FACTORS ASSOCIATED WITH ADHERENCE TO ANTI-RETROVIRAL DRUGS AMONG PATIENTS ACCESSING CARE AT NIGERIA INSTITUTE OF MEDICAL RESEARCH LAGOS, NIGERIA

BY

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ATTESTATION

I hereby declare that the work in the thesis entitled "Factors associated with poor adherence to anti-retroviral drugs among patients accessing care at Nigeria Institute of Medical Research, Lagos, Nigeria" has been carried out by me in the Department of Community Medicine under the supervision of Dr. A.U. Shehu

The information derived from the literature has been duly acknowledged in the text and a list of references provided. No part of this thesis was previously presented for another degree or diploma at this or any other Institution.

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CERTIFICATION

The thesis entitled "Factors associated with poor adherence to anti-retroviral drugs among patients accessing care at Nigeria Institute of Medical Research Lagos, Nigeria" by Ganiyu Jamiyu meets the regulations governing the award of the degree of Master of Public Health (Field Epidemiology) of the Ahmadu Bello University, Zaria and is approved for its contribution to knowledge and literary presentation.

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DEDICATION

To all people living and affected with HIV/AIDS who have fought stigma and discrimination but still kept hope alive of getting cure for the dreaded disease and for the stakeholders who have committed numerous resources and work tirelessly to see that those infected have access to quality treatment, care and support for HIV/AIDS.

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SUMMARY

HIV has remained a major public health problem despite huge financial resources expended by stakeholders at finding cure and mitigating the impact of the disease. With the global estimate of 34 million people living with the virus and 2.5 million new infections, Nigeria ranks second among HIV/AIDS burdened countries with a prevalence of 4.1% and estimated 3.2 million people living with the disease. In spite free HIV treatment in Nigeria, poor adherence to Antiretroviral Therapy has continued to pose a greater challenge to achieving remarkable clinical and immunological outcomes due to ARV drug resistance. This study identified factors associated with poor adherence to antiretroviral drugs among patients accessing care at Nigeria Institute of Medical Research, Lagos, Nigeria.

A cross-sectional study was conducted from January 1st to March 31st, 2014 on HIV-infected aged ≥ 15 years being on treatment with antiretroviral drugs three months prior to commencement of study. Data were collected using semi-structured questionnaires to obtain information on patients' adherence level, knowledge on ART, socio-demographics and provider-patient related factors. Data were subsequently entered and analyzed in Epi Info version 3.5.1 for descriptive statistics and to calculate odds ratios and adjusted odds ratios to identify the relative effect of explanatory variables on the dependent variable. A qualitative study was also carried out to further explore factors associated with poor adherence.

Of the 426 patients interviewed, 285 (66.9%) were female; mean age 39.3(±SD) of 8.9 years and out of 112 (26.3%) who had poor adherence, 70 (62.5%) were females and 40 (37.5%) were males. Poor adherence were associated with not receiving adherence counselling (OR 5.1; CI 95%: 2.1 – 13.5) unsatisfactory attitude of health workers (OR 4.8; CI 95%: 1.8 – 12.7), undergoing adherence counselling sessions of less than three times (OR 2.1; CI 95%: 1.2 – 3.9), and receiving counselling from non-health workers (OR 11.1; CI 95%: 1.2 – 100.2). Major reasons for poor adherence were forgetfulness (47.7%), and frequent travelling (9.2%). FGD revealed poor attitude of the health workers

and stigma and discrimination as barriers to adherence to treatment. Multivariate analysis revealed unsatisfactory attitude of health workers (AOR 4.8, p-value 0.01), undergoing adherence counselling sessions of less than three times (AOR 2.1, p-value 0.01) and receiving adherence counselling from non-health workers (AOR 10.9, p-value 0.03) as independent factors associated with poor adherence to ART.

The study revealed receiving adherence counselling, attitude of health workers, number of counselling sessions received and whether counselling was given by health worker as the major determinants of adherence to anti-retroviral treatment. On-the-job training for Health workers on attitudinal change and improving adherence by providing regular follow-up, increasing patients' awareness of the ART treatment, including its benefits and side-effects, eliminating problems of access and alleviating the impact of cost by making all drugs available was included in the routine supportive supervision.

Key words: Adherence factors, Adherence level, counselling, Human Immunodefiency Virus.

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LIST OF ACRONYMS

AC	-	Adherence Counselling
AFENET	-	Africa Field Epidemiology Network
AIDS	-	Acquired Immune Deficiency Syndrome
APIN	-	AIDS Prevention Initiative in Nigeria
ART	-	Antiretroviral Therapy
ARV	-	Antiretroviral drugs
CBO	-	Community Based Organization
CDC	-	Centers for Disease Control and Prevention
DOTS	-	Directly Observed Therapy Short course
FBO	-	Faith-Based Organization
FMOH	-	Federal Ministry of Health
GH	-	General Hospital
GON	-	Government of Nigeria
HAART	-	Highly Active Antiretroviral Therapy
HAD	-	HIV/AIDS Division
HCT	-	HIV Counselling and Testing
HIV	-	Human Immunodeficiency Virus
IHVN	-	Institute of Human Virology of Nigeria
LGA	-	Local Government Area
LASUTH	-	Lagos State University Teaching Hospital
LSACA	-	Lagos State Agency for Control of AIDS
LSMOH	-	Lagos State Ministry of Health

LUTH	-	Lagos University Teaching Hospital
MDGs	-	Millennium Development Goals
M & E	-	Monitoring and Evaluation
NACA	-	National Agency for the Control of AIDS
NASCP	-	National AIDS/STI Control Program
NEPHWAN	-	Network of People Living with HIV/AIDS in Nigeria
NFELTP	-	Nigeria Field Epidemiology and Laboratory Training Program
NGO	-	Non-governmental Organization
NIMR	-	Nigeria Institute of Medical Research
OIs	-	Opportunistic Infections
PCR	-	Polymerase Chain Reaction
PEPFAR	-	President Emergency Plan for AIDS Relief
PHC	-	Primary Health Care
PI	-	Principal Investigator
PLHIV	-	People Living With HIV
PMTCT	-	Prevention of Mother-to-Child Transmission
STIs	-	Sexually Transmitted Infections
TB	-	Tuberculosis
USAID	-	United States Agency for International Development
UN	-	United Nations
WHO	-	World Health Organization
EDM	-	Electronic Drug Monitoring
UDVL	-	Undetectable Viral Load

CHAPTER ONE

INTRODUCTION

1.1 Background

Joint United Nation Program for HIV/AIDS estimated that between 31.4 million and 35.9 million people are currently living with HIV/AID worldwide of which 4.8 million are in Asia (China;78 0,000, Thailand; 490,000 and Indonesia; 380,000), 490,000 in Latin America (Brazil; 490,000), 2.3 million in North America, Western and Central Europe, 1.3 million in USA, 53,000 in Oceania, 230,000 in Caribbean, 300,000 in Middle East and North Africa and 23.5 million in Sub-Sahara Africa (Tanzania; 1.6 million, South Africa; 5.6 million, Uganda; 1.4 million, Zambia; 970,000, Zimbabwe; 1.2 million, Kenya; 1.6 million, Ethiopia; 790,000 and Nigeria; 3.1 million). The number of AIDS-related death was reported to be 1.7 million and 2.5 million were due to new infections. Out of 14.8 million persons eligible for HIV treatment, only approximately 54% are on ARV treatment.[1]

In the last ten years (2001-2011) the landscape of national HIV epidemics has changed dramatically, for the better in most countries, especially in sub-Saharan Africa where 69% of HIV/AIDS cases live. Countries are making historic gains towards ending the AIDS epidemic: 700 000 fewer new HIV infections across the world in 2011 than in 2001.[1] Nigeria with estimated population of 173, 611, 131 and growth rate of 3.2% [2,3] has a current HIV prevalence of 4.1% with about 3.2 million infected with the virus and estimated 1.6 million eligible for Anti-retroviral drugs.[4] With estimated 34% of the general population accessing basic health care, the epidemic is more ravaging in the rural

areas, which compounds the issue of accessibility to comprehensive HIV/AIDS services located in the urban settings.[4]

Federal Government, as part of its care and support strategies initiated the National Antiretroviral Drug Access Programme in 2002 in 25 tertiary sites across the country, and was subsequently scaled up to more sites in succeeding years with support from Presidential Emergency Plan for AIDS Relief (PEPFAR), United States agency for International Development (USAID), Global Fund Round 5, 8 & 9, World Bank, UN Agencies and fund from Millennium Development Goals (MDGs). Implementation of the programme was facilitated and guided by a committee set up by the Federal Government of Nigeria.[5]

The predominant model for HIV/AIDS Care and support is a 'hub and spoke' model which encourages seamless networking between different levels of Health facilities and non-medical resources.[4,5] The tertiary health centres which serve as 'hubs' provide specialized clinical care, mentoring and technical oversights to the secondary health centres which are considered as 'spokes'. In line with the model, the spokes are expected to receive referrals from feeder sites that constitute the Primary Health Care (PHC) centres. However, with the renewed efforts and commitment by Federal Ministry of Health and its stakeholders to avail and increase access to HIV/AIDS services to the patients in rural communities, and to decongest the overburdened tertiary health facilities, the Ministry adopted the concept of decentralization of ART services to the PHCs, where some facilities now offer pick-up of ARV drugs by PLHIV and others initiate ART for

naïve patients.

Adherence monitoring among large number of HIV/AIDS patients in most ART centres in Nigeria is a major concern to achieving ART programme success. There is limited manpower to deal with adherence challenge at individual patient level. Previous studies revealed that adherence among PLHIV in Nigeria and other Africa countries ranges from 55-85%,(6) which is below the expected of greater or equal to 95%. Poor adherence (< 95%) is found to be an issue among patients on ART irrespective of sex, age, socio-economic status and the health facility.[7]

Poor adherence (< 95%) leads to rise in viral load and reduction in CD4 count leading to increase in morbidity and mortality among patients on ART with ultimate poor clinical outcomes and failure in the entire national ART programme.[7] In addition, poor adherence to ART results in low survival, clinical, immunological and virological response for patients. Adherence to ART is one of the very important factors which determine treatment success and occurrence of viral resistance.[8] The need for near perfect adherence to lifelong antiretroviral therapy (ART) during treatment is a major challenge in the administration of highly active anti-retroviral therapy (HAART) to HIV infected patients. Appropriate use of antiretroviral therapy (ART) has improved the health of many human immunodeficiency virus (HIV) positive individuals who otherwise may have died. Notably, the efficacy of any treatment depends on sustained high levels of adherence to ART.[8,9]

Previous research findings identified factors such as high pill-burden, high cost of

transport fares, feeling too sick after taking ART, medical side-effects, changing work schedules, stigma and discrimination, too busy, health care attitude and poor education as some of the factors associated with poor adherence to ARV drugs among patients.[9,10] Adherence is dependent on medication adverse effects and level of education of patients. Financial constraints, medication side effects, confidentiality, occupational factors and stigmatization were the major reasons accounting for non-adherence.[11] It is further challenged by various social and clinical obstacles where inadequate suppression of viral replication by ART are resulting due to poor adherence to therapy, low potency of the antiretroviral regimens, viral resistance to antiretroviral medications, and pharmacokinetic interactions causing inadequate drug delivery.[12,13] The transmissibility of the antiretroviral resistant viruses from person to person further compounds the problem as a clinical and public health challenge.[14,15]

Numerous interventions have been put in place by government and relevant stakeholders to address some of these challenges, and these include free ART services, decentralization of services, recruitment and training of more health workers and development of workplace policies against stigma and discrimination, and development and periodic review of the National HIV Treatment Protocol for healthcare providers in the country aimed at ensuring standard and uniformity of practices in the management of HIV/AIDS patients in health facilities towards better clinical and non-clinical outcomes.[4,5]

Despite these efforts, especially the free ART services, resistance to first-line ART has continued to increase from initial 0.0% in 2002 to 4.0% in 2012. However, resistance to ARV drugs still occurs in those who achieved ≥95% adherence. The reported rates of

drug resistance among patients who received ARV therapy in Sub-Saharan Africa have shown large variation between 3.7%–49% after 24–163 weeks of ART.[16] Many contributing factors may explain the differences among countries and among African cohorts. Apart from factors associated with adherence, poor health care systems, practices of prescribing ARV therapy, access to biological monitoring, as well as the high level of HIV polymorphism that characterizes the virus circulating throughout sub-Saharan Africa.[16]

The implementation of free ART services coupled with scale-up of services to other health facilities, which indirectly were influenced by factors identified by previous studies, have not really address poor adherence issues. Therefore there is need for more studies to aim at identifying other factors that may seem likely to be contributing to poor adherence to ART as carried out by previous researchers.[17,18] The need for further will help to explore additional factors contributing to poor adherence which were not identified in previous studies. This study is aimed at determining the proportion of HIV/AIDS patients that have poor adherence to ART, assess level of knowledge about ART among HIV/AIDS patients and to identify factors that influence adherence to ART among study population.

