierra Leone, South Africa, Swaziland, Togo, United Republic of Tanzania, Zambia and Zimbabwe) and stabilizing in 11 countries (Angola, Benin, Cameroon, Democratic Republic of the Congo, Ghana, Kenya, Lesotho, Niger, Nigeria, Senegal and Uganda) (WHO, 2011). The prevalence of HIV infection among adults aged 15-49 years decreased from 5.9% in 2001 to 5.0% in 2009 (WHO, 2011).

Despite the large amount of aids made available in addressing the AIDS epidemic, shortfall in both money and number of people being reached are apparent. The coverage of ARV drugs was 37% as at the end of 2009, at this period only Botswana and Rwanda in African region has achieved universal access of 80% ARV coverage (WHO, 2011).

#### **HIV situation in Nigeria**

Nigeria, is the most highly populated African nation with a population of 140 million people, having an adult HIV prevalence of 4.4 per cent. The country has the world's third largest burden of HIV/AIDS after South Africa and India. The population of people living with HIV/AIDS in Nigeria is estimated to be 3.86 million, and AIDS-related deaths average 310,000 per year. Children living with HIV/AIDS are of the order of 290,000 while children with one or both parents killed by AIDS-related conditions are believed to be as many as 1.8 million (NACA/Global Fund, 2007).

The first case of HIV/AIDS was identified in 1986 following which the National Expert Advisory Committee on AIDS (NEACA) was established in 1987. The National AIDS and STDs Control Programme (NASCP) was established in 1988 to replace NEACA Control efforts which suffered political will and poor funding over the years until the



nation reached a turning point in 2000. That year the National Action Committee on AIDS (NACA) was established to lead an all-embracing, multi-sectoral response, for which it got unprecedented levels of political support and funding from the government and international development partners. The Committee in early 2007 was transformed into National Agency for the Control of AIDS, also NACA (NACA/Global fund, 2007). The overall goal of the effort is to reduce HIV/AIDS-related mortality and morbidity through:

1. Scaling up comprehensive HIV/AIDS treatment, care and support for people living with HIV/AIDS to all 37 States in the country
2. To expand access to Counseling and Testing services to cover 37 states of the country
3. To strengthen the role of the community, civil society organizations and networks of PLWHA in providing and supporting HIV/AIDS treatment and care
4. To increase access to Care and Support services for orphan and vulnerable children in 37 states of the country
5. To increase the capacity of the private sector to implement workplace HIV/AIDS programmes in 12 states, and

To strengthen the capacity of implementing institutions for effective programme management, coordination, monitoring (NACA/Global fund, 2007)

Nigeria in line with WHO guidelines adopted antenatal (ANC) sentinel surveillance as the system for assessing HIV epidemic. The first HIV Sentinel Survey in 1991 showed a prevalence of 1.8%. Subsequent sentinel surveys produced prevalence of 3.8% (1993), 4.5% (1996), 5.4% (1999), 5.8% (2001), 5.0% (2003), 4.4% (2005), 4.6% (2008) and 4.1% (2010) (Nnorum, 2011, FMOH, 2010). This trend is shown in the graph in fig 1.

The 2008 ANC sentinel surveillance survey report indicated 4.6% as the overall HIV prevalence among women attending ANC during the period. The highest zonal prevalence (7.0%) was in South-South but lowest in South West (2.0%) in 2008. The HIV prevalence among the states varied even more. The State prevalence ranged from 10.6% in Benue to 1.0% in Ekiti. Seventeen States and FCT had prevalence of 5.0% and above (Nnorum, 2011)

The number of persons living with HIV (PLWHA) in Nigeria by the end of 2008 was estimated to be 2.95 million. Of this 2.63 million were adults (>15 years) and 278,000 were children. About 323,000 adult and 57,000 childhood new infections occurred in

2008. At the same time it is estimated that the number of persons requiring ART has significantly risen to about 833,000 partly due to large number of people on ART coupled with the increased survival rate of PLWHA and the growing population. These figures will keep rising in future due to these same reasons (Nnorun, 2011).

The national population survey of 2007 showed an overall HIV prevalence of 3.6 % (4.0% among females and 3.2% males). Among the high risk groups (FSW, MSM, IDU, and LDTW), female sex workers constitute an important reservoir of HIV infection for continuous transmission to the general population. HIV prevalence was found to be high among this group and their more regular clients like the long distance truckers and transport workers. (Nnorun, 2011). Generally HIV/AIDS prevalence was observed to be higher in urban towns than rural areas except in a few cases.

1.1.



Fig 1: National HIV Prevalence trend 1991 - 2010 (IHSS 2010)

Fig.1 shows the trend of HIV prevalence among pregnant women attending antenatal clinics in Nigeria from 1991 to 2010. The HIV prevalence increased steadily from 1.8% in 1991 through 4.5% in 1995 and peaked at 5.8% in 2001. Thereafter, it declined to 4.4% in 2005 and stabilized between 4.4% (2005) and 4.1% in 2010.

Source: ANC HIV Sentinel Survey Nigeria 2010.



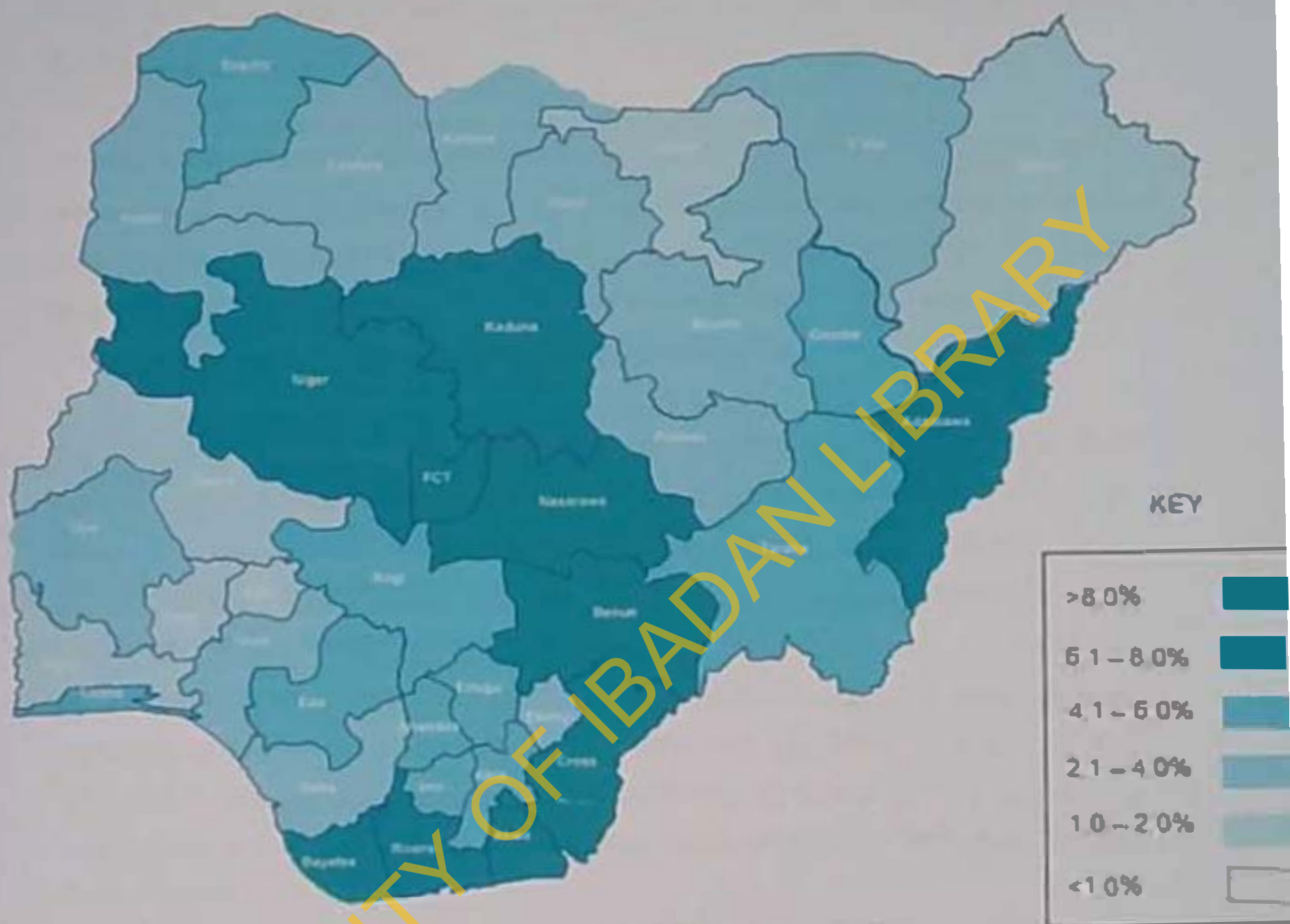


Figure 2: Geographical distribution of HIV Prevalence by states NIISS 2010



Figure 2: Geographical distribution of HIV Prevalence by states NEISS 2010

## Access to ARV drugs In Nigeria

Access to ARV drugs is a major problem in Nigeria from the time of inception of ARV therapy in Nigeria till date and this has necessitated the scaling up of the initial 25 ARV centers to 71 centers in 2005 and eventually 215 ARV centers in 2007 (WHO/UNAIDS/UNICEF, 2008).

Progress in world health is the key to achieve universal access to HIV/AIDS prevention treatment and care. Sequel to this, WHO as co-sponsor with UNAIDS, leading the health sector response to HIV/AIDS is committed to monitor and report annually on global progress in various country's health sector and ensuring intervention to support scale up of drug procurement, supply management and human resources.

The number of PLWHA receiving ARV drugs for the years ranging from 2004 to 2007 was reported to be 13,000 (2004), 41,000 (2005), 95,000 (2006), 198,000 (2007), 359,181 (2010). The number needing the ARV drugs were 620,000 (2004), 670,000 (2005), 710,000 (2006), 750,000 (2007) and 1,400,000 (2010). This denoted a coverage of 2% (2004), 6% (2005), 13% (2006), and 26% in 2007, (WHO/UNAIDS/UNICEF, 2008) and 26% in 2010, (NACA, 2011), (Table 2.1). Generally ARV coverage has consistently been experiencing increase since 2004 when the coverage was only 2% to 26% in 2007 and 2010 and is still increasing till date due to availability of free drugs and tremendous improvement in the health services rendered since the intervention of PEPFAR and Global health interest.

As at December 2007 about 15,345 children under 15 years were receiving ARV drugs. In 2007 of the 190,000 pregnant mothers needing ARV drugs to prevent mother to child HIV transmission, only 12,278 received ARV drugs which represented only 7% coverage, (WHO/UNAIDS/UNICEF, 2008), (Table 2.2). The antenatal coverage from 2000 to 2007 was 58%. The number of living orphans due to death of parents by HIV as at 2007 was 1,200,000, while 170,000 death was recorded due to HIV/AIDS in 2007 (WHO/UNAIDS/UNICEF, 2008).



**Table 2.1 Access to ARV drugs in Nigeria ADULTS**

Year	2004	2005	2006	2007	2010
Estimated people receiving ARV therapy	13,000	41,000	95,000	198,000	359,181
People needing ARV therapy	620,000	670,000	710,000	750,000	1,400,000
%ARV coverage	2%	6%	13%	26%	26%

Source (2004 to 2007) UNAIDS/WIHO/2008, and (2010) NACA 2011

**Table 2.2**

**Pregnant women needing ARV to prevent mother to child transmission of HIV**

Year	2004	2005	2006	2007
No receiving ART	1050	532	6168	12278
No needing ART	180,000	190,000	190,000	190,000
% ART coverage	<1	<1	3	7

Source: UNAIDS/UNICEF/WIHO 2008



## Virological nature of HIV

The HIV causative agent is a member of the lentivirus genus of the retrovirus family (Akamu & Okanu, 2004). The virus membrane is studded with proteins that enable it to bind to and enter cell and the size is 70 -130nm (WHO, 1999). When the virus enters the human cell, it attaches itself to CD4 antigen which is present on the cells in the body immune system, the helper T lymphocytes and on some macrophages. It sheds its lipid coat and injects its RNA into the human cells. The single stranded RNA then duplicates itself with the use of reverse transcriptase enzyme resulting in a double stranded DNA which incorporates itself into the human DNA. In this way the virus forms part of the human genetic material making the infection irreversible and thereby leading to a life-long infection (Sofoluwe, Schram and Ogunmekon, 1996). This entry stage is called primary infection (acute stage) and characterized by a peak in viral load coupled with fever, malaise, myalgia and lymphadenopathy. The viral load stabilizes at this stage only to increase again when the infected individual progresses to severe diseases (AIDS). A person infected with HIV may show no symptoms of AIDS for many years but can transmit the virus to uninfected persons (Population Bulletin, 1997). The destruction of the white blood cells and their functions by the HIV results in the patients inability to deal with microbes such as pneumocystis carinii, cryptosporidia, mycobacteria, herpes virus and cytomegalovirus. ARV drug therapy can delay progression to AIDS in HIV infected persons and prolong the life of PLWHA.

## Therapeutic Intervention in management of HIV/AIDS

In December 1995, the food and drug agency of America licensed the first protease inhibitor for AIDS therapy. In July 1996, encouraging results from clinical trials of drug cocktails containing this new class of antiretroviral agents were reported at the IAP International Conference on AIDS. The introduction of these potent antiretroviral drugs led to a great change in the care of PLWHA world over and gave the PLWHA hope for survival. ARV treatment actually does not provide a cure but has been recorded with both good immunological and virological response in PLWHA receiving the drugs such that it has drastically reduced HIV related mortality and morbidity (Mohammed and Sarki, 2002, Patella, Deforaknol and Clement, 2003). Highly active Antiretroviral Therapy (HAART) has been shown to decrease the rate of hospitalization and opportunistic infection in those infected with HIV.

## Classes of ARV drugs

Antiretroviral (ARV) drugs are broadly classified by the phase of the retrovirus life-cycle that the drug inhibits. When several such drugs, typically three or four, are taken in combination, the approach is known as Highly Active Antiretroviral Therapy, or HAART. The various classes of antiretroviral drugs currently available are:

1. **Nucleoside Reverse Transcriptase Inhibitors (NRTIs)**, so called "nukes" inhibit reverse transcription by being incorporated into the newly synthesized viral DNA strand as a faulty nucleoside. This causes a chemical reaction resulting in DNA chain termination. Eight of these drugs are currently available. Antiretroviral combination drug therapy involves two NRTIs and one drug from another class.
2. **Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)** block reverse transcriptase by binding to the reverse transcriptase enzyme. With the enzyme blocked it thereby interferes with the enzyme function and HIV cannot reproduce.
3. **Protease Inhibitors (PIs)** target the HIV protease enzyme called HIV-1 protease, which the virus uses to complete viral replication. By binding to this enzyme, PIs inhibit its activity and therefore prevent viral replication.
4. **Fusion or Entry Inhibitors (FIs)**; For HIV to enter a human cell, it must first attach itself to proteins on the cell's surface. It first attaches to CD4 and the next stage it attaches to protein called co-receptors like CCR5 and CXCR4. Some HIV virus are selective while some can use either. The fusion inhibitors do not target the virus directly rather they bind to the co-receptor sites so that HIV cannot exploit it to enter the cell. If HIV cannot attach to the cell, it cannot gain entry to replicate. The setback is that they do not work against all strains of HIV. Maraviroc and Enfuvirtide are the two currently available agents in this class.
5. **Integrase Inhibitors (IIs)** inhibit the enzyme integrase, which is responsible for integration of viral DNA into the DNA of the infected cell. There are several integrase inhibitors currently under clinical trial, and Raltegravir became the first to receive FDA approval.
6. **Maturation Inhibitors** inhibit the last step in gag processing in which the viral capsid polypeptide is cleaved, thereby blocking the conversion of the polypeptide into the mature capsid protein (p24). Because these viral particles have a defective core, the virions released consist mainly of non-infectious particles. Alpha interferon is a



currently available agent in this class. Two additional inhibitors under investigation are Bevirimat and Virocon.

Therapy with the above drugs aim at inhibiting viral replication to maintain effective immune response to most microbial pathogens in HIV infected persons, thereby reducing viral load while increasing body immunity by increasing the CD4 lymphocytes. As a result of this, quality of life of PLWHA is improved with resultant reduction in morbidity and mortality. ARV therapy also reduces the risk of HIV transmission. Zidovudine taken from 28 weeks of pregnancy thereafter the pregnant woman is given single dose of Nevirapine as she enters into labor reduces HIV transmission from mother to child while single dose nevirapine is given to the child from birth followed with Zidovudine (AZT) for one week. Antiretroviral combination therapy defends against resistance by suppressing HIV replication as much as possible.

Combinations of antiretrovirals create multiple obstacles to HIV replication, and reduce the possibility of a superior mutation. If a mutation that conveys resistance to one of the drugs being taken arises, the other drugs continue to suppress reproduction of that mutation. With rare exceptions, no individual antiretroviral drug has been demonstrated to suppress an HIV infection for long; these agents must be taken in combinations in order to have a lasting effect. As a result, the standard of care is to use combinations of antiretroviral drugs. Combinations usually comprise two nucleoside-analogue RTIs and one non-nucleoside-analogue RTI or protease inhibitor. This three drug combination is commonly known as a triple cocktail. Combinations of antiretrovirals are subject to positive and negative synergy, which limits the number of useful combinations.

In recent years, drug companies have worked together to combine these complex regimens into simpler formulas, termed fixed dose combination. For instance, two pills containing two or three medications each, taken twice daily greatly increases the ease with which they can be taken, which in turn increases adherence, and thus their effectiveness over the long-term. Lack of adherence is a cause of resistance development in medication-experienced patients. Patients who maintain proper therapy can stay on one regimen without developing resistance. This greatly increases life expectancy and leaves more drugs available to the individual, should the need arise.

Because of the complexity of selecting and following a regimen, the severity of the side-effects and the importance of compliance to prevent viral resistance there is great need to

emphasizes the importance of involving patients in therapy choices, analyzing the risks and the potential benefits to patients of compliance with the ARV drugs before placing a patient on ARV drugs therapy as it is for lifetime.

#### **Mode of action of ARV drugs:**

NRTI were the first ARV drugs used in HIV management with Zidovudine being approved in 1987. Reverse transcriptase is the enzyme that copies virus RNA into DNA in the newly infected cell. NRTI acts by inhibiting syntheses of DNA by reverse transcriptase. The triphosphorylated nucleoside building blocks like adenosine (A), guanosine (G) and pyrimidine nucleoside thymidine (T) and cytidine (C) have the same structural resemblance to NRTI which resembles monophosphorylated nucleosides and therefore requires only two additional phosphorylation to become active inhibitors of DNA syntheses. The reverse transcriptase fails to distinguish the phosphorylated NRTI from their natural counterpart (the triphosphorylated nucleoside building blocks) and attempts to use the drug (NRTI) in the DNA syntheses. When NRTI is incorporated into a strand of DNA being synthesized, the addition of further nucleoside is prevented and a full length copy of viral DNA is not produced (Gullick, 2003).

NNRTI in 1996 was first approved and used in USA with Nevirapine as the first to be approved. NNRTI inhibits syntheses of viral RNA not as false nucleoside but binds to the nucleoside so as to inhibit activities.

The PI group was first approved in 1995 via approval of Saquinavir. Protease inhibitors bind to active site of viral protease enzyme thereby preventing the processing of viral proteins into functional forms. Viral particles are still produced when protease is inhibited but these particles are ineffective at infecting new cells. PI binds to HIV envelope protein GP41 which is involved in viral entry and thereby prevent HIV from entering target cells. By blocking interaction between regions of gp41 molecules, PI interferes with conformational changes in the envelope molecules required for fusion with the target cell membranes.

The fusion inhibitors were licensed in Europe and USA in 2003 but only to be used by people who have already tried other treatment.

Currently there are more than 20 anti-retroviral drugs approved in USA and Europe for treatment of HIV infection but they are not all available in all countries.



Single dose (one tablet) combination ARV drugs are available and in use world over and in Nigeria, and this has gone a long way to solve the burden of multiple drug regimen for patient on first line drug therapy.

### Challenges to compliance in ARV treatment

However the promise of revolutionary HIV/AIDS treatment also brings significant challenges. Highly active anti retroviral therapy includes complex regimen that require strict compliance with complicated treatment schedule. Of great concern are treatment resistant variants of HIV that rapidly develop in response to under dosing and intermittent irregular use of anti retroviral agents (Kalichman et al, 1999, Mohammed et al, 2002). Adherence is essential to HAART therapeutic effectiveness because its mechanism of function relies upon initiating and maintaining viral suppression. Evidence suggests that rates of virologic failure (progression from HIV to full blown AIDS) significantly increases when less than 95% of prescribed dosages of protease inhibitors are taken (Mohammed et al 2002). Machillinger et al 2005 found that very high adherence varying from 80% to 100% is required for full durable viral suppression by the protease inhibitors. Poor timing compliance may also lead to virologic failure (Mohammed et al, 2002).

#### 1. Resistance to ARV drugs

Drug resistant HIV strain is beginning to emerge as a public health problem in Nigeria and all over the world. At the National Institute of Pharmaceutical Research and Development, the first case of drug resistant strain HIV was discovered from a study instituted in 2002 after the introduction of government anti retroviral therapy program (Agrival, 2003). This denotes a public health problem as the emergence of resistant strain would mark the development of a new epidemic that will result in the transmission of resistant HIV virus (Agrival, 2003).

It has been found that valuable treatment for HIV can dramatically suppress viral load, enhance CD4 count and decrease morbidity and mortality rate to HIV infection. If antiretroviral medications are not taken as prescribed, treatment failure may ensue. Non adherence is widely viewed as a risk factor for drug resistant virus which can be transmitted through unsafe sexual and drug use practices. It appears that patient must ingest at least 90-95% of their prescribed doses consistently to maintain virologic suppression. However, sub-optimal doses of ARV drugs causes incomplete viral

suppression that greatly increase the probability that drug resistant mutants will emerge (Durante, Bova, Jennie, Danvers, Holness, Burgess, Williams, 2003).

Antiretroviral medications with different mechanisms of inhibiting HIV are used in combination to keep the development of drug resistant mutants to a minimum. Despite this, currently in industrialized countries up to 23 percent of incident infection are with virus strain, resistant to one or more drugs (Illiyasu et al, 2005).

## 2. Side effects

ART treatment is associated with side effects and complex dosage regimen for life time. The objective of HAART is to reduce HIV viral loads to undetectable levels (Mohammed, Richardson-Albone, Magnus, Fawal, Vermud, Kissinger, 2004). ART drugs prolongs survival with HIV by interrupting the life cycle of HIV and thus inhibiting the replication of the virus and once therapy has been initiated one must continue with the drugs and the emergent side effects for life.

## 3. Adherence and Virology

Peterson and Colleagues carried a study to assess the effects of different levels of adherence on virologic, immunologic and chemical outcomes with 81 patients and found out that non adherence was significantly associated with virologic failure ( $P < 0.001$ ). Eighty two percent of patient with compliance with therapy of less than 70%, experienced virologic failure compared with only 22% who were adherent at least 95% of the time. Additionally patients with 95% or greater adherence ( $n = 23$ ) had higher increases in CD4 lymphocyte counts (23 Vs 6 cells/UL,  $P = 0.15$ ) and fewer hospitalization days (2.6 Vs 12.9 days per 100 days of follow up,  $P = 0.001$ ) than those with lower adherence rates ( $n = 23$ ). Other studies have also reported increased rates of virologic failure with decrease adherence (Barbara, 1994 – 2003).

### Concept of compliance:

Antiretroviral adherence is the second strongest predictor of progression from HIV to AIDS after CD4 count. Incomplete adherence is common in all groups of treated individuals. The average rate of compliance with ART is approximately 70% despite the fact that long term viral suppression requires near perfect adherence. The resulting virologic failure diminishes the potential for long term clinical success (Machilinger et al, 2005).



## 1. Definition of Medication Compliance, Adherence and non compliance:

**Medication compliance:** describes the ability to take all ARV prescribed medication, following the initiation of HAART in the correctly prescribed doses, at the prescribed time intervals and in the right manner, observing any dietary restrictions (Hiko et al 2012). Alternatively it could mean a patient correctly following medical advice.

**Adherence:** is a patient's ability to follow a treatment plan. Drug adherence means collaboration between patient and provider. Here the physician works with the patients to decide how best to meet his need. The patient is carried along and meant to understand the need to carry out the instructions or rules, be part of it, plan how best to do it so that you will benefit from it and allow it to fit into your lifestyle. Adherence in most cases is used interchangeably with compliance but compliance has a hierarchical controlling provider in charge connotation (Leslie et al, 1998).

**Non Compliance:** This entails missing at least one dose of prescribed drug, not observing the required time interval nor the dietary restriction, not taking the correct doses of drugs and also patients who take their drugs less than 95% of the time after HAART is initiated.

### Compliance/Adherence in HIV treatment

**Adherence** in developing countries of Africa has been found to be as good as adherence in developed countries. In South Africa, adherence study carried out with 28 persons attending a public HIV clinic and receiving ART revealed 87.2% adherence. In Uganda a 34 self paying patients followed up for 90 days using 3-day self report, 30-day self report, unannounced pill counts and Medication Event Monitoring System (MEMS) caps showed 92.9%, 91.6% and 90.35% adherence respectively. In Senegal a research conducted among 58 patients for 20 months showed 87.9% adherence (Machtlinger et al, 2005) while yet another research in Senegal with 138 PLWHA for 24 months showed 93% adherence (Isabella et al, 2003). In ~~Hebrews~~ <sup>Hebrews</sup> a study with 109 patients attending private clinics revealed that more than half (54%) showed 95% adherence. A research work on adherence carried out in Center for Special Studies, Olabisi Onabanjo Teaching Hospital, Sagamu, Ogun State Nigeria showed that overall, 79.2% of respondents achieved 95% adherence level, (Daniel, Ogun, Oduroga, Fola, Ogundahunsi Salako, Oladapo, Osho, Adenekan, Kolapo, Olowole, Krain, Boyle, Jacobs, 2003). This optimal adherence

was observed to be slightly higher in the free medication subset compared with the self-purchased subset. Another research carried out in State House Clinic Abuja recorded 95.5 % adherence (Mohamed 2003). Contrary to the above findings, a research work carried out in UNTH between May 2004 and April 2005 reported that about 75% of PLWHA have not adhered to ARV drugs in the past 12 months (Onwujekwe .2006). Compliance with medications is as crucial as the development of the drugs themselves because the drugs won't do any good if people can't use them properly.

Although patients taking anti-retroviral drugs generally achieve higher level of adherence than do patient on other chronic medication therapy, the regimens are complex and lifelong, yet a large proportion of patients are unable to achieve the targeted level of adherence. Therefore, interventions to facilitate patient's compliance with anti retroviral medication are critical for optimal HIV care (Golin, Honghu, Hays, Miller, Beck, Ickovics, Kaplan, Wenger, 2002)



**Table 3: Summary of Adherence studies in HIV/AIDS treatment**

Author/year	Setting	Sample size	% of PLWHA adherence
Machilinger et al 2005	Senegal	58	87.9% adherence
Laniece et al 2003	Senegal	158	91% adherence
Machilinger et al 2005	Botswana	109	54% showed 95% adherence
Daniel et al 2003	Ogun Nigeria	53	79.2% showed 95% adherence
Onwijekwe 2006	Enugu Nigeria		75% did not adhere
Mohamed et al 2003	Abuja, Nigeria	110	95.5% adherence

## Factors Affecting ARV drug adherence

### Patients perspective

Some factors were found to predict ARV drug failure amongst which is ART adherence.

These factors were enumerated as follows:

- 1) ART adherence
- 2) Genetic differences in drug metabolism
- 3) Severe baseline immune suppression
- 4) Prior drug resistance and
- 5) Concurrent opportunistic infection

Of these the most alterable is ART adherence (Machtlinger et al, 2005). Since the evolution of highly active antiretroviral drugs, the two major problems at stake have been.

- 1) Coping with the ART side effect like nausea, vomiting, diarrhea and pill burden.
- 2) Development of resistant mutation to antiretroviral which results in viral rebound and eventual drop in CD4 count (Sandro, 2000).

Thus for successful therapy, patients must adhere to medication. A lot of factors predict patient adherence and non compliance with ART regimen. In antiretroviral therapy, the ability of a patient to comply with a prescribed treatment regimen could be affected by a variety of factors at the patient, provider and treatment levels. Patients give many reasons for not taking their medication. According to the research conducted by Clifford and colleagues (2000) the most common reason given by patients for not taking their medications were organizational such as being busy, forgetfulness, being away from home, changing routine, which were reported by 45% - 52% of patients. Emotional reasons and issues about medication were mentioned by 16 - 27% patients; side effects were mentioned by only 17% of patients and therefore may be less important than organizational issues in this study population.

A survey carried out by Wenger and colleagues in 1997 with 1,910 subjects revealed that adherence was higher if medications fit into the patient's daily schedule or if patient believe that antiretroviral agents were effective and that failure to adhere would have

serious consequences. Also increasing age was found to affect adherence positively. Illicit drugs affect adherence negatively. However, Paterson and colleagues (2000) showed that race has no effect on adherence.