1.2 Problem Statement

Nigeria still remained second highest burdened country with HIV pandemic in the world with like hood of becoming the leading country with the disease burden if over 3.2 million people living with HIV are not adequately treated and properly monitored, as more non infected persons might get infected even by those living with the virus on

treatment but adhere poorly to ART. This scenario is not different from current situation in HIV clinic of Nigeria Institute of Medical Research Yaba, Lagos where more than 10,500 of over 22,000 patients are accessing ARV treatment and care. Without strict anti-retroviral treatment adherence monitoring, some of those patients on ART might develop treatment failure and with increasing viral load will continue to transmit the virus to their sexual partners or spouses. This might automatically increase the existence high burden of HIV/AIDS. This might also add to the growing cases of TB-HIV co-infections and other opportunistic infections.

Additionally, with poor adherence, some might develop and transmit resistance strains to their spouses and or sexual partners who have been responding well on ART with resultant treatment failure. Apart from poor adherence being an important factor in drug resistance and treatment failure, it is also a powerful predictor of survival. Therefore, with report of over 2.5 million cumulative and annual deaths of over 200,000 in Nigeria, failure to strictly monitor patients' adherence might compromise patients' survival leading to more deaths from the disease.

There is no data on level of adherence and the detail factors associated with poor adherence in NIMR, Lagos. Therefore, interventions applied to address adherence issues are often non specific as they are not backed by previous research findings at the facility making adherence challenge a recurrent issues to tackle among patients.

1.3 Justification

The justification for this study is key to addressing growing concern that despite the huge

amount of resources expended to mitigate the impact of the disease as there is no known cure, the burden of the disease which apart from its continuous rise, those on treatment for HIV have continued to infect others partly due to inadequate knowledge about adherence counseling. The development of drug resistance, treatment failure and deaths also appear to be on the increase among those on treatment due poor adherence. The effect of poor adherence among patients is evidenced by rising numbers of patients on second and third lines ARV regimen at NIMR and the country at large. This study will determine the proportion of those who adhere poorly and factors associated with poor adherence to ART towards formulating evidence based policy and guidelines that will address adherence challenges.

Being one of the earliest studies in the HIV clinic, it will provide baseline and guide for other studies including conduct of similar studies nationwide and offer basis for effective and evidence-based interventions that will promote well-being, reduction in morbidity and mortality from drug resistance and treatment failure due to poor adherence in NIMR, Lagos, which can be extended to other HIV clinics. These interventions will include developing targeted and holistic adherence counseling strategies that will resolve major adherence challenges including routine supportive supervision if not in place.

In line with above, there is need to assess knowledge, socio-demographic and provider related factors that are associated with poor adherence that will provide guide for specific interventions that will address specific adherence issues among numerous determinants of adherence.

1.4 Research Questions

- What proportion of patients have poor adherence to ART at NIMR, Lagos
- Does level of knowledge about ART among HIV/AIDS patients influence adherence to ART at NIMR, Lagos
- What socio-demographic factors influence adherence to ART among HIV/AIDS patients at NIMR, Lagos
- What patient-provider related factors influence adherence to ART among HIV/AIDS patients at NIMR, Lagos

1.5 Objectives of the Study

1.5.1 General objective

To identify factors contributing to poor adherence among patients accessing ART service at Nigeria Institute of Medical Research (NIMR), Lagos State.

1.5.2 Specific objectives

- To determine the proportion of HIV/AIDS patients that have poor adherence to ART.
- To assess level of knowledge about ART among HIV/AIDS patients.
- To identify socio-demographic factors that influence adherence to ART among HIV/AIDS patients.
- To identify patient-provider related factors that influence adherence to ART among HIV/AIDS patients.

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CHAPTER TWO

LITERATURE REVIEW

Review of the literature on adherence to Anti-retroviral drugs (ART) indicated that some studies have been conducted in some facilities within and outside Nigeria. This chapter presents the review of the literature on the research topic.

The terms "adherence" and "compliance" are often used interchangeably. "Compliance" had traditionally been used to describe a patient's ability to take medications as prescribed, but recently this term has fallen into disfavour. Some have suggested that compliance connotes a paternalistic relationship between the physician and patient and that the noncompliant patient performs deviant behaviour or exhibits weakness of character. Adherence is defined as taking medications or interventions correctly according to prescription "Adherence" better represents the more complex web among patient, provider, and medication and reflects the fact that following a medication regimen is not necessarily a simple choice.[19,20]

Regardless of which term one uses, adherence involves several complexly related factors, including difficult medical regimens, medication toxicity, and perception of the regimen's value. Understanding these forces can facilitate clinical recognition of non-adherence and implementation of strategies to improve adherence. Non-adherence to medication regimens has been appreciated since antiquity. Hippocrates warned that physicians "should keep aware of the fact that patients often lie when they state that they have taken certain medicines." The importance of adherence has been demonstrated in various disease states. For example, poor adherence to tuberculosis therapy has been associated

with clinical failure and the emergence of drug resistance. In fact, one of the major successes in treating tuberculosis in the United States involves a critical improvement in patient adherence: directly observed therapy (DOT).[21,22]

One problem in studying adherence is the lack of a standard measurement. However, the key to improving clinical and virologic outcomes when treating HIV infection will be the development of practical methods to increase adherence to antiretroviral regimens. An important step toward developing effective interventions that improve adherence to HAART will be based partly on our understanding of the forces behind non-adherence to complex antiretroviral regimens. Patients' self-reports of how often they take their medication are frequently used to measure adherence. However, like many subjective adherence measurements, self reports have significant limitations. Studies of the validity of patients' self-reported adherence in various disease states suggest that patients may say whatever they think their physician wants to hear. Self-reported adherence significantly exceeds adherence measured by more objective means, such as pill counts or electronic monitoring. Therefore, when a physician assesses adherence in the clinic, a patient's admission of poor adherence is a specific, but insensitive, marker of non-adherence.[23,24] Interestingly, despite the shortcomings of self-reports of adherence in individuals, several studies have demonstrated their association with viral outcome. This finding suggests self-reports may yield valuable information in measuring adherence at the group level but that on an individual level, self-reports have major limitations. Some researchers have suggested that diaries may be an inexpensive way to increase the accuracy of information about adherence. However, data suggest that most patients do not complete diaries and

that when they do, they may fill in the information immediately before a clinic visit.[19,24]

Pill count is another way to measure adherence. The advantage of pill counts is that they are potentially affected less than other methods by subjective patient responses. Adherence assessed by pill counts correlates better with adherence measured from electronic bottle caps than dose self-reported adherence. In a study by Miller et al. 2000, the mean amounts of prescribed medication taken by 81 patients were 96% for self-report, 85% for pill count, and 73% for electronic bottle caps. This result suggests that pill counts may be a more accurate method of assessing adherence to HAART than are self-reports. However, pill counts have limitations as many patients forget to bring their pill bottles to the clinic when instructed. Whether forgetting to bring pill bottles to scheduled visits is associated with non-adherence is unclear. Furthermore, performing pill counts is time-consuming. In addition, patients' responses to having their pills counted by clinicians in a non-research setting are unknown. We suspect that in a clinical setting, many patients may find pill counts unacceptably intrusive or paternalistic, and this may harm the physician-patient relationship.[25,26]

Bottles fitted with caps harbouring electronic chips that register each time a pill bottle is opened or closed constitute the most sophisticated method currently available for measuring adherence. These devices are extremely useful in the research setting. Researchers can periodically download information from such caps and so identify the precise time a patient opened a pill bottle. Two systems are currently available: MEMS (Medication Event Monitoring System, APREX Corporation, Union City, Calif) and the eDEM Monitor (AARDEX Corporation, Palo Alto, Calif). Electronic monitoring makes it

more difficult for patients to "game the system" and appear more adherent than they really are, although a patient could open the bottle and not swallow the pill.[19,25,26]

However, it has been found that a number of HIV-infected patients, unlike patients taking other complex regimens, use pillboxes to assist with their adherence. This habit precludes the use of electronic devices as an adherence measurement and excluding patients who use pillboxes from clinical trials of adherence may compromise the study's external validity by ignoring this important subpopulation. In addition to this limitation, the expense of these devices limits their clinical utility.[19,25]

Several research studies have tried to exploit the biologic changes induced by antiretroviral medication to measure adherence. For example, zidovudine and stavudine raise the mean corpuscular volume, didanosine alters urinary uric acid levels, and indinavir raises bilirubin levels. While these data provide objective measurements and have been used as markers of adherence, such changes are only marginally sensitive and specific markers of medication adherence and give no information about individual patterns of missed doses. In addition, results may be confounded by pharmacokinetic factors, such as poor drug absorption or drug-drug interactions, which may mimic poor adherence.[19,20]

Drug levels of antiretroviral medications have been used to gauge adherence in the research setting, but they reflect only recent adherence (ie, within 24 hours). Other limitations include patients "gaming the system" by taking medications only immediately before scheduled blood draws and the lack of commercial availability of the needed

assays. Some clinical studies have used provider estimates of adherence, and several studies have even confirmed that such estimates independently predict virologic response to HAART. However, other investigations have found that clinicians managing HIV-positive patients are frequently inaccurate in assessing adherence to HAART, and studies in other disease states demonstrate similar results. Therefore, a clinician's subjective assessment of adherence may be as problematic as a patient's.[19]

Studies of protease inhibitor monotherapy demonstrated that drug-resistant virus was most likely to emerge in patients with suboptimal adherence, and this relationship almost certainly holds true for combination therapy as well. Several studies have demonstrated that lapses in antiretroviral adherence lower the likelihood of suppressing viremias below detectable levels with resultant decrease in CD4 count and poor clinical outcomes. Other studies have found similar relationships between missed doses and viral load. Among persons with a viral load below 400 copies/mL, MEMS-measured adherence varied considerably, from 33% to 100%.This broad range suggests that while an undetectable viral load may be a clinically satisfying response to HAART for both patient and provider, it is not invariably a marker of adequate adherence. A significant proportion of these patients may require interventions to improve adherence and increase the likelihood of maintaining durable suppression of viral replication. Alternatively, inability to suppress detectable viral replication may occur because of pre-treatment resistance, poor drug absorption, drug-drug interactions, or other factors.[19,20,22,24,25,26,27]

2.1 Conceptual Framework

Figure 2.1 shows the network of linkages on how likely factors can lead to poor

adherence. These factors are categorized into socio-demographic which include socio-economic, socio-cultural and patients' variables such as age, sex, marital status, level of education and employment status and types. There are also patient related factors such as knowledge about ART, pill burden, forgetfulness, alcohol, side effects, depression, feeling well due to absent of symptoms and feeling sick due to emergence of new symptoms. The provider related factors include being judgemental, unfriendly attitude, lack of privacy and confidentiality, long waiting time, communication quality and clarity, poor patient-provider relationship which often lead to lack of trust and confidence by the patients. All these factors directly and indirectly lead to poor adherence.

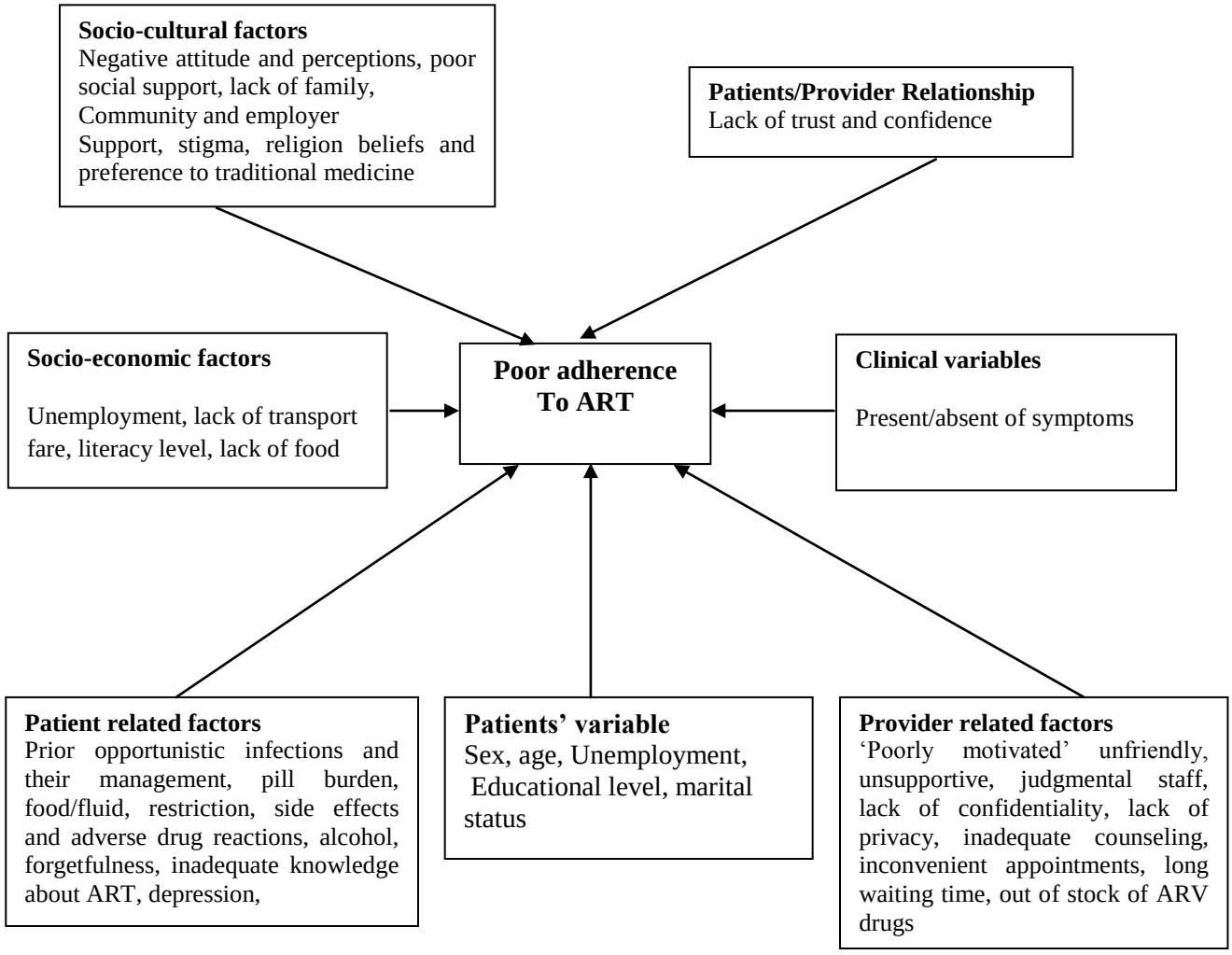


Figure 2.1: Problem analysis diagram of possible factors contributing to poor adherence to ART[28]

2.2 Proportion of HIV Patients with Poor Adherence

Proportion is the quotient of two numbers of which numerator necessarily included in the denominator and quantities have to be of the same nature.

A review by Vreeman et al. 2008 and colleagues indicated that the majority of the studies in developing countries report adherence levels of more than 75% (range 45–100%),[28] while in developed countries the majority report less than 75% (range 20–100%).[29] Another systematic review by Mills et al. 2006 and colleagues obtained a pooled estimate of adequate adherence by Sub-Saharan Africa patients of 77% (95% confidence interval, 68–85%; based on a total of 12,116 patients), whereas the figure for North American patients was 55% (95% confidence interval 49–62%; based on a total of 17,573 patients).[30] The same study revealed that poor adherence is a major concern globally despite being better in Sub-Sahara Africa.

A peer review in 2011 by Carlos et al. on ART adherence in persons with HIV/AIDS in Cuba found self reported poor adherence to be 29.4% (847) while 70.6% reported good adherence.[31] In a cross-sectional study using both audio computer-assisted self-interview (ACASI) and visual analogue scale (VAS) methods in Viet Nam, Hoa and colleagues in 2013 found 24.9% (n=615) of respondents to have had poor adherence while 75.1% (n=615) had good adherence.[32] Bijal et al. conducted a study in Mumbai India in 2007 and found 73% out of 279 respondents to have good adherence.[33] Wasti et al., 2012 in Nepal reported 85.5% adherence level among study respondents.[34]

A meta-analysis conducted by Okafor et al., 2013 in Lagos reported mean adherence level

of 84.3% in Sub-Sahara African countries.[35] A 2010 interview-based descriptive and analytical study in a health centre carried out by Bha et al. and colleagues in South Africa among 168 patients who received ARV drugs showed that 37.5% of the patient had poor adherence.[36] A study on factors associated with poor adherence to ART in Ethiopia by Alagwa in 2013 showed that 12.6% (n=357) had poor adherence by self-report on one week recall and 7.0% (n=357) poor adherence by pharmacy refill recall in a week after ARV prescription.[37] While in a study by Mitiku et al., 2013 in Eastern Ethiopia reported adherence level of 87% among 239 study participants in the week before the interview,[38] Wakibi et al. in Nairobi Kenya in 2011 reported adherence level of 82% among 416 study participants over 18 years.[39] Peltzer et al., 2010 in Kwazulu-natal used visual analog scale (VAS) to measure adherence and found good proportion of patients with adherence level of 82%.[40]

A study conducted in Specialist Hospital Sokoto, Nigeria using Simple Random Sampling technique to select participants from a total of 1,300 eligible patients by Agu et al. 2013 found 52.2% (n=365) to achieved 100% level of adherence, 4.4% (n=365) had 90-99% adherence level while the remaining 43.4% had < 90% adherence level.[41] A study conducted at Zaria in 2010 by Olisah et al revealed that 73% of participants had good adherence to HAART and 63.6% of participants with depressive disorder had poor adherence to ART compared to 21.1% of participants without depressive disorder ($p<0.05$).[42] A study by Pennap et al. 2013 at STI clinic of Federal Medical Centre Keffi, Nasarawa State found that the level of poor adherence was 37.2% (n=250) as compared to 62.8% for good adherence, of which 31.2% had not missed taking their ARV drugs after

seven days of given prescribed drugs.[17] While Falang et al. in 2012 in Jos reported adherence level of 87.9% among 461 study participants.[18] Another study conducted by Bello et al. 2011 at Sobi Specialist Hospital, Ilorin, Kwara state found that 29.2% (n=257) had poor adherence to ART six months prior to the study. This study was carried out among HIV patients' age group 16 to 60 years who enrolled for ART from May 2009 to December 2010.[43] A study on factors influencing adherence to ART medication in Ilorin, Kwara State by Salami et al. 2010 found that proportion of poor adherence among adult patients over 30 days of prescription of ART was 28.1 % (n=253) as against 70.8% for good adherence.[44] A similar study among depressed HIV patients in Ilorin in 2013 by Shittu et al. found proportion of respondents with good adherence to be 81%.[45] A study of adherence to ART among pregnant women on PMTCT service by Ezeudo et al. at Owerri in 2014 revealed 79% of mothers took HAART/ARD prophylaxis during pregnancy, delivery and breastfeeding of their infants while 21% of them did not.[46] Onyeonoro et al conducted a study at Umuhia in 2013 and found mean adherence level among study population to be 97.9%.[47]

In a randomized control trail among non-adherent patient in Port-Harcourt by Maduka et al., 2013 at post‑intervention, 76.9% of the intervention group and 55.8% of the control group achieved adherence ($\chi 2$ = 5.211, P = 0.022, RR = 0.75 (0.55-0.96), Cohen's w = 0.224). Also, median CD4+ cell count of the intervention group increased from 193 cells/ml to 575.0 cells/ml against 131.0 cells/ml to 361.5 cells/ml in the control group (P = 0.007).[48] In a cross-sectional analytic study conducted by Oku et al. 2013 at the Specialist treatment clinic of the University of Calabar Teaching Hospital among 411

HIV positive patients of at least 18 years of age and had been on ART for 3 months found that proportion of patients with poor adherence were 39.1% while more than half (59.9) of respondents' attained 95% adherence (good) to prescribed ART regimen. A little over two-thirds of the respondents 282 (68.6%) were on at least 2 pills per day.[14] In a similar study conducted by Kayode et al in 2012 at UCH, self reported adherence among respondents indicated that 230 (75.4%) complied with the prescribed ARV medications irrespective of the drug side effects while 75 (24.6%) did not comply with their medications once side effects of the drugs began to manifest.[49] While Olowooke et al., 2012 in Ile-Ife in South-western Nigeria reported good adherence level of 77.7% among study respondents,[50] Ogundahunsi et al. from Sagamu in 2008 reported adherence level of 79.2% among study participants.[51] In a study conducted in Lagos in 2011 by Ekama et al. and colleagues among 170 pregnant women on ARV drugs using a three day recall found that 137 (80.6%) achieved good adherence level of ≥95% while 33 (19.4%) had poor adherence, and the desire to protect the unborn child was the greatest motivation (51.8%) for good adherence. Fear of being identified as HIV positive (63.6%) was the most common reason for poor adherence. However, the study was limited to women attending PMTCT service at the HIV clinic.[52] A study conducted at Island General Hospital Lagos among 200 respondents in 2012 by Sekoni et al found that 89.4% had good adherence while 10.6% had poor adherence based on 7 days recall[53] while Kasumu et al who conducted adherence study at University of Lagos Teaching hospital in 2014 revealed that self-reported adherence level was 78.4% (good adherence) and older age was significantly associated with good adherence ($p<0.05$). A third of the respondents who

missed doses did so because they were away from home.[54]