A work done by Gordillo and colleagues (1999) identified socio-behavioral factors that affect patient compliance with antiretroviral regimen to include depression and poor social support. Fatigues in most cases are evidently linked to depression/psychological distress in HIV positive population. Thus patients who complain of fatigue should be monitored for adherence problems (Barbato, 2005). Chesney (1997) point out that depressed mood is one variable that predicts non adherence across studies. Treisman (1997) believes that understanding major depression, recognizing and treating it effectively, dramatically improves both compliance and ability of the staff to take care of the patient in many other ways. This finding was further confirmed by a group of providers in Washington State, (Leslie et al, 1998).

Psychosocial factor are found to be predictive of non adherence (Mohammed et al, 2004). Among persons studied in one HIV/ AIDS clinical trial, missed doses of anti retroviral drugs were most likely to occur because of forgetting (43%), sleeping through a dose (36%), being away from home (32%) changing ones routine (27%) being too busy to take the dose ( 22%), feeling sick (11%) and experiencing depression (9%). People who refuse to take antiretroviral therapy commonly state that the drugs are ineffective and toxic. Social support is associated with adhering to ARV drugs, with greater social support predicting more consistent adherence (Turner et al, 2005).

Relationship between patients and primary care provider also affects adherence. Patients who trust their provider and are satisfied with their quality of care are more likely to adhere to treatment regimens (Golin et al, 2002).

Substance abuse patients have a host of problems including resistance to comply with instruction, potential drug interaction and conditions of living in poverty. Seropositive patients with a history of injection drug use were more likely to be non adherent to antiretroviral therapy than those who had not used injection. Injection drug users delay initiating anti retroviral treatment but were adherent once treatment was started.

Some other variables seen to be predictive of better adherence in the literatures reviewed were improved CD4 cell count and lowered viral load; emotional support and continued interaction with peers, belief that ARV will extend life and that poorer adherence leads to



viral resistance. Demographic factor found to increase adherence includes higher income, education and older age.

Babara and colleagues (2005) reported that adherence decreased substantially with increase in number of antiretroviral drugs in the regimen. Carmina et al. (2003) showed that simplified antiretroviral regimen (i.e. switch from a known, efficacious yet complex therapy to a simpler but equally potent one) increases the adherence and the quality of life of those living with HIV by reducing their viral load. Educating patients well on dose frequency, drug related side effects encourage adherence (Turner, 2005, Leslie et al, 1998).

Establishing good communication between the patient and the health team like doctors, nurses pharmacists and social workers promotes an open discussion about difficulties in maintaining adherence and the different approaches that a patient may take to adhere to drug regimen (Turner, 2005). Good social support system helps people living with HIV to adhere rigidly to their regimen. These social supports may come from the health care team (Physicians, case managers, nurses and pharmacists), family members, close friends and other patients that have successfully adjusted to their HIV treatment (Turner, 2005).

The above mentioned factors found through literature to be associated with adherence and non-adherence behavior to antiretroviral treatment has been categorized into four. Good understanding of these factors can enhance health workers attention to adherence when working with particular susceptible individuals and can help the development of interventions to improve adherence of such people.

The four categories are:

1. Patient factors
2. Provider factors
3. Illness and treatment factors
4. Contextual factors or clinical setting



## 1. Patient factors:

This could be well explained using the health belief model.

### Demographic Factors

Research has shown that this has little or no effect on patient compliance with ART (Turner 2005). All the same some other researchers found out that PLWHA who are younger, had lower income and with lower educational attainment were less likely to adhere more than their counterparts who are older and of higher socio economic groups (Golln et al, 2002).

### Patients Beliefs

Patients that believe the effectiveness of a therapy or that they are capable of taking the medication in the necessary manner (high self efficiency) are more likely than those who do not believe, to adhere to their medication (Barbara, 2005). Cultural aspects of patient health belief and life goals must be considered. Misconception about HIV transmission and traditional conceptualization of the disease amongst various ethnic groups affect adherence. Patient's knowledge of treatment plan and regimen also affect adherence.

### Readiness to accept treatment plan

It is important to establish patient's readiness to accept the treatment plan offered. This involves counseling and educating the patient and engaging the patient in problem solving in an effort to remove obstacles to treatment adherence. Assessing patients readiness and commitment to the treatment plan on a regular basis during the course of treatment allows the provider to evaluate adherence and deal with issues such as missing dose. Potentials of resistance and cross-resistance must be included in pre treatment analysis of readiness. Patients who believe that ART are effective and are presently the only means to be well and healthy are always ready and willing to accept and adhere to treatment plan at all times. Patients who understand the need for adherence are more likely to adhere to treatment regimens and to follow instructions from their medical health provider.

### General Health and Side Effects

The stage of the patient's HIV, the presence or absence of symptom might be an incentive or deterrent to adherence. An observable decrease in viral load will enhance adherence of a patient even in the presence of side effects. Other patients may feel that undetectable

viral load and absence of symptoms means they no longer need their medication, hence they may discontinue. Side effects of drugs are cited as major issues for patients to stop medication. If patient (due to side effects) feels worse than the illness, he/she may be inclined to discontinue with his/her medication.

**Self efficacy:** A patient who has worked through all the issues and says I can do it, is approximately five times more likely to be adherent than a patient with self doubt (Turner, 2005).

**Social Support:** People's openness about their HIV status impact adherence. Network of social support by friends, relatives and people who have successfully adjusted to their treatment and the health care team such as physician, pharmacist and nurses are more likely to adhere to their regimen (Turner, 2005). Stigma, shame, isolation and fear have prevented people from disclosing their HIV status and these are deterrent factors to adherence. Depression and poor social support were associated with 86% decrease in adjusted odds ratio for adherence (Babara, 1991 – 2005).

**Life Situation:** Abuse of alcohol and other hard drugs are deterrent factors to adherence. Chaotic life, forgetfulness, vacation or travel and partying impacts non-adherence. Generally speaking adherence is higher if the medication fits into the patient's lifestyle (Turner, 2005, Golin, 2002).

## 2: Provider factors:

### Provider Patient Relationship

The relationship between the patient and the provider is a critical factor in how well the former adhere to their medications (Treisman, 1997, Williams and Friedland, 1977). Mutual trust, respect, empathy and genuine interest, openness and friendliness, longtime consistent relationship, are important aspects of this provider patient relationship. HIV positive patients rely more on their physician for guidance on antiretroviral treatment and this confidence increases their adherence. A long standing and trusting relationship between an HIV positive person and a single provider is seen to enhance compliance with HIV drugs (Machillinger et al. 2005). Provider's warm and caring disposition to patient ~~increases~~ adherence. It is expected that patients with greater continuity of care satisfaction, with medical care and trust in their provider tend to be more adherent (Golin et al. 2002).

Long waiting time and other procedural barriers have been found to decrease compliance with both keeping appointment and taking medication.

### **Provider Belief and Lack of Time**

The providers that believe in ART efficacy based on evidence-based medical practice convey such confidence to their patient and this potentiates the patient's compliance with the therapy (William and Friedland, 1997).

### **Lack of Knowledge, Ability or Time**

Spending adequate time with patient to develop a treatment adherence plan is considered a crucial component of a strategy leading to successful adherence. This is especially true for patients with multiple stressors like homelessness, mental health diagnosis or substance use. (Leslie et al, 1998). Some providers lack adequate training on how to handle patient or encourage adherence. Hence, the need to train providers to acquire knowledge and clinical skills to take care of HIV patients.

## **2. Illness and treatment factors**

### **Treatment Complexity**

Factors that affect the treatment regimen includes number of pills prescribed, complexity of the regimen, frequent doses, dietary restrictions, long term duration of treatment, side effects and various forms of administration (Leslie et al, 1998). Studies have shown that complexity of regimen and side effects are associated with non adherence. Also the numbers of pills per dose, frequency and how well it fits into a patients' daily route are determinants of adherence (Machilinger et al, 2005, Golin et al, 2002). Some studies have shown higher adherence in HIV positive patients receiving monotherapy than those on dual NRT therapy (Sanitro, 2000). Turner and Colleagues (2005) reported that adherence decreases substantially with an increase in the number of antiretroviral drugs in the regime. Reduced adherence has also been associated with the increased dosing frequency of ARV drugs. Side effect like nausea, vomiting, fatigue, headache, lipodystrophy and other metabolic abnormalities negatively affect adherence (Sandra, 2000). It is also expected that use of adherence aids such as pill box, medication timer etc will be associated with better adherence (Golin et al, 2002). Clifford et al (2000) showed that patients who reported that their antiretroviral regimen fit into their daily routine were nine times more likely to be adherent.



## **Illness Characteristics**

The HIV positive patient must first believe that they are ill and that the benefit of taking their medication outweighs the cost. The stage of the illness, the patients perceived susceptibility to illness and its consequences (all explained by the health belief model) are important determinants of adherence (Smith et al, 1997).

## **4. Contextual factors**

### **Medical Practice or Clinical Setting**

The aspects of clinical setting that influence adherence include: proximity to patients home, travel expenses, lengthy delay between clinic contact and appointment, long waiting time, lack of service such as child care and poor privacy (Leslie et al, 1998).

### **Systemic factors**

Other health care issues such as poor access to drugs, unavailability of drugs, unaffordable medication and care affects mostly the poor and those without adequate insurance. Other factors include managed care, which requires provider to monitor the time spent with patient as to enable them increase their adherence. Financial difficulties are another factor.

### **Life Situation Issues**

Some disordered lifestyle issues like homelessness, lack of steady financial income and no coverage for medical services negatively affect adherence (Leslie et al, 1998).

### **Institutional Systems**

Some institutions like prisons and hospitals constitute barriers to ARV medication because of the gaps created between the patients and their medication schedule.

### **Social / Environmental factors**

Patients with more social support are expected to be more adherent (Golin et al, 2002).



## CONCEPTUAL FRAME WORK

A frame of reference used by the investigator to explain relationship between different variables of interest under study is called conceptual framework. In the field of health education these theories and models are used as strategies to understand human behaviors and the factors that influence their behaviors and ways to develop programs to enhance positive health seeking behavior.

The interview instrument was based on the Health Belief Model (HBM) a theoretical construct for understanding health behaviors. The HBM is derived from a well established body of psychological and behavioral theory which hypothesize that health behaviors depend mainly on the desire to avoid illness (or get well) and the beliefs that a particular action will prevent or relief illness. This concepts have been stratified into various dimensions described as perceived susceptibility, perceived seriousness, perceived benefits, perceived constraints, perceived threat, cues to action and likelihood of taking recommended action. This model was operationalized in the study as shown below.

Perceived susceptibility describes an individual's belief that he or she is at risk of contracting an illness an example is the fact that HIV would easily be contracted through risky sexual behaviour. Perceived seriousness and perceived threat refers to an individual's belief about medical, clinical and social consequences of contracting an illness or of leaving it untreated. The perception an individual has about susceptibility and seriousness to the health condition is known as 'disease threat' which predicts the person's willingness to take recommended preventive action. The fact that HIV is a killer disease especially if not treated, moreover it doesn't have a cure, poses a big threat. This results into driving force for people to take their ARV drugs which stimulates willingness to take one's ARV drugs. This aspect of the health belief model was operationalized in the questionnaire with such questions as 'Are you willing to continue treatment as long as it takes'. The action to be taken would be valuable if it reduces the individual susceptibility to suffer opportunistic infections frequently or develop into full blown AIDS which results into premature death.

At same time other barriers like cost, stigma, side effect, scarcity of drug and pill burden might block this positive health seeking behavior, and these are referred to as 'perceived constraint'. Perceived constraint refers to an individual's beliefs about the problem he or

she may encounter when attempting to perform a particular health behavior. It involves weighing the effectiveness of an action against perceived negatives. It was observed from literature review that drug side effect experienced by patient was a constraint as such the respondents were asked if they had ever experienced side effects from taking ARV drugs and whether the side effects stopped them from taking their ARV drugs. The respondents were also asked to enumerate reasons that may have prevented them from taking their ARV medication. From these, factors that restrain compliance with ARV drugs were elucidated.

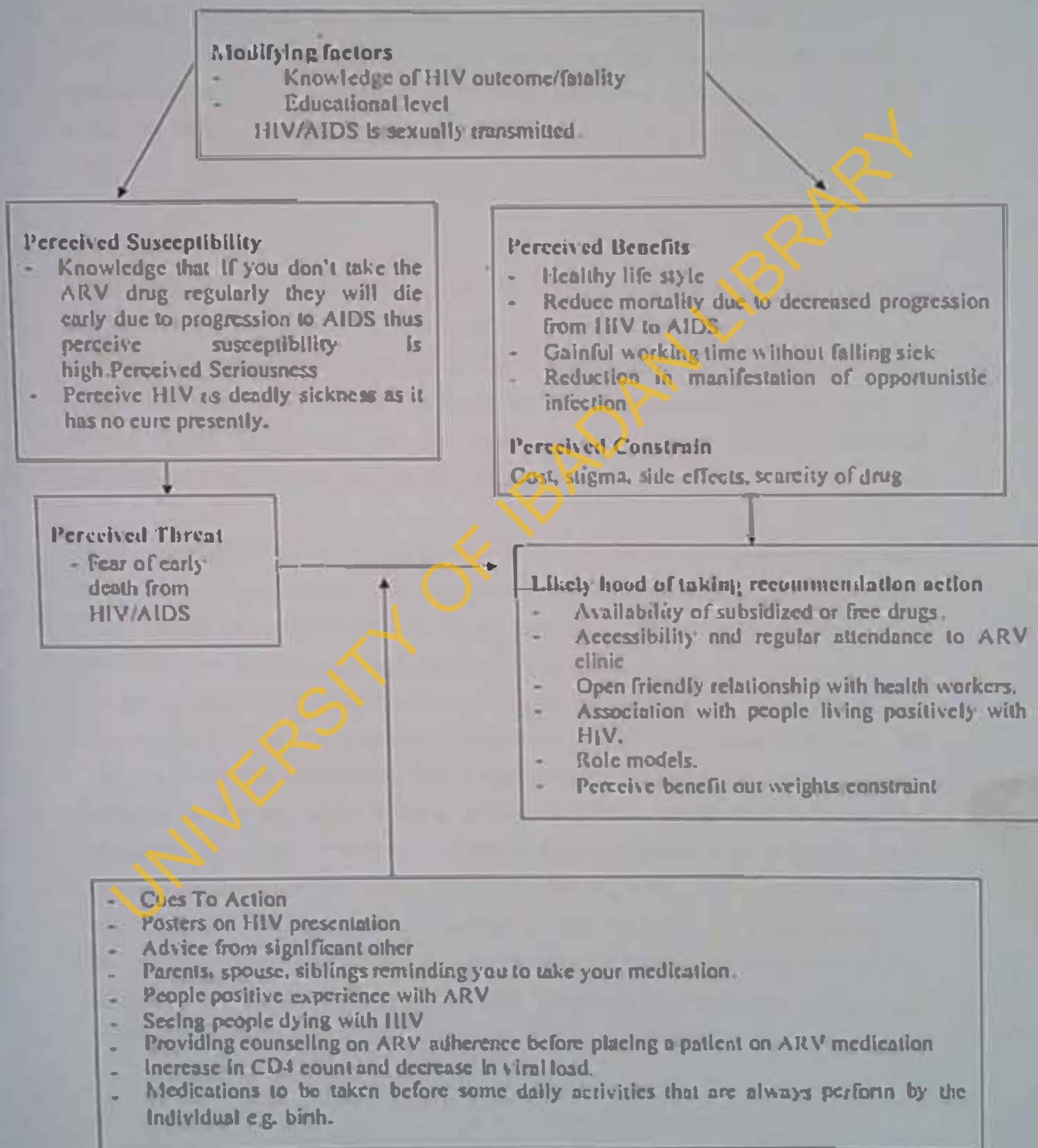
Perceived benefits describe an individual's belief about the efficacy and feasibility of a particular action for treating or preventing illness. The individual must believe that the recommended action will yield potential improvement to his/her health, example identifying ones HIV status early and ensuring that HIV positive persons enroll early into the HIV treatment program and seriously comply with their ARV drugs as recommended by their health provider, results in improvement in health. This was operationalized in the questionnaire by such questions as "How has your health been since you started taking your ARV drugs". Such perceived benefits like obvious improvement in health and appreciable reduction in occurrence of opportunistic infections are the main driving force that sustain this positive health behavior of judiciously adhering to ARV drugs all through one's life time.

Likelihood of taking a recommended action was strengthened by the availability of free drugs currently, unlike previously when the drugs were paid for and were unavailable. The respondents were asked if they are willing to continue with the treatment.

Cues to action which might be external (e.g. counseling and social support from health workers and family members) or internal (e.g. motivators to stay healthy) are necessary to trigger a decision to act. The application of HBM to a patient with HIV/AIDS, theorizes that a particular behavior is based on the way these various dimensions interact (Malcolm, Rosen and Stone, 2003). The respondents were asked if they were reminded to take their ARV drugs by anybody and whether they received social assistance and counseling from anybody or organization. From these and perceived benefits, the factors that motivate compliance with ARV drugs were elucidated while the deterrent factors were derived from perceived constraint.



# THE HEALTH BELIEF MODEL AND FACTORS AFFECTING COMPLIANCE WITH ANTIRETROVIRAL DRUGS REGIMENT





## CHAPTER THREE

### METHODOLOGY

#### Study Design

This was a descriptive cross sectional study that sets out to determine the level of adherence of the respondents, established the motivating and restraining factors to adherence. The study was focused on PLWHA who were receiving ARV therapy in University of Nigeria Teaching Hospital, Ituku Ozalla during November to December 2007.

#### Description of Study Area

Enugu State is in the South East of Nigeria lying approximately from 6°30'E to 7°50' latitude and from 5°25'N to 7°05'N longitude. On its West is Anambra State, on the North are Kogi and Benue States, on the east is Ebonyi State, and on the South is Abia State. The study was conducted in Enugu which is a regional city and the capital of former eastern region, and now the capital of Enugu State. Enugu is inhabited predominantly by the Igbo who are the predominant tribe in Eastern Nigeria.

Enugu Metropolis and its environs are in 3 local government areas namely Enugu East with its headquarters at Nkwo Nike, Enugu North with the centre at Ogui Urban and Enugu South with its headquarters at Uvwal. Enugu was founded by the British and the modern city dates from the discovery and development of coal mines in 1909. Although Enugu started as a coal mining town, the coal industry has long ceased to be its main economic support. It is now essentially an administrative city. In 1929, the headquarters of the then Southern Province was transferred from Lagos to Enugu and in 1939, the city became the capital of the former Eastern Province of Nigeria. With the introduction of the regional administration in 1946, it became the capital of Eastern Nigeria. After the Second World War, it became a major civil service town, east of the Niger River. Its status in the country was like that of Kaduna in the north, Ibadan in the west and Benin City in the Mid-west. Enugu is also a renowned educational and cultural centre with a population of about 2.453 million persons. There are many secondary schools, teacher's training colleges and technical colleges.

The study participants were recruited from the University of Nigeria Teaching Hospital (UNTH) Ituku/Ozalla, Enugu. The Hospital began early in the 20<sup>th</sup> Century as a standard general hospital on the attainment of Nigeria's independence in first October 1960. However, at the end of the Nigeria Civil War in 1970, the then government of East Central State transformed it into a Specialist Hospital with effect from July 1, 1970. Today, the situation has changed dramatically and the hospital has moved from the old site to the permanent site at Ituku-Ozalla. The current bed capacity of the hospital in the Permanent Site is over 500 beds. The Federal Military Government took over the hospital by decree number 23 of 1974, but left the Management in the hands of the Council of the University of Nigeria, Nsukka.

Today, this new site of the UNTH at Ituku/Ozalla is permanent and fully functional. It is located at 21 kilometers from Enugu, along Enugu-Port-Harcourt Express Way. All services hitherto rendered at the old site have now been moved into the Permanent Site with effect from 8<sup>th</sup> January 2007.

### UNTH HIV Clinic

In order to improve the life of PLWHA and achieve a high level of adherence amongst the people living with HIV, UNTH was one of the twenty five centers selected by the federal government of Nigeria to provide treatment for PLWHA in 2002. In 2003 the United States President's Emergency Program for Relief (PEPFAR) in conjunction with the AIDS Initiative of Nigeria (AIN) embarked on a scaling up program of the various ARV centers in the country. Presently UNTH has a comprehensive HIV clinic comprising of; Physician trained in HIV care ranging from consultants in general medicine to consultant dermatologist, Pharmacists, nurses, social workers, counselors and health educators trained in HIV and dedicated to HIV care. This staffs are constantly sent for update training. They ensure that daily patient counseling and health education are carried out at the various units in the HIV clinic. They educate patients on the benefits, side effect, drug interaction, psychosocial stress, adherence and risk of developing resistance to ARV drugs. Currently the clinic is comfortable and patient friendly, and the drugs are given free and are dispensed online. The clinic was operational only on Thursdays and all the patients were divided into four and each batch enrolled into one of the four Thursday's of the month. In 2008 the Thursday's HIV clinic was turned into a daily clinic in which case the patients within a group could visit the clinic in any of the five working days within the week.



## Study Population

The study participants were recruited from PLWHA who were receiving ARV drugs from the HIV clinic in UNTH from mid November to mid December 2007. UNTH HIV clinic was started in the year 2002 as an initiative of the Federal Government of Nigeria to set up twenty five HIV clinics in various parts of the country. The clinic at the time the research was carried out was operating only on Thursdays to give a one month drug supply to the PLWHA registered and receiving ARV drugs from the clinic. All the patients attending the HIV clinic were divided into four groups, each group to collect ARV drugs in one of the four 'Thursdays' of the month. Patients proven to be HIV positive and their health or CD4 counts had necessitated their placement on ARV drug were recruited into the ARV drug treatment program. The PLWHA received generic anti retroviral drugs and were expected to pay N1000 a month. Due to shortage of drugs it was not possible to absorb all the patients that came to the clinic. As a result of this most HIV patients were kept on waiting list pending availability of space and drugs so they could be recruited into the ARV drug treatment program. However by the year 2005 a scaling up program on ARV drugs was embarked on by the Federal Government of Nigeria in conjunction with the United States President's Program for AIDS Relief resulting in abolishing the N1000 and giving the drug free to as many patients as possible. By 2007 the HIV clinic moved its operation from Enugu town to the permanent site at Iuku Ozalla, Enugu. In 2007 a total of about 1200 patients were collecting ARV drugs from UNTH HIV clinic. Both male and female PLWHA who have been on the drug from six months and, that are willing to participate were recruited to a total of 341 persons. It was ensured that all recruited respondents have been on ARV drugs long enough as to give authentic response to the questions based on their experience. This was actualized by recruiting patients that have been on ARV drugs from six months and above.

## Study Variables

The major variable derived from the study objectives includes (1) demographic characteristics of respondents, (2) Respondents compliance with ARV drugs, (3) Respondents experience with ARV drugs, and (4) factors motivating and restraining adherence.



## Sample Size calculation

Sample size for the research was determined using Leslie & Kish formula.

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

Leslie & Kish formula for estimate of sample size

Where n = minimum sample size

Z = standard normal deviation corresponding to the probability of 1.96

(i.e. probability of making a type I error = 0.05)

p = prevalence of compliance with antiretroviral medication.

Approximated to 87.9% = 0.879 which is from research work carried out in Senegal, one of the African countries, Machilinger et al 2005

q = 1 - p = 1 - 0.879 = 0.127

d = degree of precision = 0.05

$$n = \frac{(1.96)^2 \times 0.879 \times 0.127}{(0.05)^2}$$
$$= \frac{0.42878}{(0.05)^2}$$

= 171.5 x 2 (this number will be double to 343 as 171.5 is small)

= 343 respondents were recruited.

## Sampling Procedures

Systematic random sampling procedure was used to select the study participants at regular intervals from the weekly Thursdays' ARV clinic, for the questionnaires. The copies of the questionnaires were administered to the selected People Living with HIV with the help of trained research assistants over a period of one month. The required 343 number of participants was divided by four and it came up to about 86 persons. This was the required number of participant to be selected for each week. For the four Thursdays' of the month, the 86 required participants were systematically selected by administering the questionnaire to every third PLWHA seated in the Pharmacy ARV dispensary waiting hall. Take for instance the questionnaire was given to the first person, then 4, 7, 10, 13 and so on as they were seated in the waiting hall till the required number of participants was gotten. The people that refused to participate were left out and the next willing person was taken.

## Development of research instrument

One instrument namely the questionnaire was used for data collection (see Appendix III).

**Questionnaire:** The questions in the questionnaire were framed so as to elucidate demographic factors, level of adherence, motivating and restraining factors. The questions were subjected to series of review by experts including my supervisor and other lecturers and students of the Department of Health Promotion and Education. Finally a 33-item questionnaire was designed and used for data collection for the research work.

Based on these variables and research design, the null hypothesis to be tested were proposed as highlighted in chapter one. The questionnaire was divided into four sections consisting of the major variables described above. The instrument was designed to be self administered. Section A focused on socio-demographic information about respondents. Section B was on medical data of respondents. Section C focused on the adherence of respondents to Anti-retroviral drug therapy. Section D explored economic/social support and health care services that respondents were receiving and how these affect compliance with ARV drugs.

## Validation and Reliability

The validity of the contents of the questionnaire was further strengthened through continuous review of literature. Subsequently several drafts of the questionnaire were critically reviewed by the researchers supervisor, other lecturers and colleagues in the Department of Health Promotion and education who had conducted several research on HIV/AIDS.

A pilot study was carried out with 10% of the study participants which was 40 persons in a similar location (Military Hospital in Enugu) that has similar characteristics with the study area. This was done so as to determine the effectiveness of the research instruments in use. Finally a revised copy of the questionnaire was made based on the results of the pre test. Filter questions were placed at various points in the questionnaire to ensure that respondents are not faking responses for example question 20: 'how are you taking the drugs'; and question 21: 'Do you ever fail to take your ARV drugs'. Question 22: 'In the past week, have you ever forgotten to take your ARV drugs' and question 23 'How many tablets have you missed in the last 7 days'. This was done to ensure the reliability of the questions in the questionnaire.

## Training of Research Assistants

Five research assistants were recruited and trained for data collection by me: at UNTH Enugu. The contents of the training included the purpose of the study, interpersonal communication and data collection procedure. Areas to probe for, while administering and collecting the questionnaires were emphasize such as the 7 days adherence table and complete filling of the questionnaire were ensured before collecting back the questionnaires. Ethical issue like confidentiality, informed consent and modes of administration of the questionnaire were discussed.

## Data Analysis

### Data management and analysis

The data generated from the respondents was edited for completeness and accuracy in the field. Numbers were assigned to each question for easy identification and for correct data entry and analysis and this helped to develop a coding guide which was used to code each question into the computer. The statistical package SPSS Version 10 was used to analyze the coded data using descriptive statistics, to test chi-square and alpha reliability analysis of the statistical package SPSS version 10. The positive results derived from Chi square analysis were further analyzed using Logistic Regression annalysis.

Level or rate of Adherence was computed as the actual no of doses taken divided by the number of doses prescribed over a seven days study period and expressed as a percentage, Yao Petchoo et al (2008).

$$\frac{\sum \text{actual no of doses taken for seven days for all participants} \times 100}{\sum \text{doses prescribed over seven days for all participants}}$$

or

$$\frac{\sum \text{tablets dispensed minus sum of tablets returned}}{\sum \text{Total tablets prescribed}}$$

Within the study period, all expressed in percentage.

### CALCULATION:

From the seven days adherence table the sum total tablets taken by all the participants over the one week period preceding the study was 4942.



The sum total tablets prescribed for all the patients for the one week preceding the study was 341 multiply 14 = 4774. Putting these into the adherence formulae we have:

$$\begin{aligned} \text{Sum of dose taken by all participants} &= \frac{1502}{341 \times 14} \times 100 \\ \text{Sum total dose prescribed for all participants} &= 94.302\% \end{aligned}$$

From the above, the calculated level of adherence as reported by the study participants was 94.3% which even though it is high is slightly below the expected 95% that is termed excellent adherence.

### Ethical consideration

A request letter for ethical approval was written by the researcher to the ethical board of UNTII. Also an informed consent form was attached to my questionnaire and sent together with a copy of my proposal and introductory letter from my supervisor to the ethical committee of UNTII. This clearly stated, the principal investigators name, title of research project, purpose and procedure of the research. Respondents were also reminded of the rights to refuse or withdraw from participation. The benefits and risks of the research were conveyed to respondents.

Confidentiality of respondents was ensured as their names were not included in the questionnaire. It was hoped that at the end of the study, the research findings will be conveyed to the administration of UNTH and UNTH PLWHA community.

Finally, the research was conducted from mid November to mid December of the year 2007 with PLWHA collecting ARV drugs at UNTH Iluku/Ozalila after receiving approval from the ethical board of UNTII permitting me to go and carry out the research. Attached at the appendix are photocopies of the ethical permit letter (Appendix I) and informed consent (Appendix II).