2.3 Knowledge about ART among HIV/AIDS Patients

Another study by Wasti et al. 2012 from Nepal reported that lack of knowledge and negative perception towards ART medications also significantly affected poor adherence.[34] Another study by Nachega et al. 2005 in South Africa showed that of 105 HIV clinic patients evaluated, 89% had good knowledge about the cause of HIV infection and 83% knew about modes of transmission, 59%t reported they were not worried about ART side effects and 49% believed that ART can cure HIV, a belief that was associated with a low level of education ($p<0.001$).[55] A study by Boateng et al. in 2013 among women in the reproductive age group (18-49years) in the Ashanti region of Ghana found clients had good knowledge about ART. More than 90% (n=229) of the HIV positive women had inadequate knowledge about ART and these women were more likely to default ART (OR = 3.5; 95% CI = 1.89, 6.21).[56]

Another study by Agu in 2012 showed that 65.8% (n=2329) knew that all medicines cause some kind of adverse effects; 55.1% knew the adverse effects of their medicines; 60.8% knew what to do when they suspect adverse drug reactions (ADRs) and it included mainly reporting to the healthcare provider by 88.1% of respondents. However, only 31.9% had experienced ADRs previously. The knowledge of ADRs was associated with gender, educational and employment status of the patients.[57] A study in Jos by Falang et al. 2012 reported good knowledge to HIV infection of 96.1% (n=461) and drug therapy 87.4% (n=461) among participants, and good knowledge of ARVs (OR 1.23) was

associated with good adherence.[18]

A study conducted in a tertiary health facility in South Eastern Nigeria by Onyeonoro and colleagues in 2013 found that most of the respondents have good knowledge of ART and adherence, 64.2% (n=282) thought that ART cures HIV/AIDS, about half of them (50.7%) were of the opinion that ART reduces the risk of HIV transmission. However, the general perception of adherence was good.[47] A study in 2012 by Olowookere at al. titled 'Knowledge and attitudes regarding HIV/AIDS and antiretroviral therapy among patients at a treatment clinic' at Obafemi Awolowo University Ile-Ife, Nigeria revealed that 76% (n=318) of the respondents reported knowing that ART suppresses HIV activity. Most (77.7%) respondents had good knowledge of HIV/AIDS while 75.2% had good knowledge of ART. Respondents with good knowledge about HIV/AIDS and a positive attitude about the disease tended to be more adherent to ART ($p<0.01$).[58] In a study conducted at LUTH in 2014 by Kasumu et al. showed that 83.1% of respondents had good knowledge about ART with the more educated having significantly better knowledge ($p<0.05$), 98.1% had positive attitude towards ART and most of them had positive perception about their healthcare providers across most of the areas asked.[54] In a study conducted in Lagos in 2011 by Ekama et al. found good knowledge of ART was found to be significantly associated with good adherence.[52]

2.4 Socio-Demographic Factors that Influence Adherence to ART

A Another study by Wasti et al. 2012 from Nepal reported major social-demographic factors influencing adherence to be being female (OR = 6.91 p = 0.001), illiterate (OR = 4.58, p = 0.015), travel time to hospital >1 hour travel time to hospital >1 hour (OR =

2.84, p = 0.035) and transport costs (for repeat prescription).[34]

Bha et al. also revealed that amongst men, poor adherence was seen in those who were single (48.9%), with tertiary education (60%) and in those who were unemployed (56.1%) in women was associated with being single (36.5%).[36] A 2012 peer review in Ethiopia by Reda et al. reported common socio-demographic reasons for missed doses which include financial trouble that prevent patients from collecting medication on time due to distance barrier or lack of transportation facilities to the ART clinic, vomiting of medication without re-dosing, missed clinic appointments and pharmacy collections, confusion between multiple health care providers, and self-discontinuation. Furthermore, patients' beliefs that medications need to be taken with food leads them to avoid taking medications whenever food is unavailable thereby interfering with adherence. Sometimes patients are forced to choose between paying for transportation to the ART facility and using the money for food. Studies in Uganda and Tanzania reported that transportation costs are considered serious obstacles to taking ART. This has implications not only for day-to-day adherence but also losses to follow up. Determinants of ART adherence for HIV-infected persons in sub-Saharan Africa were examined with ethnographic research methods at HIV treatment sites in Jos, Nigeria, Dar es Salaam, Tanzania, and Mbarara, Uganda. The findings indicate that individuals taking ART routinely overcome economic obstacles to ART adherence through a number of deliberate strategies aimed at prioritizing adherence: borrowing and "begging" transport funds, making "impossible choices" to allocate resources in favor of treatment, and "doing without". Furthermore, factors such as age (especially adolescence have a negative effect), male gender, and

changes in health status (improvement as well as deterioration) have also been identified as important factors which affect adherence among patients.[59]

A study in Kenya by Wakibi et al. in 2011 revealed that out of the 416 patients interviewed, 403 answered all adherence questions and were analyzed. Females were 262 (65%) and males 141 (35%); their age ranged between 18 and 64 years old. Most patients were married 213 (53%); 246 (61%) had at least secondary education, 145 (36%) had primary education and 10 (3%) had no formal education. Three hundred (75%) respondents earned less than $120 per month. Main (38%) reason for missing therapy were being busy and forgetting. Accessing ART in a clinic within walking distance from home (OR = 2.387, CI.95 = 1.155-4.931; p = 0.019) and difficulty with dosing schedule (OR = 2.310, CI.95 = 1.211- 4.408, p = 0.011) predicted non-adherence.[39] Additionally, Talam et al. conducted a study in Kenya in 2008 among HIV patients on ART and found 261 (68%) were females and 123 (32%) were males. Half of the participants 198(51.6%) were between the age group of 26-35 years while 27(70%) were between 18 and 25 years. The mean age of the patients was 36.1 (SD 8.5 years). About 52.1% of the participants had attained secondary or post secondary education and both males and females had comparable education. 272(70.8%) of the respondents were married. There were more males 104 (84.6%) married than there were females 168(64.4%). About half of the patients 182(49.4%) were unemployed and this affected females more 140(53.6%) than males 42(34.1%). Majority of the working patients 296 (77.1%) worked during the day.[60]

A study by Sasaki et al from Zambia in 2012 revealed the median age of study respondents was 35 years old (range: 18–68), 94 (59.9%) were female, and 105 (66.9%)

were married. Around half of patients (n = 77, 49.4%) had not completed the standard primary education of seven years and 107 (68.2%) were farmers. Sixty-one (38.9%) reported experiences of food insufficiency in the previous 30 days. With regard to the transportation, 127 (80.9%) did not need to pay the transportation fee to access the district hospital or rural health centers. Over half of patients (n = 80, 51%) travelled to the health facility on foot and85 (54.8%) required more than one hour for this journey. According to the multivariable analysis, full adherence was associated with being female [Adjusted Odds Ratio (AOR), 3.3; 95% Confidence interval (CI), 1.2-8.9], having a spouse who were also on ART (AOR, 4.4; 95% CI, 1.5-13.1), and experience of food insufficiency in the previous 30 days (AOR, 5.0; 95% CI, 1.8-13.8). Some of the most common reasons for missed doses were long distance to health facilities (n = 21, 53.8%), food insufficiency (n = 20, 51.3%), and being busy with other activities such as work (n = 15, 38.5%).[61]

The 2012 study in Jos by Falang et al. reported that age (OR 1.04), sex (OR 1.14), and employment (OR 1.29), have strong impact on adherence to ART, [18] while a study by Pennap et al. 2012 at Keffi found more females (61.6%) than males (38.4%) and most of the participants were of age 25 to 34 (36.8%). About 70% of the volunteers had at least an elementary education and were into various endeavours. 8.1% (n=250) living far away from the medical centre and 6.5% (n=250) had inability to afford the cost of transportation to the medical centre (6.5%) and patient's educational level, marital status and occupation were found to be significantly associated with adherence ART in this study.[17] Danladi et al from Jos University Teaching Hospital conducted a study in 2013 and found age, three times a day frequency of drug intake, singles and educational levels

such as primary, secondary or tertiary school, strongly affected adherence ($P < 0.05$).(62) A 2013 descriptive cross-sectional study conducted by Okoronkwo et al. and colleagues showed a high poor adherence rate of 85.1% (n=221). Males were more likely to complain from busy schedule, feeling healthy, fear of partner disclosure, long waiting period, and long term regimen. Patients with no formal education were more likely to attribute poor adherence to poor communication, side effects of drugs, and stigma and while employed patients seemed to miss their drugs more than the unemployed and artisans.[63] A 2009 study by Uzochukwu and colleagues in Enugu found mean age of the respondents to be 34.6 years, 62.5% (n=174) were female and 52.9% married. A majority of them were business men and women. Nearly half 48.3% (n=174) of household heads had a monthly income of less than 5000 naira (US$38.5). Most respondents (91.4%) lived more than 20km from the treatment centre ($p<0.04$) and being female ($P<0.00$), aged less than 35 years ($p<0.03$), being single ($P<0.04$), and having higher educational ($p<0.01$) status were significantly associated with poor adherence.[64] A cross sectional descriptive study carried out among 192 HIV patients in Port Harcourt by Asekomeh et al. 2010 reported that there was no statistically significant association between socio-demographic characteristics such as age, sex, level of education and level of adherence to ARV therapy ($p>0.05$).[7]

Another study conducted by Afolabi et al. 2009 in Ile-Ife found mean age of participants to be 40.2 + 10.3 years and demographic factors such as age, gender and marital status did not seem to have any significant association with adherence level ($p>0.05$). However, participants who earned a total monthly income of ₦5000 (about US$40) or more and

those who had formal education were more likely to adhere than were those who earned less than ₦5 000 and those without formal education.[65] A similar study carried out by Olowookere found mean age of participants to be 39.1 years (SD 9.6 years). The majority 54% (n=318) of the PLWHA were females, 79.6% (n=318) had completed secondary education and 67% were married. Thirty per cent of the PLWHA were civil servants, 41.2% were traders, 13.2% were artisans, 6.3% were soldiers/police and 9.4% were unemployed. None of these socio-demographic variables was found to be associated with adherence level.[50] In another study conducted by Kayode et al in 2012 at UCH Ibadan found a statistical significance relationship exists between marital status and adherence to ARV medications ($p=0.043$) ($p<0.05$). Respondents who were singles (92.3%) tend to comply better to ART than other groups who were married (87.8%) and widowed (66.7%).[49] This is similar to findings by Ekama et al who reported marital status to be statistically associated with good adherence. However, there was no significant difference on the level of adherence to ARV medications between males and females respondents.[52] A study by Ogundahunsi in 2009 in Sagamu, Ogun State revealed male: female ratio of 1:1.5. The mean age of respondents was 40.5 years; the majority were Christians 79.2% (n=53), married 47.2% (n=53), and of lower socio-economic status 77.3% (n=53). Overall, 20.8% achieved poor adherence level of less than 95%. Good adherence rate (79.2%) was higher in the free-medication subset compared with the self-purchased subset, although the difference was not statistically significant. Socio-demographic variables were also not significant predictors of poor adherence.[51]