## CHAPTER FOUR

### RESULTS

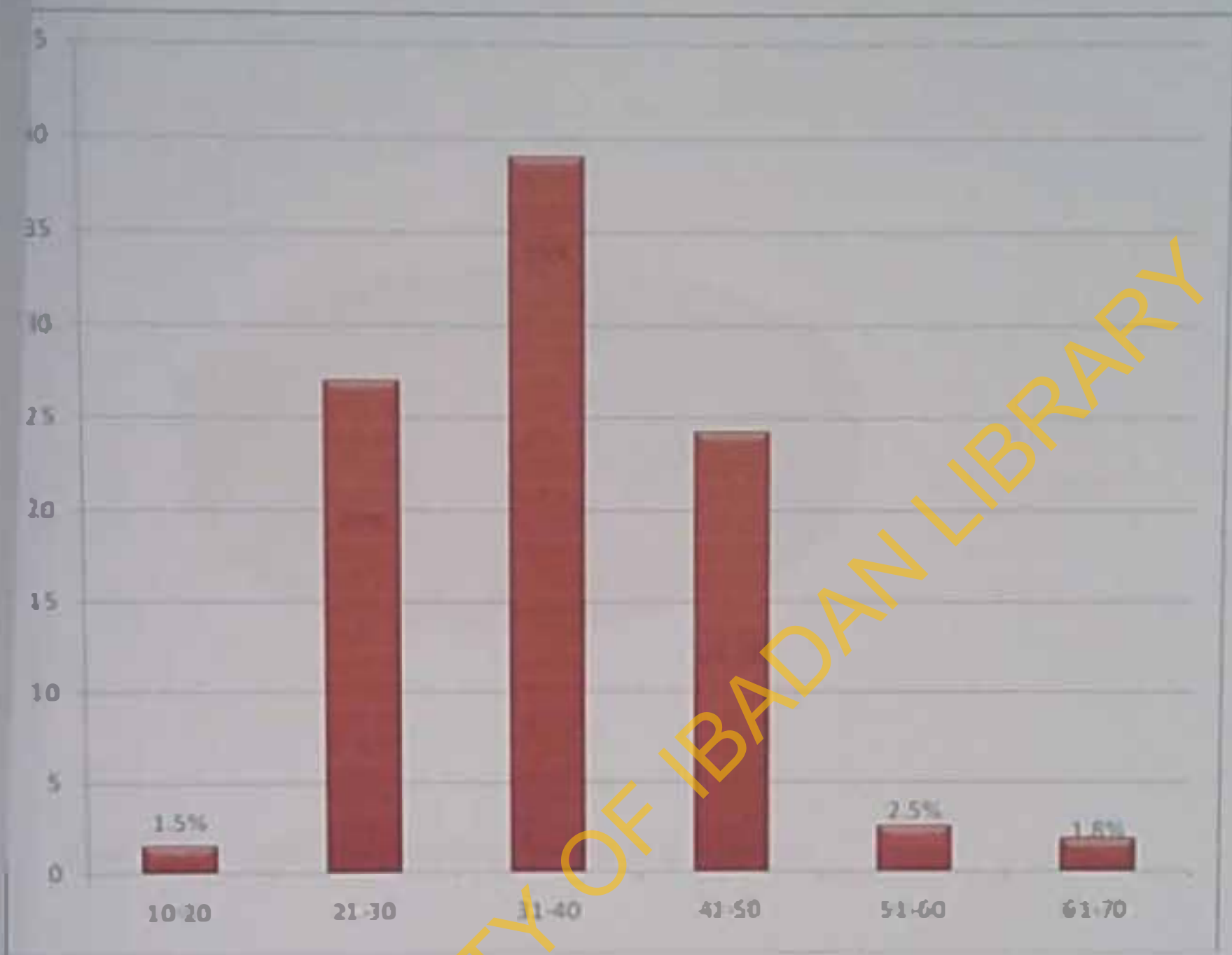
The results of the survey using the questionnaire as instrument for data collection are shown as follows:

#### Demographic Characteristics

The socio-demographic characteristics of the respondents are shown in Table 4.1, Fig 4.1 and Fig 4.2. Their age ranged from 12 years to 70 years. Amongst the 341 participants, majority (39%) fell within the age bracket of 31 – 40 years (Fig 3). These are the sexually active able bodied men and women constituting the workforce that sustain the economy of every nation. Their mean age was 36.9 ± 9.8. There were more (60.7%) female respondents than males (39.3%) (Fig 4.2).

Slightly above half 173 (50.8%) of the respondents were married with 28.7% being singles, 17.3% were widowed and 3.2% were separated (Table 4.1). Survey of the educational data of the respondents revealed that majority (41.9%) of the respondents attended secondary school, 29.6% participants attended tertiary institution while 21.1% respondents attended primary school with 9.3% as not formally educated.

The occupational profile of the respondents showed that the respondents were predominantly artisan and traders (58.6%), followed by professionals and civil servants (25.8%), house wives and students (9.6%) and farmers (5%). The predominant religion was Christianity (98.5%). Majority (78.3%) of the respondents were from ~~monogamous~~ homes (Table 4.1).



**Fig 4.1: Percentage age distribution of respondents (in years)**





**Fig 4.2; Sex distribution of respondents in percentage**

Table 4.1. Demographic characteristics of respondents (n=344)

Characteristics	No	Percent (%)
<b>Marital status</b>		
Single	98	28.7
Married	173	50.8
Separated	11	3.2
Widowed	59	17.3
<b>Educational qualification</b>		
No formal education	18	5.3
Primary	72	21.1
Secondary	143	41.9
Tertiary	101	29.6
Others	7	2.1
<b>Occupation</b>		
Professional/civil servants	88	25.8
Artisans/traders	200	58.6
Farmers	20	5.0
Housewives/students	33	9.6
<b>Religion</b>		
Characteristics	336	98.5
Islam	2	0.6
Traditional religion	3	0.9
<b>Type of family</b>		
Monogamous	267	78.3
Polygamous	74	21.7

## Respondents compliance with ARV drugs

This section describes the way and manner with which the respondents have been taking their ARV drugs. A large majority (89.1%) of the respondents reported to have completely taken their drugs as prescribed, whereas 42.8% had failed to take their drugs at one time or another from the time of their enrolment into the ARV drug treatment program to date (Table 4.2). About 25.8% reported to have missed some dose of ARV drugs a week preceding the study whereas 74.2% completed their drug regiment without missing a dose see table 4.2. An overwhelming majority (96.8%) of the participants declared their willingness to continue with the ARV therapy despite the fact that the drug does not cure HIV (Table 4.2).

Analysis of the data generated with the seven days recall adherence table in the questionnaire showed that out of the 341 respondents, 79.2% reported to have taken their ARV drugs completely without missing any dose within the one week preceding the study (excellent adherence), whereas 20.8% missed a tablet or more (Table 4.2 and Fig 4.3). The data collected from the seven days recall adherence table was used to calculate the level of adherence of the PLWHA studied using stipulated formulae from literature review see page 42 and table 4.3. The level of adherence as reported by the respondents was calculated to be 94.30% see page 42.



**Table 4.2: Compliance with ARV drugs (n=341)**

Variables	No	%
How drugs were taken		
As prescribed	304	89.1
When I feel like	11	3.2
Sometimes I forgot	26	7.6
No that failed to take ARD at any time		
Yes	146	42.8
No	195	57.2
No that missed dose of ARD a week preceding the study		
Yes	88	25.8
No	253	74.2
Willingness to continue therapy		
Yes	330	96.8
No	11	3.2

**Table 4.3 Respondents Adherence to ARD during the week preceding the study (n = 341)**

Number of tablets taken per patient over one week (n)	Total no of PLWHA (I)	Percentage (%)	Total tablets taken (n I)
0.00	7	2.1	00
2.00	2	9.6	4
4.00	1	0.3	4
7.00	4	1.2	28
8.00	1	0.3	8
10.00	4	1.2	40
11.00	7	2.1	77
12.00	24	7.0	288
13.00	21	6.2	273
14.00	270	79.2	3780
Total	341	100%	4502



**Fig 4.3: Adherence of respondents using the one week recall adherence table**

## Respondents perceived motivating factors to ARV drug compliance

This section elucidates the factors that inspire the PLWHA to studiously take their ARV drugs as prescribed by their health care provider. Eighty seven percent of respondents disclosed their HIV status to family members or close friends. Majority (56.6%) knew about ARV drugs through doctors while 17% and 15% of participants knew about ARV drugs through friends/relatives and via counseling in hospital respectively. A large majority (83%) of the participants reported to have received counseling prior to enrolment into the ARV drug therapy (Table 4.4).

Most of the respondents (69%) took their ARV drugs without being reminded to take their drugs. About 20.8% were reminded by family members while 6.7% used alarm clock and 2.9% were reminded by friends (Table 4.4). Slightly above half (55.1%) of the respondents received various kind of social assistance ranging from finance, clothing, food items to emotional support from relatives, friends and NGOs and health workers. Of this, majority (47.2%) received social assistance from their family members. About 4.7% received financial and material assistance like clothing and food items from HIV support group, 2.6% from friends, 0.6% from health workers, while 44.9% reported not to have received any social assistance from anybody (Table 4.4).



**Table 4.4: Respondents' perceived motivating factors to ARV drug compliance**

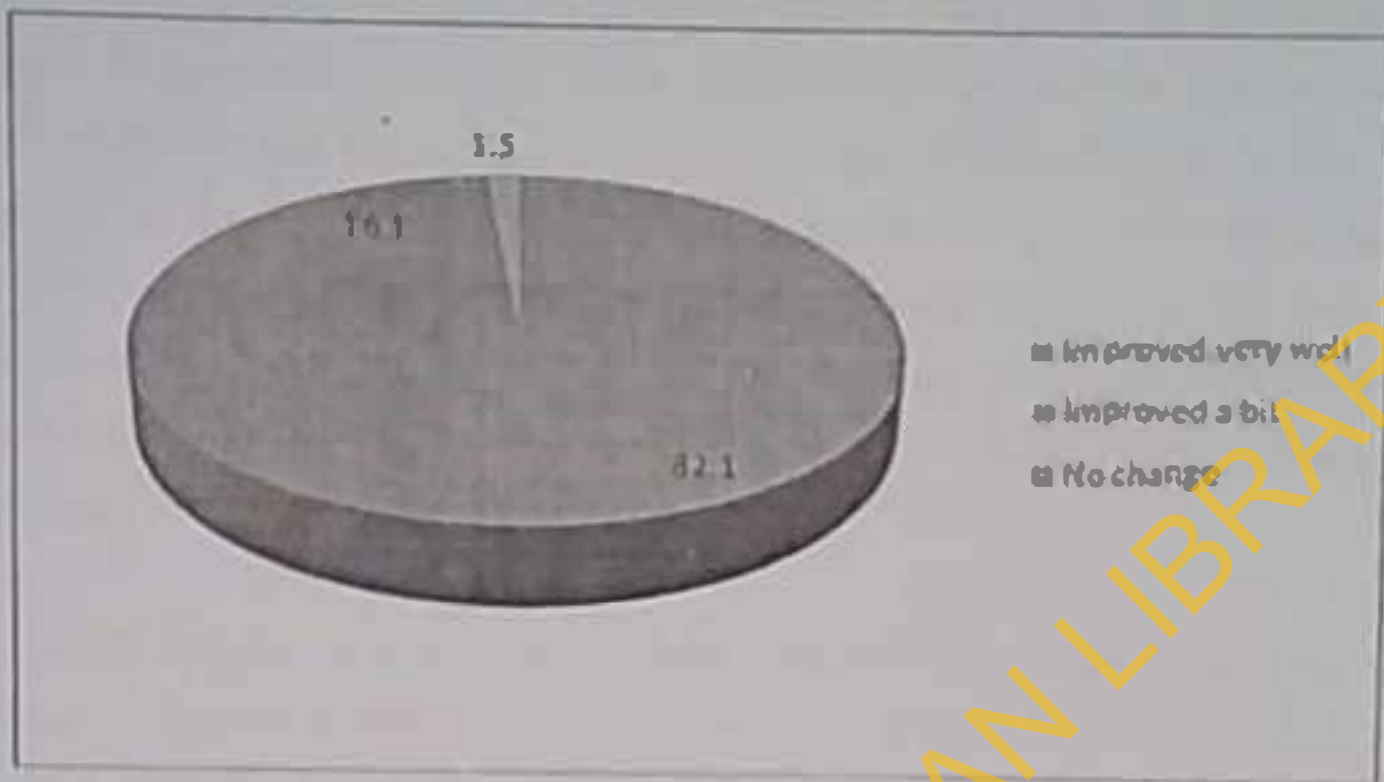
(n = 341)

Variables	N	%
<b>Informed family/friends of HIV status</b>		
Yes	297	87.1
No	44	12.9
<b>How they knew about ARV drugs</b>		
Doctors	193	56.6
Friends/relatives	58	17.0
Counseling in hospital	53	15.5
Radio	23	6.7
Support group	14	4.1
<b>Counseling prior to enrolment into ARV drugs treatment.</b>		
Yes	283	83.0
No	58	17.0
<b>Use of reminder</b>		
Friends	10	2.9
Family member	71	20.8
Alarm	23	6.7
Pill chart	2	0.6
Self	236	69.0
<b>Social support from</b>		
Family members	161	47.2
Friends	9	2.6
HIV support group	16	4.7
Health workers	2	0.6
Nobody	153	44.9

### Respondents perceived benefits of ARV drugs

Improvement in health was one physically observable benefits of ARV drugs that stimulates compliance to ARV drugs amongst PLWHA. It was observed that most PLWHA on commencing treatment with ARV drugs, experienced tremendous improvement in their health especially, those that had been down with one health problem. Eighty two percent of the respondents that were receiving ARV drug treatment reported marked improvement in their health, with about 15% reporting little improvement in health while 1.5% did not experience any improvement in their health (fig 4.4).

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**Fig. 4.1: Perceived Impact of ARV drugs on the health status of respondents**



### Respondents perceived restraining factors to compliance

This section explored the factors that were reported as barrier to compliance with ARV medication and these are reflected in Tables 4.5 and 4.6. The factors found through literature review to cause PLWHA not to adhere to their medication such as side effects of the drugs, forgetfulness, travelling were explored in this section. Out of the 341 respondents 40.2% had experienced at least one type of side effect since they started taking ARV drugs. Of the 137 PLWHA that experienced drug side effect, only 5% stopped their ARV medication because of the side effect (Table 4.5). The side effects experienced by the respondents varied in their frequency of occurrence with rashes (56.6) topping the list, followed by abdominal pain (30.7%), diarrhea (30.7%), vomiting (27.7%) and dizziness (24.8%). (Table 4.6).

Most (93.8) of the respondents were on double dose ARV drug regimen. The respondents enumerated various other factors that made them to miss their dose of ARV drugs. Some of those restraining factors mentioned by respondents were travelling (19.1%), forgetfulness (17.3%), lack of access to food (7.9 %), government workers strike (5.3%) and anger (1.2%), (Table 4.5).

Slightly less than half (48.4%) of the participants have been on ARV medication for a duration of six to eighteen months preceding the study while 36.7% have been on ARV for nineteen to thirty six months, with only 14.95% having been on ARV drugs for more than 37 months.

**Table 4.5: Respondents' perceived restraining factors to ARV Drug compliance**  
(n = 341)

Variables	N <sub>2</sub>	%
<b>Side effect from ARV drugs</b>		
Yes	137	40.2
No	204	59.8
<b>No that stopped ARV drugs due to side effect</b>		
Yes	17	5.0
No	120	35.0
Missing	59.8	59.8
<b>Multiple dose regimen</b>		
2 tablets	320	93.8
>2 tablets	21	6.2
<b>Reasons for missing doses</b>		
Travelling	65	19.1
Forgetfulness	59	17.3
Lack of food	27	7.9
Government workers strike	18	5.3
Anger	4	1.2
Nothing	151	44.3
Multiple answer	17	4.9
<b>Duration on ARV drugs</b>		
6 to 18 months	165	48.4
19 to 36 months	125	36.7
37 to 72 months	51	14.9

**Table 4.6 Types of reported side effects (n = 137)**

Side effect	Yes	%
Rashes	77	56.2
Abdominal pain	42	30.7
Diarrhoea	42	30.7
Vomiting	38	27.7
Dizziness	34	24.8
Total	232	169

- Multiple response



### Compliance by demographic characteristics

Majority (79.8%) of the respondents within the age bracket of 31 to 40 years took their ARV drugs better than those younger than 31 years (79.2%) and older than 40 years (78.4%) (Table 4.7). Slightly more (82.0%) males, than (77.4%) females, adhered rigidly to their ARV drugs (Table 4.7). However there was no significant difference between sex of participants and how they took their drugs. ( $p > 0.05$ ). Slightly more (82.2) of the married respondents took their drugs as prescribed compared with the singles (75.3%), widowed (78%) and the separated (72.7%). However no significant difference was observed between the married and the singles and how they took their drugs ( $p > 0.05$ ). Also no significant difference was observed with compliance and educational status ( $p > 0.05$ ) (Table 4.7). Farmers were observed to adhere slightly more (90%) to their ARV drugs than artisan and traders (79.7%), then civil servants (79.3%). The house wives and students (67.6%) showed the least adherence with  $p > 0.05$  (Table 4.7)). Slightly more of the participants from monogamous homes (79.7%), took their drugs better than those from polygamous home (77%). However there was no significant difference in how the two groups took their ARV drugs ( $p > 0.05$ ), (Table 4.7)

Table 4.7

## Compliance by Demographic Characteristics

(n 341)

Variable	Compliance			$\chi^2$	P-value
	Yes	No	Total		
<b>Age</b>					
less than 30	76(79.2%)	20(20.8%)	96(100%)	.064	0.968
30 to 40	107(79.8)	27(20.2%)	134(100%)		
Above 40	87(78.45%)	24(21.6%)	111(100%)		
<b>Sex</b>					
Male	109(82.0%)	24(18.0%)	133(100%)	1.064	0.302
Female	160(77.4%)	47(22.6%)	208(100%)		
<b>Marital status</b>					
Single	73(75.3%)	24(24.7%)	97(100%)	2.113	0.549
Married	143(82.2%)	31(17.8%)	174(100%)		
Separated	8(72.7%)	3(27.3%)	11(100%)		
Widowed	46(78.0%)	13(22.0%)	59(100%)		
<b>Level of education</b>					
Not educated	16(88.9%)	2(11.1%)	18(100%)	1.098	0.384
Educated	254(78.6%)	69(21.4)	323(100%)		
<b>Occupation</b>					
Farmer	18(90%)	2(10%)	20(100%)	3.491	.175
Artisans/traders	157(79.9%)	40(20.3%)	197(100%)		
Civil servants/professionals	67(79.3%)	18(20.7%)	87(100%)		
House wives/students	25(67.6%)	12(32.4%)	37(100%)		
<b>Type of family</b>					
Monogamous	213(79.77%)	54(20.22%)	267(100%)	.250	0.629
Polygamous	57(77.0%)	17(23.0%)	74(100%)		
<b>TOTAL</b>	270(79.2%)	71(20.8%)	341(100%)		

### Compliance by motivating factors

It was observed that that majority (80.6%) of the people that had received counseling prior to enrolment into the ARV treatment program adhered to their treatment regimen more than those without counseling prior to enrolment (72.4%). However, no significant difference was observed ( $p>0.05$ ).

Slightly more (80.0%) of the patients that were reminded to take their drugs took their ARV drugs better than those (78.8%) that were not reminded. However there was no significant difference between the two groups ( $p>0.05$ ), (Table 4.8).

Eighty percent of those that reported improvement in health as a result of the ARV took their ARV drugs as prescribed better than those (20%) that did not report any improvement in health. However, a significance difference was observed between those that experienced improvement in their health status and those that did not report any improvement in their health and how they took their drugs ( $p<0.05$ ), (Table 4.8). Subsequent analysis with logistic regression reveals that those who reported improvement in their health were 15.2 times more likely to adhere with ARV medication than those that did not adhere (OR=15.2,  $p=0.01$ ,  $\alpha=0.05$ ), (Table 4.9).

However majority (84.0%) of those that received social assistance adhered to their ARV drugs better than those (73.2%) that did not receive any social support. The difference between the two groups and how they took their drugs was found to be statistically significant ( $p<0.05$ ), (Table 4.8). Further analysis with logistic regression showed that those that receive social assistance were 1.829 more likely to comply with ARV medication than those without social assistance (OR=1.829,  $P=0.027$ ,  $\alpha=0.05$ ), (Table 4.9).

Table 4.8

## Compliance by Motivating Factors

(n = 341)

Variables	Compliance			$\chi^2$	P Value
	Yes	No	Total		
Had received Counseling					
Yes	228(80.6%)	55(19.4%)	283(100%)	1.902	0.168
No	42(72.4%)	16(27.6%)	58(100%)		
Use of reminder					
yes	84(80.00%)	21(20.0%)	105(100%)	0.143	0.835
No	186(78.8%)	50(21.2%)	236(100%)		
Social/financial support					
Received support	158(84.0%)	30(16.0)	188(100%)	5.891	0.015
No social support	112(73.2%)	41(26.8%)	153(100%)		
Reported effect on health					
Improved	269(80.0%)	67(20.0%)	336(100%)	10.735	0.001
Not improved	1(20%)	4(80.0%)	5(100%)		
Total	270 (79.2%)	71 (20.8)	341(100%)		

Table 4.9 Table for Logistic Regression

Variable	Odds ratio (OR)	P value
Improvement in health	15.15	0.017
Received social support	1.83	0.027



## Compliance by Restraining factors

A large majority (77.2%) of the participants despite the side effect they experienced continued taking their ARV medication as was prescribed by their health practitioner while only 22.8% of those that experienced side effects did not adhere to their ARV regimen. It was also observed that slightly more (80.4%) of those that did not experience any side effect took their drugs better than those (77.3%) that had experienced side effect. However there is no significant difference in the taking of drugs between those that experienced side effect and those that did not experience any side effect ( $p > 0.5$ ), (Table 5.0).

The respondents reported many other factors that restrained them from taking their ARV drugs as prescribed. However more (29.1%) of the respondents that indicated forgetfulness, travelling, anger, lack of food or government strike as reasons for missing their dose of ARV drugs did not adhere to their medication whereas only 8.6% of the people that reported non of the aforementioned reasons failed to adhere. There is however a significant difference between the people that indicated any of the above reasons as responsible for missing their ARV drugs and those that mentioned non of these reasons ( $p < 0.05$ ) (Table 5.0).

Slightly more (81.6%) of those on ARV drugs for nineteen to thirty six months took their ARV drugs better than those (78.0%) newly placed on ARV drugs for six to eighteen months and those (72.7%) on ARV for a longer period of thirty seven months and above. However there was no significant difference with the duration on ARV drugs and how drugs were taken ( $P > 0.5$ ) (Table 5.0).

Table S.0 Compliance by Restraining factors

(n = 311)

Restraining factors	Compliance			X <sup>2</sup>	p Value
	Yes	No	Total		
Ever missed taking your ARV drugs due to (forgetfulness, travelling, lack of access to food, govt. strike)					
Yes	123(71.0%)	50(29.0%)	173(100%)	27.796	0.000
Nothing	138(91.4%)	13(8.6%)	151(100%)		
Multiple	9(52.9%)	8(47.1%)	17(100%)		
Ever experienced side effect with ARV drug					
Yes	106(77.3%)	31(22.7)	137(100%)	.501	0.498
No	164(80.4%)	40(19.6%)	204(100%)		
Duration in months					
6-18	130(78.9%)	35(21.1%)	165(100%)	2.026	0.567
19-36	102(81.6%)	23(18.4%)	125(100%)		
37-54	21(72.4%)	8(27.6%)	29(100%)		
55-72	16(72.7%)	6(27.3%)	22(100%)		
Total	270(77.2%)	71(20.8%)	341(100%)		

## Testing of Hypothesis

Some hypothesis was tested in this research work. The respondent's adherence was tested against respondent's demographic variables such as sex, age, occupation, education and religion. Other variables like receipt of social support, side effect and effect of ARV drugs to respondent's health were tested with respondent's compliance with ARV drugs.

Hypothesis 1 states that 'there is no association between demographic characteristics such as age, sex, marital status, and occupation and respondents compliance with ARV drugs'. The respondents within the age bracket 30 to 40 years were found to be slightly more (79.7 %) adherent than the youths (79.2%) and the elderly (78.5%), (Table 4.7). However the difference was not statistically significant, ( $p > 0.05$ ) therefore the null hypothesis was accepted (table 4.7). Also 'there is no association between sex of respondents and compliance with ARV drugs'. The male respondents (82.2%) showed slightly higher adherence than the females (77.3%). The difference between the male and female respondents and their compliance with ARV drugs was not statistically significant, therefore the null hypothesis was accepted, (Table 4.7). There is 'no association between the marital status of respondents and their compliance with ARV drugs'. The married respondents were found to be slightly (82.2%) more adherent to their ARV drugs than the (78%) widowed and the (75.3%) singles see (Table 4.7). However the difference was not statically significant therefore the null hypothesis was accepted.

'There is no association between the occupation of respondents and compliance with ARV drugs'. The farmers were found to be slightly (90%) more adherent than the artisans and traders (97.9%), the civil servants and professionals (79.3%) with the least adherent being the housewives/students (78%). However the difference was not statistically significant and so the null hypothesis was accepted (Fig 4.7). In summary there is no significant statistic difference between demographic variables and respondents compliance with ARV drugs, therefore the null hypothesis was accepted.

The second hypothesis states that 'there is no association between side effect and respondents compliance with ARV drugs.' 77.2% of those that experienced side effect adhered to their ARV medication whereas only 80.4% of those that did not experience side effect adhered to their ARV drugs. However the difference was not statistically significant and so the null hypothesis was accepted (Table 5.0).

The third hypothesis states that 'There is no association between receipt of social support and compliance with ARV drugs'. Those PLWHA that reportedly received social assistance were slightly more (84.0%) adherent than those that did not enjoy any social assistance (73.2%) from any source. However the difference was statistically significant and so the null hypothesis was rejected (Table 4.8 and Table 4.9).

The fourth hypothesis states that 'there is no association between reported effect of drugs on respondent's health and compliance with ARV drugs'. It was observed that those PLWHA that reported improvement (80.5%) in health from taking ARV drugs adhered better than those that did not report any improvement (20%) in their health. The difference was found to be statistically significant and so the null hypothesis was rejected (Table 4.8 and Table 4.9).



## CHAPTER FIVE

### DISCUSSION/CONCLUSION AND RECOMMENDATIONS

#### DISCUSSION

##### Demographic characteristics

The females were observed to be in the over whelming majority in the sample for this study. This could be attributed to physiologic factors. The women are three times as likely as men to become infected through sexual intercourse because the vaginal wall is delicate and prone to sores and abrasions which may create pathway for transmission of STIs including HIV, (Ajuwon, 1996-97). Secondly it is easier for an infected man to infect the partner than an infected woman to infect her partner, because of the nature of the reproductive organ of the woman. The female reproductive organ serves as a receptor. During coitus once there is semen that is infected with HIV, it can stay for a longer period in the woman body than that of man. So the risk of a woman getting infected once she has encounter with a man that has HIV/AIDS is higher than when a man encounters a woman with HIV/AIDS. Thirdly many women rely on their partners for sustenance.

In such situation, such women would have limited control over the sexual behavior of their partner especially where a woman is absolutely dependent on the male partner for survival and up keep. Also some cultural barriers like female genital mutilation poses a risk factor for HIV transmission as the mutilation and subsequent scarring could result into vaginal tears during intercourse with an infected person thus increasing further the efficiency of male to female transmission. Also the elderly aristocratic men in our society are in the habit of having sex concomitantly with the underprivileged young school girls and widows in our society thereby predisposing them to HIV infection. This results in increase susceptibility of women to HIV infection more than their male counterpart and this accounts for the number of women infected with HIV outnumbering the men.

It was also observed that more women almost double the number of men respondents were infected. This could be attributed to the fact that women readily come up for testing and declare their status while men tend to be in denial. From antenatal to child birth the women frequents the hospital readily and in the process their HIV status is readily detected and documented more than men. However the men were found to be slightly

more adherent in taking their ARV drugs than women. Amongst the study participants it was observed that those mostly affected were the middle aged (30 to 40 years). Thus HIV/AIDS was found to affect mostly the strong vibrant able bodied men and women at the peak of life. This age group constitutes the workforce that sustains the nation's economy and their individual homes. They constitute the national labor force so if HIV/AIDS is not well handled it will result to loss of productive workers, economic break down and loss in gross national income. This will subsequently threaten development in all sectors of the societies and will translate into a global public health problem. The finding is in line with the report of UNAIDS 2002. To circumvent this globally, emphasis is laid on counseling and subsidizing ARV drug and ensuring that ARV drugs reach every person infected with HIV.

Thus the global involvement of PEPFAR, UNAIDS and WHO to ensure steady supply of subsidized generic ARV drugs to developing countries, targeted at improving quality of life and longevity of PLWHA while controlling the spread of the disease. Despite the fact that the disease burden was observed to be more on the middle aged persons (30 to 40 years) yet they were found to be slightly more (79.7%) adherent than the youths (79.2%) and the elderly (78.4%). The impact of the HIV infection is on the workforce of the nation and the bread winners in various homes, and any instability in their health or income portends doom to those dependent on them and the nations economy at large, as such the drive to be alive and strong to actualize their vision in life propels them to take their drugs studiously. The daily health education on the importance of compliance with ARV drugs has more impact on them than the observed trend in compliance with ARV drugs by the various age groups. It was also observed that adherence tend to decrease as one ages. This is because the elderly person most times having actualized their goals and vision earlier in life do not have much at stake so their compliance with ARV drugs tend to dwindle because of their complacent attitude towards their medication. Despite this observation age was found not to predict adherence. This is in line with the finding of Malcolm et al (2003), Montessori et al (2000) and Mohamed et al (2002), that age, sex, marital status, level of education and occupational status do not significantly affect adherence.