Sekoni et al conducted a study in Lagos in 2013 and found most respondents were

between 25 and 44 years of age (69.0%), and the mean age was 35.75 years ± 10.74. Female respondents were 64.5%, and 86.3% of respondents had at least secondary school education, of which 45.2% had tertiary education. Most of the respondents (42.6%) were married and there were more Christians (56.9%) and members of the Yoruba ethnic group.[53] In another study by Kasumu et al. from Lagos in 2014 found modal age group was 26-35 years, and the mean age was 35.3 years ± 7.9 SD. Most of the respondents were female (60.4%), married (65.1%), with secondary education (51.2%), Christians (80.6%) and Yoruba (44.0%). Over half of the respondents (56.0%) were self-employed, while 31.6% were in salaried jobs and 12.5% were unemployed.[54]

2.5 Patient-Provider Related Factors

2.5.1 Patient related factors that influence adherence to ART

A 2012 study in Nepal by Wasti et al. reported non-disclosure of HIV status, alcohol use, side-effects, transport costs (for repeat prescription), pills running out, not wanting others to notice, and being busy as the most common patient related reasons for poor adherence.[34] Bha et al. 2010 also found that poor adherence was higher among women who consumed alcohol regularly (47.1%). Medication-related adverse effects were reported in 47% of patients, notably, neuropathy, headache, nausea, loss of memory, diarrhoea and fatigue and common reasons for missing doses were: being away from home (57.1%), simply forgot (41.3%), side effects.[36] A study conducted by Hansana et al. in Vietnam in 2013 found reasons for not taking medicine as required were being busy (97.0%), and being forgetful (62.2%). In the multivariate analysis, educational level at secondary school (OR=3.7, 95% CI:1.3-10.1, p=0.012); illicit drug use (OR=16.1, 95%

CI:1.9-128.3, p=0.011); dislike exercise (OR=0.6, 95% CI:0.4-0.9, p=0.028), and forgetting to take ARV medicine during the last month (OR=2.3, 95% CI:1.4-3.7, p=0.001) were independently associated with non-adherence.[66] A similar study by Bijal et al in India revealed adherence was positively associated with age ≥50 years (adjusted odds ratio [aOR], 3.90), presence of co-morbid conditions (aOR, 1.92), medication self efficacy (aOR, 4.01), absence of pain in the past month (aOR, 2.14), and support from family and friends (aOR, 2.57). Lack of reminders from family members to take medication (aOR, 0.27) was negatively associated with adherence.[33]

Talam et al 2008 in Kenya reported commonly cited reasons for missing the prescribed dosing time among 384 patients were being away from home (50%), forgetting (50%), being too busy (50%), stigma (70%), feeling sick (80%) and changes in work routine (60%).[60] A similar study conducted in 2013 by Mitiku, et al. in Eastern Ethiopia among the 239 study participants showed main patient related reasons for poor adherence to be forgetting to take ART (47.2%), traveling (18.9%), and being busy doing other things (15.1%).[38] A study in 2011 by Wakibi et al. in Kenya found main reason for missing therapy by patients to be being busy and forgetting in 38% (n=403) of participants while accessing ART in a clinic within walking distance from home and difficulty with dosing schedule were predictors of poor adherence.[39]

A review by Monjok and colleagues in 2010 reported in Nigeria that most common patient related reasons identified for patient poor adherence include the cost of therapy (even when the drugs are heavily subsidized), medication side effects, non availability of ARV drugs, and the stigma of taking the drugs.[67] A 2012 study by Falang et al. found

alcohol intake, pill burden pill burden (OR 1.20), HIV disclosure status (OR 1.08) and twice daily ARV drug intake as some of the patient related factors affecting adherence to ART among HIV patients in Jos, Plateau State,(18) while a similar study in 2011 by Bello et al. also reported adverse antiretroviral drug effects and stigmatization as main patient related factors associated with poor adherence.[43]

A study conducted by Shittu et al at Ilorin in 2013 found adherence to be higher among non-alcoholics than current or ex-alcoholics. Forgetfulness, 37.1% and stigmatization, 18.2% were the major reasons proffered for non compliance with ART. Stigma was found to have had profound effect on the adherence.[45] A study involving 221 participants by Okoronkwo et al. 2013 reported commonest occurring patient related factors for poor adherence to be forgetfulness (53.8%), busy schedule (38.8%), side effects of drugs (31.9%), and stigma (31.9%).[63] Another study by Uzochukwu et al. 2009 found some patient related reasons for poor adherence to include physical discomfort following each dose (side effects); non-availability of the drugs at the treatment site; forgetting to carry the drugs during the day; fear of social rejection; treatment being a reminder of HIV status; and selling of own drugs to those unable to enroll in the subsidized treatment programme.[64] A study by Erah and Arute in 2008 reported poor financial status, medication adverse effects, lack of confidentiality, occupational factors and stigmatization as the major reasons given for poor adherence. Despite having all prescribed medicines always in stock during the study period some patients had stock out of medicines at home.[68] A similar study by Oku et al at Calabar 2013 reported overall self-reported adherence rate in this study was 59.6%. Being busy, forgetting to take medications, felt

depressed, and inconvenient timing were the main reasons cited by respondents for skipping doses. The independent risk factors for adherence to HAART included: nonpayment for ART services [OR 2.30; 95% CI: 1.02-5.10] Increased transport costs [OR 2.0; CI: 1.16-2.72], improved perceived health status [OR 2.45; CI: 1.90-5.03], and fewer number of children [OR 2.22; 95% CI: 1.21-4.09] were the positive determinants of adherence to HAART. Conversely, increased pill load significantly decreased the likelihood of adherence to HAART. [OR 0.62; 95% CI: 0.41-0.94.].[14] Sekoni et al found that amongst respondents who missed their ARV medication, slightly more than half skipped doses because they got tired of their drugs (52.2%), 17.3% due to the presence of someone when it was time to take their medication, 13.1% because they had travelled without their medication whilst 13.1% because they felt better and the remaining 4.3% because of side effects. Furthermore, there was no statistically significant association between stigma and medication adherence but PLWHAs who did not experience overall stigma were more adherent to their medication (90.8%) compared to those who experienced overall stigma (87.0%).[53] In other studies in Lagos, while Kasumu reported that a third of the respondents who missed doses did so because they were away from home,[54] Ekama et al also reported that disclosure of HIV status and having a treatment supporter was statistically associated with good adherence.[52] Okonkwoh et al from NIMR Lagos conducted a qualitative study in 2011 and found that the major causes for non-adherence were at individual factors, socio cultural factors and the medication regimen which include stigma, patients' knowledge and belief on ART.[69]

2.5.2 Provider related factors that influence adherence to ART

Structural factors not directly related to patient or medications can also influence adherence. Carlos et al., 2011 in a study in a study in Brazil reported that high adherence were associated with communication with the specialist physician, change in treatment, memory, self-efficacy, as well as commitment to and opinions about treatment.[31] A peer review by Margaret A. Chesney from San Francisco US reported that a good patient-health-care provider relationship may be an important motivating factor for taking and adhering to complex combination drug therapies. A qualitative study of homosexual youths showed that primary-care providers exhibited judgmental behaviour, stereotyping, homophobia, and failure to address socio-cultural issues when administering care. Such experiences are likely to lead some people with HIV infection to avoid the health care system. On the other hand, factors that have been identified as strengthening patient-health-care provider relationships include perceptions of health-care provider competence communication quality and clarity, compassion, willingness to include patients in treatment decisions, adequacy of referrals, and convenience of visiting the care provider. Conversely, frustration for health-care providers is associated with lack of patient adherence to treatment, miscommunication, missed appointments, complexity of treatment regimens, and medication side effects. In light of these problems, it is important to find approaches that encourage health-care providers to work with patients as "partners" in care and to involve treatment supporters.[10] A study by Langebeek et al from Netherland in 2014 highlighted that higher trust/satisfaction with the HIV care provider was associated with good adherence.[70]

Some researchers from Africa have even contended that some provider-related factors could be the most important barriers to ART adherence in limited resource settings like Kenya, Zimbabwe and Uganda. These include non-accessibility of antiretroviral medications and healthcare facilities for diagnosis and treatment of HIV/AIDs, out-of-pocket payments, high cost of ART and other health services, presence of healthcare providers experienced in ART provision, patient-doctor and other provider relationships, health care providers' beliefs and attitudes, waiting time and opening hours availability of counseling services, and social, economic, or psychological support for people living in both developing as well as developed countries can influence adherence positively or negatively.[13,55,59] Ensuring the privacy and confidentiality of ART clinics and waiting areas need to be given special emphasis as documented by Skovdal et al and Reda et al in studies conducted in 2011 in Zimbabwe and Ethiopia.[13,59] For instance, Skovdal and colleagues reported about patients who refused to leave consultation rooms citing to nurses Mr. so and so is outside. Adherence support and clinic policies are also important predictors of adherence as well as lack of adherence monitoring mechanisms.[13,59]

A study conducted by Nachega et al. and Mills et al in South Africa in 2010 indicates that improving adherence is cost effective and helps to reduce health care costs especially those of hospital care.[71] A study qualitative study conducted in South Africa by Andrew et al. in 2011 highlighted three main categories that positively affect their adherence to ART namely: patient, disease and health care provider-related factors. Sub-themes included issues related to acceptance, disclosure to significant others, symptomatic improvement on ARTs and the importance of supportive relationships. Participants greatly valued the

health care provider relationship and felt that the main role of the health care provider was to educate and support.[72]

In a another qualitative study by Sanjobo et al. from Zambia in 2007 revealed that patient-related, health service related, socio-economic and cultural factors were barriers and predictors of adherence among HIV patient on treatment These include lack of communication and information about ART, inadequate time during consultations, follow up and counselling, forgetfulness, stigma, discrimination and disclosure of HIV status, lack of confidentiality in the treatment centres, lack of nutritional support, feeling better, prospects of living longer, family support, information about ART, support for income generating activities and transport.[73]

In Nigeria, a study by Erah et al in Benin in 2008 reported poor lack of confidentiality as a major barrier to adherence.[68] However, Osungbade et al. in Ibadan in 2013 reported median time spent waiting to see a doctor in public health facility was half of the time spent in private health facility as well as less time to collect ARV drugs compared to patients in private health facility. Mean satisfaction scores of patients who attended public health facility were higher than scores of patients who attended private health facility in general satisfaction, technical quality of services provided, interpersonal manner, communication and time spent with doctor domains. Dissatisfaction with antiretroviral services in private health facilities could threaten attainment of anti-retroviral treatment objectives. Private health sector integration into HIV treatment services might improve service delivery and promote good clinical practice. This finding was not reported in his study.[74] Okonkwoh et al from NIMR Lagos conducted a qualitative study in 2011 and

found that the major causes for non-adherence were health services and patient-provider relationship. Most respondents reported that the nurses are rude and impolite to them which they find demotivating.[69]

2.6 Methods/Design in Previous Adherence Studies

2.6.1 Study designs and methodologies in previous adherence studies

The review of studies on adherence to anti-retroviral therapy in Asia, North and South America and Sub-Saharan Africa revealed that most studies used the cross-sectional design over other designs.[30,31,33,75,76] Carlos et al. 2011, apart from carrying out cross-sectional design also conducted qualitative method (Focused Group Discussion). Some of the studies conducted on adherence to ART in African countries like South Africa, Ethiopia, Kenya and Tanzania made use of cross-sectional design over other studies which were prospective cohort and randomised control trials.[37,39,77,78,79] Moreover, a study in Kenya by Nyambura et al. 2009, conducted qualitative methods (Focused Group Discussion and Key Informant Interview) in addition to cross-sectional design.[80]