The burden of HIV is felt more on the sexually active populace and this accounts for why majority of the respondents were married, widowed or separated with slightly above quarter (28.7%) being singles. The marital status of the respondents was observed not to



have any significant effect on adherence which is in line with the finding of Mohamed et al (2002). However the married (82.16%) respondent were observed to be slightly more adherent to their ARV medication than the widowed (78%) and the singles (75.3%).

The constant awareness campaign on HIV in the telecommunication media and the daily counseling in the HIV clinic is targeted at bringing down the prevalence rate of HIV and improving the health status of people living with HIV and AIDs. The more educated one is, the more informed the person becomes, therefore educated persons are expected to be more adherent. Nevertheless a contrary result was observed with this study. It was observed that the none educated (88.9%) adhered slightly more than the educated ones (78.6%). This could be attributed to the small number of person that were not educated amongst the study participants and so could not give reliable result. However, Duranta et al, (2003) found that educational status was not a predictor of adherence.

The research was carried out in the eastern region of Nigeria, inhabited predominantly by the Igbos. The Igbos are very resourceful and generally business oriented and this substantiates why majority of the respondents (58.6%) were traders and artisans. Most of these traders and artisans were educated and they constitute the major work force in the private sector and they are the most affected. Generally most of the people affected were professionals, civil servants, traders, artisan and farmers and are the workforce of the nation, with only 9.6% as house wives and students. This substantiates the fact that HIV affects mainly the work force and invariably every sector of the nation's economy. Occupation was not a determinant of adherence. However, farmers (90%) were observed to adhere to their ARV drugs more than artisans/traders (79.7%) or civil servant/professional (79.3%). This could be due to the ready availability of food with farmers, as some of the respondents reported that lack of access to food made them to skip dose of ARV drugs as they could not continue to take their drugs on empty stomach. The participants were predominantly Christians (98.5%), this could be attributed to the fact that the research was carried out in the eastern region of Nigeria where Christianity is the predominant religion. However religion and family type were found not to be determinants of adherence.

## Compliance with ARV drugs

A large number of the PLWHA (79.2%) took all the drugs as prescribed by their health providers without missing any dose of their ARV drugs in the last seven days preceding the study. This was appreciably high when compared with other research findings like: In Botswana 54% PLWHA attending a private clinic took 95% of their drugs, Machilinger et al (2005). Also Onwujekwe in his research work in UNTH between 2001 and 2005 reported that about 75% did not adhere to their medication regimen implying that only 25% adhered to their drugs. This could be due to the scarcity of ARV drugs at the time he carried out the research, coupled with the cost of ARV drugs then, as PLWHA were partly paying for their drugs then. The situation then, was so bad that a lot of people who could not have the opportunity of being enrolled for the ARV therapy were kept on waiting list. Some that were enrolled were caught outside the gate selling part of their drugs at a higher rate to make ends meet.

The data generated using the seven days recall adherence table, was used to calculate the level of adherence of the study participants and was found to be 96.3%. This high level of adherence among the study participants could be attributed to the fact that the level of awareness for HIV is high in the study area due to the daily health talk coupled with the fact that the drugs are given free and the clinic has been upgraded and made patient friendly courtesy of PEPFAR, UNAIDS and Global fund. Also Enugu being the capital of the then Eastern Region and the home of one of the oldest university teaching hospital have witnessed a lot of HIV and AIDS enlightenment programs in recent years. The hospital for the study being a tertiary health institution has many counselors and trained personnel's in various medical profession working in the HIV clinic that intermittently are sent for higher training. These personnel help to monitor and educate the PLWHA on the importance of strict compliance with ARV, at different points along the service line. Also the eagerness of the participants to take their ARV medication (96.8%), knowing there is no alternative cure for the disease coupled with the close monitoring by the health team has helped to maintain the high level of adherence within the study populace. This high level of adherence is similar to the finding in studies carried out in developed countries where ARV drugs are given free. Turner (2005) reported that to achieve undetectable HIV viral load, increase CD4 count and suppress development of resistant strain of HIV, 95% adherence must be achieved. Lower than 95% adherence rate have been found to result into virologic failure and resultant drug failure.



## Motivating factors to ARV drug adherence

Several factors were found to motivate adherence amongst the study participants, the most effective being counseling and improvement in health. An overwhelming majority (83%) received counseling prior to enrolment into the ARV program and this went a long way to reshape their negative attitude into positive life style. Persistent counseling and health education are the major tools used in the ARV clinic to achieve high adherence among the PLWHA. Most (83%) showed willingness to disclose their HIV status at least to family members or close friends and at the time this research was carried out most were actively involved in NGO activities and interaction with other PLWHA. HIV status disclosure helps to fight stigmatization and also attracts care and support from close allies, thereby encouraging compliance. Involvement with NGO affords them opportunity for interactions and to open up to other people living positively with HIV. In this type of forum the drive to live is stimulated by meeting and discussing with other people who are doing very well on ARV drugs. Despite this, new patients find it very difficult to disclose their status especially to their spouse which makes the issue complex in a family setting.

The PLWHAs were encouraged to use adherent aids as reminders to encourage them to take their drugs so as to curb down forgetfulness. Majority (69%) did not use reminder. About 20.8% were reminded to take their drugs by family members while 6.7% used alarm clock and 2.9% were reminded by friends. Slightly more (79.8%) of the people that used adherent aid took their drugs better than those (78.8%) that did not use any adherent aids. This is in line with the finding of Carol et al (2002) that the patients who use more adherent aids were more adherent. Nevertheless there is no significant difference in how drugs were taken between the people that used adherent aids and the people that did not use adherent aids.

About 82.1% of the study participant reported marked improvement in their health as a result of the ARV drugs they took. It was observed that with the evolution of the current ARV drugs the health of many PLWHA improved tremendously and the incidence of death dropped tremendously. This is very obvious with the seriously sick patients reporting first on admission with bouts of fever, diarrhoea and in some instance weight loss. Most patients on treatment with ARV drugs recover very fast and bounce back with life and vibrancy. Marked improvement in health status on taking ARV drugs encourages PLWHA to take their ARV drugs. This obvious improvement in health is as a result of the

lethal action of ARV drugs on the HIV virus thus, resulting in depletion of the viral load, leading to increase in CD4 Count with resultant improvement in health. The incidence of opportunistic infection were brought to barest minimum. The PLWHA now sees the benefit from the therapy and are more eager to comply rigidly to the medication regimen so as to live healthy and to survive. Majority (80.5%) of those that experienced improved health took their drugs as prescribed while only 20% of those that did not experience any improvement in health took their drugs as prescribed. The difference between the two groups was statistically significant and the data generated was further analyzed with logistic regression. Logistic analysis showed that those that experienced improvement in their health had the more likelihood of adhering to their ARV medication than those that reported no improvement (OR=152.95%, CI 1m6 to 1.10 ).

Therefore improvement in health is a strong factor that motivates PLWHA to take their ARV drug judiciously as prescribed. This is in line with the finding documented by Adam et al (2002) stating that patients are more likely to adhere well to medication they believe are making them better whether it is substantiated by medical testing or by the patients perception (perceived benefits) which could change anytime the indicator points to a worsening condition. A patient perception of effectiveness of ARV drug could result in the patient believing the effectiveness of such drug and this eventually leads to adherence. Also Leslie et al (1998) reported that people overall health and experience of side effect are major factor in their ability to adhere.

Family members, loved ones, friends and HIV support groups help to encourage people living with HIV to stay alive and healthy. Most times they extend care and support in form of money, food item, wears and emotional support. All these help to stimulate the drive to live amongst PLWHA. HIV support group form a central point for the PLWHA to gather together to socialize and rub minds culminating in monthly or bimonthly get together. They interact with each other and share some relief material like rice, money and any available items. These activities give them the feeling of belonging and being cherished. Slightly below half (42.5%) reported not receiving any social support from anybody, whereas 47.2% of the participants received social support from their family members, about 4.7% received from HIV support groups while 2.6% received from friends. Analysis of data with Chi statistics showed significant difference between how drugs were taken by those that received social support and those that did not received any social support



( $p < 0.05$ ) However further analysis with logistic regression showed that those that received social support had the more likelihood of adhering with their ARV medication compared with those without social support (OR=18, 95% CI=1.1 to 3.1). Therefore social support was found as one of the motivating factors for effective ARV medication adherence

### Restraining factors in ARV drug therapy

Therapy with anti retro-viral drugs is associated with several adverse reactions which differ severity from one person to another. Such side effects depending on the severity might cause some patients to stop their ARV medication. Amongst the study participants about 40% experienced side effects varying as follows rashes (56.2%), abdominal pain (30.7%), diarrhoea (30.7%), vomiting (27.7%) and dizziness (24.8%). Only 5% of the affected persons stopped their ARV medication due to the side effect they experienced. However this was not statistically significant as it was observed that most of the participants continued taking their medication despite the side effect they experienced. This is in line with the findings of Adam et al (2002), Klitzman et al (2004) that side effect is not a determinant of compliance with ARV drugs. This positive health behavior observed with the study participants could be the resultant effect of the health talk on side effects of ARV drugs and how to cope with such side effect when they occur coupled with the emphasis on adherence that for one to survive and live healthy you must take at least 95% of the ARV drugs as there is no alternative to survival with the human immune virus in ones blood stream. However contrary to the above findings, Leslie et al (1998) found that people experiencing side effect could also be non adherent.

Travelling (19.1%) was a major reason for skipping doses of ARV drugs. This is in line with the finding of many researchers like Chesney (1997), Johnson Robert et al (2000), Leslie et al (1998) that reported travelling as major cause of non compliance to ARV drugs. Some PLWHA travel outside their station on emergency or with a view to come back same day, but due to unanticipated exigencies may stay and not come back the same day and in the process they end up not having ARV drugs to take and this will eventually lead to skipping of doses of their ARV drug medication. The PLWHA are only allowed to refill their ARV drugs from the centre they are registered. At times some of them might plan and embark on long distance journey with their drug supply for the month in question but might eventually over stay and exhaust the supply and this would eventually



result in skipping of doses and none adherence. This is very common with youths. One of the study participants missed taking all her ARV drugs for the one week preceding the study simply because she travelled to the village for the burial of her late mother. After the burial rites, she now came to the centre to refill her ARV drugs for the month.

Many respondents tend to skip doses of ARV drugs due to forgetfulness (17.3%). Forgetfulness is the commonest reason for skipping doses of ARV drugs especially in timing. A patient could sleep through a dose and so miss to take the dose. Busy schedule in the house or office most times causes one to forget to take their ARV medication. Eventually when it flashes to their mind and they remember, the time stipulated for the medication has passed and in some cases it is time for the next dose. They end up taking the medication at a wrong timing or missing out one dose completely. This skipping in the number of dose taken or in timing compliance might result in the development of resistant strain of HIV which could not respond to the patient's medication. Subsequently as the patient continues with the medication, there is no apparent positive improvement in the health or increase in CD4 count or appreciable reduction in viral loads. The patient's health gets worse, and the only option left would be to change the medication to another class of drug, while the populace is at risk of battling with the spread of the new resistant HIV strain that might emerge. Mohamed et al (2002) made a similar observation. Chessney (1997), Sandro Sinil (2000) and Mohamed et al (2002), reported that forgetfulness was one of the major research findings that caused PLWHA to skip their dose of ARV drugs.

About 7.97% of the respondents reported that they did not have food to take and so could not take their ARV medication on empty stomach. Recurrence of this has led to irregularity in taking of the ARV drug. This is in line with the findings of Mohamed et al (2002). The level of poverty and unemployment in the nation is high such that only very few persons can afford three standard meals a day and the per capita income is low. In such situation it is difficult for one to comply with a life time medication without enough food and yet be struggling to survive. In such situation, economic/ social support from relatives or NGOs is of great importance to enhance adherence.

Government workers strike was also reported by 5.3% as the reason why they could not access their ARV drugs at times and so could not take their medication. When government workers are on a general strike, some health institutions go on attending to patients.

especially the ARV clinic while some others close up. It becomes difficult for those PLWHA that access their ARV from hospitals participating in ongoing strike to be able to refill their drugs when workers are on strike. The unfortunate ones that run out of ARV drugs at such times and during public holidays have no option than to skip their dose of ARV drugs. The various reasons for missing dose of ARV ranging from forgetfulness, travelling, anger, lack of food and government workers strike were grouped together and further analyzed using chi square statistic. A significant difference was observed in the way drugs was taken between those affected by the above reasons and those that did not stop their medication because of any of the enumerated reasons ( $P < 0.05$ ). As the above result is significant it further confirms that these are important deterrent factors to ARV drug medication.

The participant compliance with ARV drug was not dependent on multiplicity of doses of ARV drugs taken. Most participants were not perturbed whether they ingest multiple drugs at once or not. This observation could be attributed to the fact that at the time the research was carried out the participants were all on single dose compressed combination tablet therapy (one tablet in the morning and one tablet in the evening) so the impact of multiple pill burden was not in contention even for those on second line drug. However Mohamed et al (2002) reported that pill burden does not affect compliance to ARV drugs. Majority of the respondents (48.4%) were observed to have been on ARV drugs for six to eighteen months. However those that have received ARV drugs for nineteen to thirty six months and are already experiencing the benefits of the therapy (seen by the improvement in their health and disappearance of opportunistic infection), tend to be more serious in taking their ARV drugs than others. The people that have been on the medication for a very long time (55 and above), have reduced zeal in taking the ARV drugs and so tend to be less adherent. This is in line with the finding of Leslie (1998), that people with chronic disease who are not experiencing any symptoms and are doing better may stop taking their medication because they believe they do not need it. This could explain why people that have been on ARV for longtime tend to adhere less. They are well, having been on the therapy for long, they could just decide to go on drug holiday. However it was observed that duration on ARV therapy is not determinant of ARV adherence.



## CONCLUSION

The advent of ARV drugs has transformed HIV Globally from being regarded as a killer disease to a chronic ailment, with complete compliance with ARV drugs being the predictor of the success. From the demographic data gathered in this research Human immune deficiency virus is seen to have more impact on the sexually active, able bodied young men and women (30 to 40 years) that form the workforce of every nation. This is why HIV has a drastic impact on every sector of the economy If the disease is not kept in check. The females are the most affected (60.7%) Demographic factors like age, sex, level of education, marital status and occupation did not have any significant effect on compliance with ARV drugs. A large number of the respondents (79.2%) took their ARV drugs completely as prescribed without missing any dose a week preceding the research. Also the calculated level of adherence from the data collected from the respondents was 94.3% which is high.

However some factors were found to motivate adherence. It was found that patients that reported visible improvement in their health from taking ARV drugs, were more eager to adhere to their ARV drugs regimen so as to stay healthy and strong. Also social support and care from family, friends, NGO was found to stimulate the innate feeling of being cared for and subsequently the drive to live, thereby enhancing adherence with ARV drugs.