In Nigeria, most the adherence studies conducted in the last decade used the cross-sectional design[17,18,47,63,81] to describe the scope of adherence to the ART. The cross-sectional appeared to be the best design for describing the scope of problems relating to adherence as indicated by other studies conducted in Sokoto, Kano, Ilorin, Keffi, Enugu, Nnewi, Port Harcourt, Calabar, Sagamu, Ile-Ife and Lagos.[17,45,51,52,54,63,,6581,82,83] Apart from the use of cross-sectional studies, most of the researchers also preferred the use of systematic random sampling for selection of patients for administering of questionnaires over consecutive, purposive and simple random sampling techniques.[47,52,53,54,82] In

addition, Afolabi et el. (2009) in Ile-Ife and Ilesah conducted both cross-sectional design and FGD.[65]

The patient self-reporting measure has frequently been employed in adherence to anti-retroviral therapy studies in United States of America (New Jersey), Australia, South America (e.g Brazil and Cuba), Asia as in India and Vietnam. A meta-analysis of adherence studies conducted in sub-Saharan Africa and North America by Mills *et al*. (2006) indicated that 71% of the North American studies used patients' self report.[30] According to Pinheiro et al., 2002 and other researchers prefer the patient self-reporting measure, because of its practicality, low cost and the fact that adherence detected by this method has proved to be related to viremia below detection[10,84] and to serum levels of protease inhibitors. Furthermore, several studies conducted in Vietnam, Cuba, Brazil, New Jersey has demonstrated association between self-reported adherence with viral outcome. This finding also suggests self-reports may yield valuable information in measuring adherence at the group level but not that on an individual level.[22,31,66,76,85] Additionally, Paige et al. 2006 in New Jersey combined pharmacy refill record with patient' report for assessment of adherence to ART, However, other studies conducted in developed cities like New York and Los Angeles on the comparative accuracy of the measures of adherence have shown a poor association between self-report or pill counts and undetectable viral load (UDVL) compared with the association between electronic drug monitoring (EDM) and UDVL. Liu et al. has also shown that several measures for the same patient result in different assessments of adherence and predict virus load with various levels of success. In their study, mean treatment adherence for the same group of

persons monitored from 24 to 48 months, depending upon the measure, ranged from 63% for a MEMS-based measure to 83% for pill count and 93% for self report. The level of adherence based on a composite measure, using a combination of these three methods, was 76%. These researchers used the MEMS measure as the "backbone" of their composite measure. That combined measure had the highest receiver-operating characteristic, indicating the best prediction of undetectable virus load at 6 months.[86] Therefore, these comparisons show that MEMS-measured adherence performs best in relation to a clinical outcome, but a composite measure may be an even better solution-at least Electronic monitors offer a more objective measure of treatment adherence than do self-reports. These monitors also offer the best way to assess adherence to taking pills on a particular dosing schedule (i.e., daily intervals). However, the cost of these devices limits their use in non-research settings, and the caps can malfunction or get lost. Patients often refuse to participate when the study uses a large bottle with a MEMS cap instead of a pillbox that can help them organize and remember their medications.[87] Pillboxes are not currently equipped with electronic devices. In addition, decanting (removing >1 dose at a time) or loosening the caps to make it easier to remove pills has been shown to be a common problem in studies using electronic monitors. A study of antiretroviral adherence in 64 predominantly white male subjects found that >40% routinely decanted their medications before joining the study, and one-third of these "decanters" continued to do so during the study.[87] Such behavior may explain why electronic monitors may underestimate the level of adherence.

Therefore, researchers suggest that more than one adherence measure should be used in

assessing adherence to the ART.[10] By choosing two measures, it is argued that the errors inherent in one measure are addressed by the other measure (triangulation) and a more realistic adherence rate is determined.

Literature review further revealed that most of other studies in Australia, Vietnam, Cuba, New Jersey and Brazil made use of patients' self-report for assessment of adherence. In a study conducted by Rosa et al. 2006 in Brazil, assessment of respondents' adherence was carried out using self-report method.(76) However, while Paige et al 2006 in New Jersey combined pharmacy refill record with patient' report for assessment of adherence to ART.[88]

Most studies in East and South African countries such as Ethiopia, Kenya, Uganda, Zambia and South Africa also made use of patients' self report to assess adherence level.[39,78,89] While Mayanja et al. 2013 in Uganda combined pill count with patients' self report to assess adherence level, Hailesellassie et al. 2014 in Ethiopia and Wakibi et al. 2011 in Kenya used special tools to calculate adherence level. In a study conducted by Woldesellassie et al. 2013 in Ethiopia, pill count, medication possession ratio and patients' self report were measures use to assess patients' adherence level.[90]

In Nigeria, majority of researchers also used patients' self report to assess adherence.[18 42,45,47,49,52,54,62,63,64,65] However, some were able to go further in combining pharmacy pick-up record, pharmacy refill and pill count with patients' self report in the measurement of adherence level.[63,83]

2.6.2 Study instruments in previous adherence studies

Furthermore, from review of other studies, questionnaires used were adapted from literature and were based on specific objectives of a particular study. However, most of the questionnaires used for studies by other researchers from North America, Asia and South America had contained information on socio-demographic (age, sex, marital status, educational level, source of income) and adherence assessment (self report and or other methods).[30,31,75,76] However, in addition to socio-demographic and adherence assessment, Carlos 2011 included in his study tool year of patient diagnosed for HIV, questions on care setting such out-patient service or Non-governmental organization, year of commencement of ART, daily dose for ART, names of ART and whether there was changes in ART combination. Pinheiro added in his questionnaire information on attitude towards ART, outcome expectation for ART, perception of ART and physical concern[84] Garcia et al apart from adopting a tool from USA called PMAQ which contained 36 questions, added information such as level of knowledge of ART, motivation to ART, food intake in relation to ART and viral load result.[76] In a study by Wasti et al in Nepal using four weeks recall for ART taken, additional information on patient socio-cultural characteristics, Patients' health conditions, service facility, perception and knowledge on ART were included in the study tool.[34] However, this is similar to the tool adapted by Hansana et al who conducted a study on a three days recall on ART taken by HIV patient and added information on patient health behaviour, severity of illness, side effects and health service related characteristics.[66] Hoa et al from Vietnam used a voice recorder as data collecting tools and ACASI software to enter data generated. Other information

collected included duration on ART, daily dosage, perception of social isolation, depression, social support, level of satisfaction, alcoholism, TB and Co-trimoxazole treatment.[32]

In Sub-Sahara Africa, literature also revealed that design of questionnaires were based on the specific objectives of the study and adapted from other studies. Most of the researchers had information on socio-demographics (age sex, marital status, religion, level of education, number of children, employment status, average number of meals per day, monthly income, cost of transportation to the clinic waiting time) and adherence assessment in their questionnaires in addition to questions made to address other specific objectives.[60,71,73,78,80,90] Waldesellassie et al in a study conducted in Ethiopia included the following information in the study questionnaire; questions on depression, stigma, patient level of satisfaction, patient belief, HIV treatment knowledge, adverse drug reaction, drug resistance, ART regimen, daily dose, other medication, patient-health care provider relationship, Laboratory data on age, weight, WHO clinical staging and CD4 count. [90]

In a study in South Africa by Nachega et al., the study questionnaire used contained socio-demographics in addition to questions on assessment of knowledge, beliefs, and attitudes toward HIV and ART. Participants were asked questions regarding modes of HIV transmission, disease progression, effects of ART, and concerns about ART. Perceived importance of ART adherence was assessed by asking the patients if they agree or disagree with the following statement: ‘‘If someone on ART misses doses of their medication, they may become very sick with AIDS.’’ Questions regarding sexual and ART use practices included information about disclosure of HIV status, ART use, and

condom use.[71]

Review of other studies in Nigeria revealed that most of the researchers adapted semi-structured interviewer administered questionnaires that contained information on socio-demographic and economic detail, adherence assessment and factors influencing adherence to ART.[14,42,51,52,54,58,63,68,81]

In a study by Olowooke et al in Ile-Ife, the questionnaire used for adherence study contained information on socio-demographic status which included age at last birthday, sex, level of education, and occupation. Occupation was classified into trading (buying and selling), civil servants (those working for government establishments), artisans, military/paramilitary workers, and unemployed while level of education was classified into no formal education, primary education, secondary education, or tertiary education. It also included questions on ART adherence, knowledge and attitude about HIV/AIDS and ART, and their perception of stigma associated with HIV/AIDS.[50] Kasumu et al in Lagos used questionnaire developed from previous literature and contained information on socio-demographic and economic details, family and health care providers' support for ART, knowledge and attitude towards ART and adherence pattern of respondents.[54] Furthermore, Sekoni et al from Island General Hospital grouped her study questionnaire into section A, B and C. Section A had information on socio-demographic, B had Medication Adherence Assessment and C had stigma Assessment. Sections A and B were developed by the researcher based on information gathered during the review of literature whilst section C was adapted from the Stigma Scale developed by Berger and colleagues.[53] However, Ekama et al from NIMR had questionnaire which was a semi-

structured, interviewer-administered questionnaire that contains sections on socio-demographic data and factors influencing adherence to ART. Knowledge of ART was measured by asking some basic questions, which were graded.[52]

Literature review on FGD and KII guides revealed similarities in contents from other studies in Sub-Sahara Africa. Sanjobo et al in Zambia conducted a qualitative study on adherence to ART of which the questions contained in the guide used were on socio-demographic, service delivery, knowledge, perception and belief about HIV/AIDS and ART, ART and adherence and barriers and motivation factors to adherence to ART. Examples of questions asked include 'what is the difference between HIV and AIDS'? and 'What could be improve in the health facility'? The contents of the guide was not different from the one used in a qualitative study conducted by Chinyere et al. of Nigeria Institute of Medical Research Lagos which also contained information on individual factor such as 'In the last one month did you miss your doses'?, socio-cultural factors such as 'how does ART affect you emotionally'?, health services related factor such as 'how are the waiting times at the hospital'?, regime factors, patient-doctor relationship such as 'what is your view about ART'?, general questions and socio-demographics.[69]

2.7 Gaps in Knowledge and Further Justification

Review of literature above revealed some of the gaps in previous adherence studies conducted in sub-Saharan Africa. According to these authors, some of the studies were part of clinical trials or other highly controlled patient environments such as the study conducted by Woldesellassie et al 2013 in Ethiopia and Maduka et al., 2012 in Port Harcourt, Nigeria.[48,90] This showed that the studied patients may have benefitted from the

structural supports provided by the trial and as such, adherence rates cannot be generalized to normal settings Furthermore, longitudinal studies that used self-report measure, according to the authors, took smaller sample sizes of patients who have been on the ART for short periods.[91] The 3-7 days adherence recall in most of the studies might also not be adequate for assessment of adherence as compared to 4 weeks.[14,17,51,52,53,65]

Despite the likelihood of recall bias for 4-week adherence measurement, this might give a true picture of adherence status of a patient on ART.[45,54,68] Additionally, most of the studies used the recall measure to assess adherence, but could not validate adherence, because viral load tests were either not available and where available were too expensive to be incorporated into routine clinical care. Therefore, there appeared to be a challenge of exaggerated adherence levels in Africa and accurate adherence rates remains unknown.[87]

Literature also discovered that most of the studies on adherence were health facility based and therefore finding could not be generalized and this might as well implies that findings from other studies were meant to respond to peculiar challenges at each facility were studies were carried out. Ekama et al. conducted a study on adherence among pregnant women on ART prophylaxis in NIMR which excluded their male counterpart. Therefore, finding from the study did not address adherence challenges among adult males, and females who were not pregnant.[52] Moreover, most of the researchers did not include qualitative method in their study. This study is aimed at combining both self-report and pharmacy refill record so as to give a better estimate of adherence rate among study participants and the inclusion of qualitative method will provide opportunity to further explore factors influencing adherence among patients on ART in NIMR, Lagos.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Description of Study Area

The HIV clinic of NIMR is located in Lagos Mainland LGA of Lagos state. It was established in 2002 as one of the earliest tertiary comprehensive HIV/AIDS health centre by the Federal Ministry of Health to provide free HIV/AIDS services to People living with HIV/AIDS in the country. It currently provides treatment and care services for over 22,000 HIV/AIDS patients. The HIV clinic from inception received addition support from AIDS Prevention Initiative in Nigeria (APIN) through the United States Presidential Emergency Plan Fund (PEPFAR) for HIV/AIDS.