Some other factors mentioned by participants as deterrent factors includes: travelling (19.1%), forgetfulness (17.3%), lack of access to food (7.9%) and government workers' strike (5.3%) . Travelling outside ones city and running short of ARV drugs is the most rampant reason for skipping doses. The second strong reason for skipping doses in timing or completely missing dose is forgetfulness .This could be as a result of busy schedule at work or at home or one sleeping over a dose.

Therefore health education should be intensified to reinforce the PLWHA positive health seeking behavior while weakening the life styles that negates adherence.



## IMPLICATION OF FINDINGS FOR HEALTH EDUCATION

In line with the global quest for effective control on the spread, prevalence and cure for HIV/AIDS and the fact that the presently existing ARV drugs are used for palliative management of HIV/AIDS, the issue of treatment compliance has become an important medical, financial, psychological and health policy issue.

The behavior of PLWHA that needs to be modified includes all the behaviors that predisposes them to non compliance such as forgetfulness, travelling and running out of drugs, lack of access to food and non disclosure of status to significant others should be tackled effectively with appropriate health education.

Consistent counseling as a tool in Health Education should be used to encourage PLWHA to disclose their status to a close relative or friend within their place of residence. Husbands should be encouraged to come out of secrecy and disclose their health status to their wives and wives to their husbands as some were observed to be reluctant to do so. Counseling should be used to encourage PLWHA to confide and disclose their status to loved ones, hence enabling their partners and loved ones to help them work out their drug plan thereby enhancing compliance with their ARV drug regimen.

Aside close relatives and 'significant others', through patient counseling, emphasis should be laid on the use of phone alarm as reminders to ensure that PLWHA remember to take their drugs regularly as prescribed. This is an effective tool to curb down forgetfulness as it affects compliance to ARV drugs.

In addition to the general counseling, some PLWHA needs individualized counselling which would involve employing more counselors and putting them at various points in the health system within the ARV clinic, such as the treatment and drug dispensary point. This will help to elucidate individualized problems, proffer solution to such problems, thereby gaining the confidence and trust of such individuals which will in turn imbibe in them, the consciousness of strictly taking ARV drugs as prescribed by their health provider, thereby enhancing compliance to ARV drugs.

Through counseling, PLWHA should be encouraged to always keep a few doses of their ARV drugs in tight multivitamine packs in their handbag as "handbag drugs". Anytime they forget to take a dose before leaving the house they can take the dose from their 'hand bag drug' thereby minimizing the incidence of non compliance due to forgetfulness.

About 19% of the respondents reported travelling outside their place of residence and running short of ARV as deterrent factor. Counseling should be used to encourage PLWHA to always ask for extra month refill before embarking on long distant journey.

## LIMITATIONS TO THE STUDY

The main limitation encountered with the work was with the respondents reported adherence using the seven days recall adherence table. There was no alternative way of checking whether the respondents reported adherence tallied with the respondent's actual adherence. Most respondents report high compliance in an experimental setting than in normal day to day life environment.

'CD4' count' and one 'month recall adherence' with participants coming for drug refill with left over drugs which are alternative ways of checkmating self reported adherence, still have their shortfalls. Currently a lot of supplements boost immunity such as 'MORINGA', 'COCONUT WATER' and some drugs like 'IMMUNASE' and 'SELENIUM'. In situation where respondents are using immune booster, CD4 count test cannot detect who is complying. On asking participants to come with drugs remaining from previous month refill, either they deliberately drop the 'actual drugs not taken' at home or ignorantly they merge previous month drugs and drugs left from other months.

## RECOMENDATIONS

The following recommendation are offered to optimize patients compliance to ARV drugs and the resultant benefits derived from taking the drugs, as non compliance will result into drug failure and development of resistant strain of human immune deficiency virus which will pose an imminent global public health problem. The recommendation is in three fold targeting first the patient, secondly the health workers and thirdly the government.

### THE PATIENT:

1. Provide continuous patient education for successful outcome of HAART therapy:  
Continuous general and individualized patient counseling must be embarked on daily in all ARV clinics. Patients should be counseled and made to understand the reason for taking the ARV drugs and the expected benefits that comes with strict compliance. Patients should be educated on potential ARV drug interaction, side effects and how to cope with the various side effects. It must be constantly emphasized that for optimal



benefit to be achieved, strict adherence in dose and in timing should be followed, at all times both for old and new patients. This health education should be carried out consistently at various points in the ARV clinics and by multiple providers and in various ways like graphics, video, vernacular, written and verbal.

## THE HEALTH WORKERS

2. Forgetfulness was observed as a strong deterrent factor to ARV drug compliance and was reported by about 17% of the respondents. therefore health workers in ARV clinics should device means of integrating and regularly sending bulk SMS messages to remind PLWHA to come for their drug refill and pick up. Also defaulters that missed to pick their drugs within their appointment day/week should be sent a second reminder SMS as a follow up.
3. It was also observed that social support enhanced adherence and that those that received social support were 1.8 times more likely to comply with their ARV drug regimen than those that did not receive any social support. Therefore, there is need for social support clubs and NGO to be started in the HIV clinic setting so that when PLWHA come for ARV drug pick up they could familiarize with other PLWHA and partake in any social assistance being shared such as food items, money and other social benefits, that such clubs and NGO could offer. By interacting with other PLWHA, they learn some adaptive, coping skills which will in turn help them to cope with challenges in life, accepting the situation that they are in and have the willingness to strive to actualize their goals in life which also enhances compliance. Advocacy and sensitization strategies should be used to encourage NGOs and family members to constantly extend love, care and social support to PLWHA as this creates an enabling environment to enhance ARV medication compliance.

## THE GOVERNMENT:

4. In the bid to address the issue of non accessibility of drug due to closure of ARV clinics on public holidays, the federal government should ensure that all ARV drug centers in the nation are functional on public holidays and when health institutions are on general strike. This will enable PLWHA to readily access, and refill their ARV drugs prescriptions, thereby ensuring continuity in treatment and compliance to ARV drug therapy.



- 5 In order to tackle the issue mentioned of non compliance due to PLWHA travelling to far places and running out of ARV drugs, there is need for Federal Government of Nigeria in collaboration with PEPFAR to network all ARV centers in Nigeria so as to enable PLWHA to be able to access and refill their ARV drugs from centers outside their domain anytime they unexpectedly run out of ARV drugs while on transit.

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## APPENDIX 1

## UNIVERSITY OF NIGERIA TEACHING HOSPITAL

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Dr. (Chief) Charles U. Alanzo, M.D.

Chairman, U N T H Management Board

\* M. G. 01 mtr 20 1100

**ОТНОСИТЕЛНО СЪВЕЩАНИЕ НА ПЪРВОЕ СЪОБЩАНИЕ**

Director of Action/Intelligence Security

~~UHH Management Board~~

**Dr. A. U. Mbach, MD, PhD, FRCGS, FRCR, FRCR, FRCR, FRCR**

Chief Medical Director

**Dr. P. U. N. NTA**

Overcoming Windows Security Barriers

Our Rel. **UNITH/CSA 329VOLS**

Date 14th September 2007

# ETHICAL CLEARANCE CERTIFICATE

## TOPIC

## FACTORS AFFECTING ADHERENCE TO ANTI-RETROVIRAL THERAPY

BY

PHARM. INTERVENTIONS LAQUETIN

FOR

A DISSERTATION FOR A MASTERS DEGREE IN PUBLIC HEALTH OF THE

DEPARTMENT OF HEALTH PROMOTION AND EDUCATION, FACULTY OF

PUBLIC HEALTH, COLLEGE OF MEDICINE, UNIVERSITY OF IRAN.

The research project on the above topic was reviewed and approved by the University of Nigeria Teaching Hospital Research Ethics Committee.

**This certificate is valid for one year from date of issue**

PROF. R. E. UMBEL

**CHAIRMAN.**

### Ethics Committee

DATE: 14TH SEPTEMBER, 2007

# FACTORS AFFECTING ADHERENCE TO ANTI-RETROVIRAL DRUGS

## HEALTH RESEARCH ETHICS COMMITTEE INFORMED CONSENT FORM

### INTRODUCTION:

My study involves evaluating the factors that affect adherence to Anti-Retroviral drugs. The participants will be interviewed using a well designed Questionnaire to find out the factors that encourage PLWHA to take their ARV medicine and the factors that prevent them from taking their ARV medication.

### STUDY PROCEDURE:

The study procedure will be purely by administration of questionnaire.

### RISK:

There is no anticipated risk but the outcome of the research will help in counseling PLWHA on adherence to ARV drugs. This will help to prevent development of resistant strains of HIV and increase quality of life of PLWHA.

### FEEDBACK:

The researcher is readily available at UNTH Pharmacy Department to answer any question from the participant.  
My contact no is 08034907832.

### RESPONSE:

I have read the above which has been explained verbally by the researcher and is well taken. I hereby consent to participate.

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(subject)

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(researcher)

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(witness)

## APPENDIX II

### FACTORS AFFECTING ADHERENCE TO ANTI-RETROVIRAL DRUGS

#### HEALTH RESEARCH ETHICS COMMITTEE INFORMED CONSENT FORM

##### INTRODUCTION:

My study involves evaluating the factors that affect adherence to Anti-Retroviral drugs. The participants will be interviewed using a well designed Questionnaire to find out the factors that encourage PLWHA to take their ARV medication and the factors that prevent them from taking their ARV medication.

##### STUDY PROCEDURE:

The study procedure will be purely by administration of questionnaire.

##### RISK:

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##### FEEDBACK:

The researcher is readily available at (NTH Pharmacy Department to answer any question from the participant.  
My contact no is 08034907832.

##### RESPONSE:

I have read the above which has been explained verbally by the researcher and is well taken. I hereby consent to participate.

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(subject)

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(researcher)

Sign \_\_\_\_\_  
Name \_\_\_\_\_  
Date \_\_\_\_\_  
(witness)



## APPENDIX III

### QUESTIONNAIRE

#### FACTORS AFFECTING ADHERENCE TO ANTI-RETROVIRAL DRUG REGIMEN

Dear Respondent,

I am a post graduate student of Public Health in University of Ibadan running a research project on factors affecting adherence to HIV medication regimen. Be assured that every information on this subject will be used to research purpose and the confidentiality of informant will be maintained. Please kindly tick most appropriate answer to the questions below:

Thanks for your co-operation.

#### 1. SOCIO-DEMOGRAPHIC DATA

1. Age (last birth day): \_\_\_\_\_
2. Sex: (1) Male ☐ (2) Female ☐
3. Level of education  
(1) Primary ☐ (2) Secondary ☐ (3) Tertiary ☐  
(4) Never went to school (5) Others specify \_\_\_\_\_
4. Current occupation: \_\_\_\_\_
5. What religion do you practice?  
(1) Christianity ☐ (2) Moslem ☐ (3) Traditional religion ☐
6. What is your current marital status?  
(1) Single ☐ (2) Married ☐ (3) Separated ☐ (4) Widowed ☐
7. Did you inform any member of your family or friend that you are HIV positive?  
(1) Yes ☐ (2) No ☐
8. Family type: (1) Monogamous ☐ (2) Polygamous ☐
9. How many children do you have? (please specify) \_\_\_\_\_

#### 2. MEDICAL DATA

10. How long have you been on ARV treatment? Months \_\_\_\_\_

11. How did you know about the ARV treatment programme?

(1) Doctor ☐ (2) Friend/relative ☐ (3) Support group ☐

(4) Radio ☐ (5) Counseling in hospital ☐

(6) Others specify \_\_\_\_\_

12. Have you ever experienced any side effect with the ARV drugs?

(1) Yes ☐ (2) No ☐

(If not go to Q15)

13. If yes to Q12, describe the type of side effect you experienced:

	Side Effects	Yes	No
1	Vomiting		
2	Diarrhea		
3	Rashes		
4	Dizziness		
5	Abdominal Pain		

14. Did the side effect stop you from taking your ARV drugs?

(1) Yes ☐ (2) No ☐ ☐

15. When you started taking the ARV drugs what was the effect on your CD4 count?

(1) Increased ☐ (2) Decreased ☐ (3) Stable ☐

16. How has your health been since you started taking the ARV drugs?

(1) Improved very well ☐ (2) Improved a bit ☐

(3) Worse than before ☐ (4) No change ☐

### 3. ADHERENCE TO ANTI-RETROVIRAL DRUGS

17. Did you receive counseling before receiving the ARV drugs?

(1) Yes ☐ (2) No ☐

18. How many tablets do you take a day?

19. Does the number of drugs taken disturb you?

(1) Yes ☐ (2) No ☐

20. How are you taking the drugs

(1) As prescribed ☐ (2) When I feel like ☐ (3) Sometimes I forget ☐

21. Do you ever fail to take your ARV drugs?

(1) Yes ☐ (2) No ☐

22. In the past week have you ever forgotten to take your ARV drugs?

(1) Yes ☐ (2) No ☐

23. How many tablets have you missed in the last 7 days. Tick (✓) for drug taken, tick "O" for missed drug below: Please be honest this is purely for research and will help PLWHA.

7 Days Adherence Table

DRUG	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
G	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Wednesday

24. Are you willing to continue treatment as long as it takes?

(1) Yes ☐ (2) No ☐

25. What are some of the problems encountered in taking your ARV drugs?

a) \_\_\_\_\_

b) \_\_\_\_\_

c) \_\_\_\_\_

26. Have you at anytime been reminded to take your ARV medication by any of the under listed.

(1) Self ☐ (2) Friend ☐ (3) Family Member ☐

(4) Alarm ☐ (5) Drive to live ☐ (6) Pill Box ☐



(7) Pill Chart ☐ (8) Nothing ☐

27. Have you been discouraged from taking drugs due to any of the under listed?

(1) Tiredness ☐ (2) Sickness Not Curable ☐

(3) Cost of ARV in the past ☐

(4) Lack of money ☐ (5) Frustration ☐ (6) Depression ☐

(7) Stigma ☐ (8) Nothing ☐

28. Have you at anytime missed taking your ARV drugs because of any of the following?

(1) Travelling ☐ (2) Anger ☐ (3) Forgetfulness ☐

(4) Lack of Food ☐ (5) Government Strike ☐ (6) Nothing ☐

#### 4. ECONOMIC/SOCIAL SUPPORT AND HEALTH CARE SERVICES

29. What are some problems that prevent you from attending ARV clinic to refill your monthly ARV drugs?

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30. From whom have you received any financial assistance since you started taking ARV drugs?

(1) Your family ☐ (2) Friend/HIV ☐ (3) HIV Support group ☐

(4) Others ☐ (5) Health workers ☐ (6) Nobody ☐

31. Apart from certified Health Centers do you know of alternative ways of getting ARV drugs.

(1) Yes ☐ (2) No ☐

32. Have you received your ARV medication from any of these alternative channels?

(1) Yes ☐ (2) No ☐

33. What other problems do you encounter at the health centre when you come to collect your ARV drugs? Specify.

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