The clinic has a well managed electronic medical record (EMR) system, which might be an advantage for the study. Since commencement of field posting at NIMR by the researcher, there were reported cases of defaulters to ART who end up coming back with treatment failure due to unspecified reasons. With the researcher being part of the workforce at the facility and providing selfless service during field posting, minimal challenge is envisage in terms of logistics and getting access to the facility database.

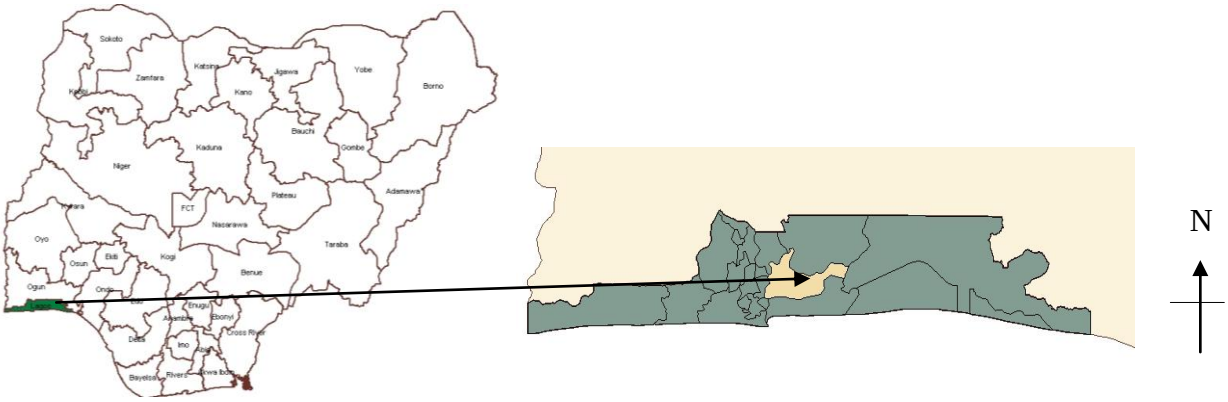


Figure 3.1: Map of Nigeria showing Lagos State with NIMR Yaba in Lagos Mainland Local Government Area indicated

3.2 Study Design

A cross-sectional study was used for the study.

3.3 Study Period

The period for the preparation and conclusion of the study was from May, 2013 to March, 2014. The pilot study and pre-test of study materials were conducted in January, 2014 while the main data collection was carried out in March, 2014.

3.4 Study Population

The study population comprised of consented HIV patients (≥15years) who commenced ART for at least 3 months prior to the study.

3.4.1 The inclusion criteria for the study

A patient who had started anti-retroviral therapy (ART) for at least 3 months prior to study.

3.4.2 The exclusion criteria for the study

- Pregnant women age ≥ 15 years on ARV prophylaxis.
- Patients who missed or stopped ART on medical ground.
- Patients who were very sick.

3.5 Sample Size Determination

i. Proportion of participants that forget to take their prescribed ARV drugs from a 2008 study conducted at Keffi .Nasarawa State Nigeria by Pennap et al.[17] was 51.5% i.e. p =0.515

ii. Significance level of 0.05 (for 2-tailed tests of significance); $Z_{\alpha/2}$= 1.96

iii. Precision (d) of ± 5%

The minimum sample size required for the study was given as:

$$n = \frac{Z\alpha^2 pq}{d^2}$$ (Kish Leslie, 1979)[92]

n = minimum sample size

p = proportion of HIV who forget to take ARV drugs = 51.5% = 0.515

q = (1-p) = 1-0.515 = 0.485

d = precision = ±5%

$$n = \frac{1.96^2 \times 0.515 \times 0.485}{0.05^2} = 384$$

The estimated sample size was 384

Correction for non-responses: = 1/1-f x n

F = non-response, then 1-f = response.

Hence for non-response of 10%, the minimum sample size became

1/1-0.10 x 384 = 426

Calculated minimum sample size (n) = 426

The number of respondents recruited into the study was 426

3.6 Sampling Technique

Systematic random sampling technique was applied for participants' selection in the study. The sampling units were individual age ≥ 15 years who have been on ART at least 3 months prior to study. From the list of patients attending the HIV Clinic obtained from Medical Records Department and based on average daily clinic attendance of 300 patients per day, a total of 50 eligible patients were recruited per clinic day using systematic

random sampling method using a sampling fraction of 1:6. The first patient was randomly selected; thereafter every other sixth eligible patient was selected each until the sample size was completed. For those who failed to consent on particular clinic days, they were subsequently replaced using the same sampling technique on subsequent clinic days.

3.7 Study Instruments

The instruments used were both for quantitative and qualitative methods. These include the followings;

- Pre-tested interviewer-administered semi-structured questionnaire
- Focused Group Discussion guide
- Key Informant Interview guide

3.7.1 Pre-tested interviewer-administered semi-structured questionnaire

The pre-tested interviewer-administered semi-structured questionnaire used for study was adapted and modified from questionnaires used in 2012 by Ekama et al from NIMR, Lagos.[52] The questionnaire contained 56 items that included questions about the patients' socio-demographic status which included age at last birthday, sex, level of education, marital status, religion and occupation. Occupation was classified into trading/artisan, farming, civil servants (those working for government establishments), artisans, and unemployed. Level of education was classified into no formal education, primary education, secondary education, or post-secondary wile religion was classified into Islam and Christianity. It also included questions on monthly salary, main source house food, money spent on household food daily, number of meals respondent could afford per day, distance from participant's home to health facility, number of hours spent by participant

to and fro home for drug pick up in each hospital visit, cost of transportation for each drug pick-up/ follow up visit, number visits made per month by participant and waiting time for drug pick up/ follow up visit. Knowledge about ART and adherence level, questions about patients and provider related factors influencing adherence including attitude of providers to their patients which include reasons for missing drugs by patients, reminder methods for taken drugs, side effects, consequences of missing drugs and whether receive adherence counseling or not. drugs and whether received adherence counseling or not were all contained in the questionnaire. Each questionnaire was administered in English language to consented respondents who understand English by field workers. Administration of each questionnaire lasted for 45 minutes to one hour. This questionnaire was completed by each study participant with the assistance of the investigators.

3.7.2. Focused Group Discussion and Key Informant Interview Guides

The FGD and KII guides was adapted and modified from guides used by Okwonkwoh et al., 2011 from NIMR, Lagos.[69] Each guide consists of four (4) sections namely; section A has socio-demographics, section B had knowledge about HIV and AIDS, section C has knowledge about Anti-retroviral drugs and section D has adherence to ART, adherence counselling and patient-provider related factors. It also contained patient information and informed consent part where respondent consent were sought before conducting the two methods.

3.8 Data Collection Methods

Data were collected for both quantitative and qualitative methods. The quantitative method was performed with semi-structured interviewer-administered pretested questionnaire. Using a non-repetitive unique identification numbers (without names of respondents), data on patients' socio-demographic, knowledge and adherence levels and patient-provider related factors were tracked. The same unique identification number was written on all other materials for each respondent such as the consent forms. This number was also the same for each participant's data entry and analysis, hence linking up questionnaire and individual adherence status. There was no other identifier such as name other than the unique individual code. Example of the unique identifier number was 001, 002, 003 and up to 426.

Based on the number of participants enrolled for the study and considering the period of data collection, three (3) interviewers were used for data collection. The interviewers were two (2) females and a male. However, there was a male and female (who was not NIMR staff) during the pilot study but considering experienced learnt during the pilot, there was need to include another interviewer from NIMR who happened to be a female so as to meet the timeline for data collection and reduce non-compliance. Two of the interviewers were NIMR staff, and this was suggested to avoid non-compliance from participants because of stigma and to maintain shared privacy and confidentiality experienced during pilot. Regular supervision of interviewers was carried out by the researcher to minimize bias during interview of participants.

The qualitative method was conducted through Focused group discussion and key

informant interview using interviewer guides on various aspect of HIV, anti-retroviral dugs and adherence issues. The Focus group discussion was conducted in a session involving eight (8) HIV patients on ART while Key informant interview was done with a male and female patient on ART for a minimum of five (5) for treatment for HIV/AIDS. The sessions were carried out by an interviewer and a note taker, with each lasting for 45 min to 1 hour.

Confidentiality of information, voluntary participation and respect for human subject was maintained throughout the study.

Training of field workers

A one-day training of three field workers was conducted before data collection for the main study. The interviewers were introduced to the study protocol which contained the study design data collection tool and method. Specific instructions and clarification were made on how to engage participants, ask and response to questions in the questionnaire. Based on the nature of patients that come to the clinic, the interviewers were those that speak English, pidgin, and Yoruba and familiar with field work activities.

3.9 Data Management and Analysis

3.9.1 Calculation of Adherence level and criteria for grading knowledge and attitude of health care workers

For quantitative method, level of ART adherence was calculated manually using the respondent's self-report and pharmacy pick-up records.

The calculated ART adherence level was derived using the following formula[47]

$$\text{Adherence (\%)} = \frac{\text{Number of pills (doses) taken}}{\text{Number of pills (doses prescribed /supposed to be taken)}} \times 100$$

W here number of pills taken = number of pills prescribed- number of pills missed over one (1) month period.

The level of ART adherence for each respondent was classified into those with 95% or greater adherence (good) and those with less than 95% adherence (poor). The good ART adherent patients were defined as those with an adherence of greater than or equal to 95%. The responses to the questions that were related to the respondent's knowledge about ART had ten (10) items and health worker's attitude to patients had seven (7) items and each were also scored and summed. 10 points was given for each question that was answered correctly for knowledge about ART while that of health worker's attitude ranges from 0-4 points depending on whether the item is negative or positive attitude. The scores were then categorized as follows: for the respondent's knowledge of ART, a score in the range of 0-50 was considered to be poor, whereas a score in the range of > 50 was considered to be good. A health worker's attitude toward their clients was categorized as unsatisfactory (0-16) or satisfactory (17-28). Respondents were asked whether they strongly agreed, agreed, strongly disagree, disagree or no response with 7 items, and answer choices were offered on a four-point Likert scale (No response [0]Strongly Disagree [1], Disagree [2], Agree [3], Strongly Agree [4] for 4 items on positive attitude while for response for the 3 negative attitude: No response [0]Strongly Disagree [4], Disagree [3], Agree [2], Strongly Agree [1]) See tables below for criteria for scoring and grading of knowledge about ART and attitude of health workers to patients.

Table below shows criteria for grading attitude of health worker: One option was allowed for each item for all the 7 items.

Table 3.1: Table below shows criteria for grading knowledge about ART by study participants

S/No.	Questions	Scores for correct answers
1	Anti-retroviral drugs can prevent progression from HIV to AIDS?	10
2	A person on Anti-retroviral drugs cannot infect their partner (s) through unprotected sexual intercourse or sharing of sharps (razor blade, needles)?	10
3	Failure to take Anti-retroviral drugs everyday can lead to treatment failure?	10
4	Anti-retroviral drugs can lead to development of side effects by patients?	10
5	A person who developed side effect (s) while taken Anti-retroviral drugs is required to stay at home until he/she is better?	10
6	Three successive adherence counseling is not required to commence HIV treatment?	10
7	It is not all HIV infected persons who require Anti-retroviral drug treatment?	10
8	Basic laboratory tests are required before starting HIV infected person on Anti-retroviral drug treatment?	10
9	Do you know ARV drugs can prevent your chance of getting opportunistic infections like TB and skin infections?	10
10	Use of condom during sexual intercourse by patient on Anti-retroviral drugs is not required to prevent getting infected with another strain of HIV?	10
	Total scores	100

Table 3.2: Below shows criteria for grading attitude of health workers

Attitude	Strongly Agree	Agree	Disagree	Strongly Disagree	No response	Maximum score
Good courtesy	4	3	2	1	0	4
Good Clarity in response	4	3	2	1	0	4
Always Stigmatized	1	2	3	4	0	4
Long waiting time	1	2	3	4	0	4
Good response to question (s)	4	3	2	1	0	4
Was privacy and confidentiality maintained	4	3	2	1	0	4
Judgmental	1	2	3	4	0	4
Total scores						28

In the qualitative method, data from FGD and KII were analyzed by reading for content, conducting quality checks, identifying patterns, coding, labelling and displaying data. Shared confidentiality and privacy were maintained during data collection, entry and analysis. Anonymity of participants was also maintained, and therefore no data was link to a particular participant's name as participants were identified by a particular number; 1, 2, 3 to 10.

3.9.2 Data collection and retrieval

During the field work, the interviewer collected data from the participants using questionnaires which were submitted on daily basis. The filled questionnaires were further checked on submission for completeness and correction effected immediately. Challenges identified during the daily reviews were addressed on the field subsequently.

3.9.3 Measurement of variables

The study collected data on the following variables: socio-demographic data of respondents, knowledge about ART, level of adherence to ART, patient and provider related factors influencing adherence.

3.9.4 Statistical analysis

General reviews of filled questionnaires were done before electronic data entry. Data were entered into Epi-info software (version 3.5.1) and Microsoft Excel 2007. Data cleaning and complete checks of entered data were performed to exclude incomplete, inaccurate and inconsistent data before analysis. Electronic data back-up was done (using CD-ROM, flash drive and e-mail). Data analysis was performed using Epi-info software (version 3.5.1) and Microsoft Excel 2007 for univariate analysis using frequencies and proportions, Bivariate analysis of association between poor adherence and knowledge of ART, socio-demographic factors and patient-provider factors using prevalence odds ratios, Fisher's exact test and / or Chi^2 (χ^2) test of statistical significance, and multivariate analysis and logistics regression to identify independent predictors of poor adherence among the study group. All analysis was done at 95% confidence interval. Level of significance for all tests was 5% (0.05). Data were summarized using tables and charts for key indicators.

3.10 Ethical Considerations

Ethical approval was sought from the Nigeria Institute of Medical Research Ethical Review Committee before embarking on the study. Ethical standards and best practice

were adhered to throughout the conduct of the study under the following headings:

3.10.1 Respect for persons and their human rights

Informed consent was sought from all adult participants. Participants who could not provide informed consent (very sick patients) did not participate in this study. Shared confidentiality, anonymity and privacy were fully guaranteed to allay fear of stigma and discrimination. Participation was voluntary and eligible participants were allowed to decline to participate in the study. Participants were identified using unique identifiers as contained in the questionnaire and information about each participant was not revealed to anyone except those involved in the conduct of the study and privacy and confidentiality were duly maintained as mentioned.

3.10.2 Beneficence

The study was designed to identify factors that contribute to poor adherence to ART so that findings appropriately disseminated to government and relevant stakeholders to guide decisions and policy review and formulations towards improving adherence among patients on ART. Additionally, study did not constitute any risk to participants as no specimen or any form of invasive procedure was required. Those found to have adherence challenge were referred to the physician and adherence counsellors for appropriate counselling and other relevant interventions.

3.10.3 Justice

Participants had equal chance of being selected for the study and findings were utilized for general improvement in adherence to ART among respondents. Confidentiality,

anonymity and privacy were fully guaranteed.

3.11 Limitations

- Health facility based study: as with other similar studies, data collected from the study was not representative of the general population and findings might not be generalized.
- Recall bias: Some of the respondents might have over- or under- reported their adherence to ART due to challenge of remembering the number of times they miss their dosages in the last one month before the study. Pharmacy refill records were tally with participants' self-report reduce challenge to appreciable level.
- Efforts to corroborate patient self- report of adherence with viral loads and CD4 responses were not possible because of financial and logistic constraints of laboratory monitoring.
- Respondents consisted only of patients who actually went to ART clinics. Defaulters from ART service and those picking up ART drugs for someone else were not interview and this means study might have missed patients other than those very sick to attend appointments.
- NIMR is one the pioneer centre of excellence for HIV treatment and care in-country with well equipped laboratory facilities. Therefore, patients attending other health facilities (e.g. General hospitals) for similar care might not be opportune to have access to such facilities as in NIMR. Hence, some findings might be biased due the differences in facilities for care.

3.12 Scope of the Study

The study covered three major scopes:

- It determined the proportion of HIV patients who had poor adherence to ART by calculating their adherence level one month before the study
- It assessed the general knowledge on ART among HIV patient on treatment
- It assessed the association/ relationship between specific patient-provider factors and poor adherence to ART among HIV patients on treatment.

CHAPTER FOUR

RESULTS

This chapter presents the findings of the study. It is presented according to the two methods of data collection used in the study. Both are presented together under same objective.

4.1 Socio-Demographic Characteristics of Study Population

This section shows the finding of socio-demographic characteristics of the study population. These characteristics included age, gender, marital status, level of education, occupation, religion, monthly salary/wages, source of household food, Amount of money (Naira) spent on buying food daily in a household, number meals afforded by each participant daily, distance from participant house to health facility, duration of time from participant house to health facility for drug pick-up, cost of transportation to and fro participant's house, average number of visit to health facility in a month by participant and waiting time for drug pick up at the health facility.

Table 4.1: Presents Socio-demographic characteristics of respondents, (n=426) NIMR, Lagos ART Adherence study, 2014

Characteristics	Frequency	Percent (%)
Age (years)		
20-29	54	12.6
30-39	177	41.6
40-49	142	33.3
50-59	43	10.2
60-69	10	2.3
Sex		
Female	285	66.9
Male	141	33.1
Marital status		
Never married	88	20.7
Married	296	69.5
Separated	16	3.8
Divorced	3	0.7
Widowed	23	5.4
Education		
None	6	1.4
Primary completed	83	19.5
Secondary completed	190	44.6
Post-Secondary	147	34.5
Occupation		
Farmer	3	0.7
Civil servant	52	12.2
Trader/artisan	285	66.9
Unemployed	45	10.6
Others	41	9.6
Religion		
Christianity	391	91.8
Islam	35	8.2

Four hundred and twenty six respondents were interviewed. The mean age of the respondents was approximately 39.3 years (Standard deviation: 8.9). Table 4.10 above below summarizes the demographic features of the respondents. Respondents in the age group 30-39 years accounted for the largest proportion (41.6%) while the least (2.3%) were in the age group 60-69 years. The male to female ratio was 1**:**2. Most of the respondents were married (69.5%) while the least of them were divorced. Those with at least a secondary school education accounted for the largest proportion of the respondents (44.6%). Approximately twenty percent of them have at least a primary school education while one percent of them have no formal education. Trading is the most common occupation amongst the respondents (66.9%) while approximately eleven percent is unemployed. The majority of them were Christians (91.8%).

Monthly salary of respondents

Table 4.2 presents the monthly salary of respondents

Table 4.2: Monthly salary of respondents (n=381), NIMR, Lagos ART Adherence study, 2014

Salary (Naira)	Frequency	Percent (%)
11,000-50,000	202	53.0
I don't know	80	21.0
< 11,000	47	12.3
51,000-90,000	33	8.7
91,000-130,000	13	3.4
>130,000	6	1.6

The proportion of respondents whose monthly salary was between 11,000 and 50,000 Naira were 202 (53.0%) while those that said they didn't know the amount they collect in a month as salary were 80 (21.0%). Twelve percent had a monthly salary of less than 11,000 Naira while 6 (1.6%) had a salary of above 130, 000 Naira.

Main source of household food by respondents

The distribution of respondents according to their source of household food is shown in figure 4.1.

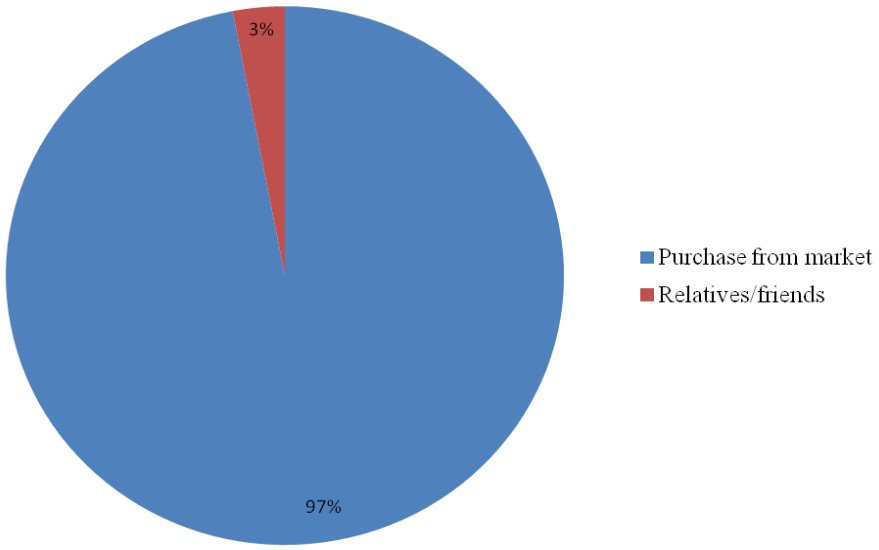


Figure 4.1: Main source of household food by respondents (n=426), NIMR, Lagos ART Adherence study, 2014

Of the 426 respondents, 415 (97.0%) purchase their households food from the market while 11 (3.0%) got theirs from relatives/ friends.

Daily number of meals by respondents

The distribution of respondents based on the number of meals afforded per day shown in figure 4.2.

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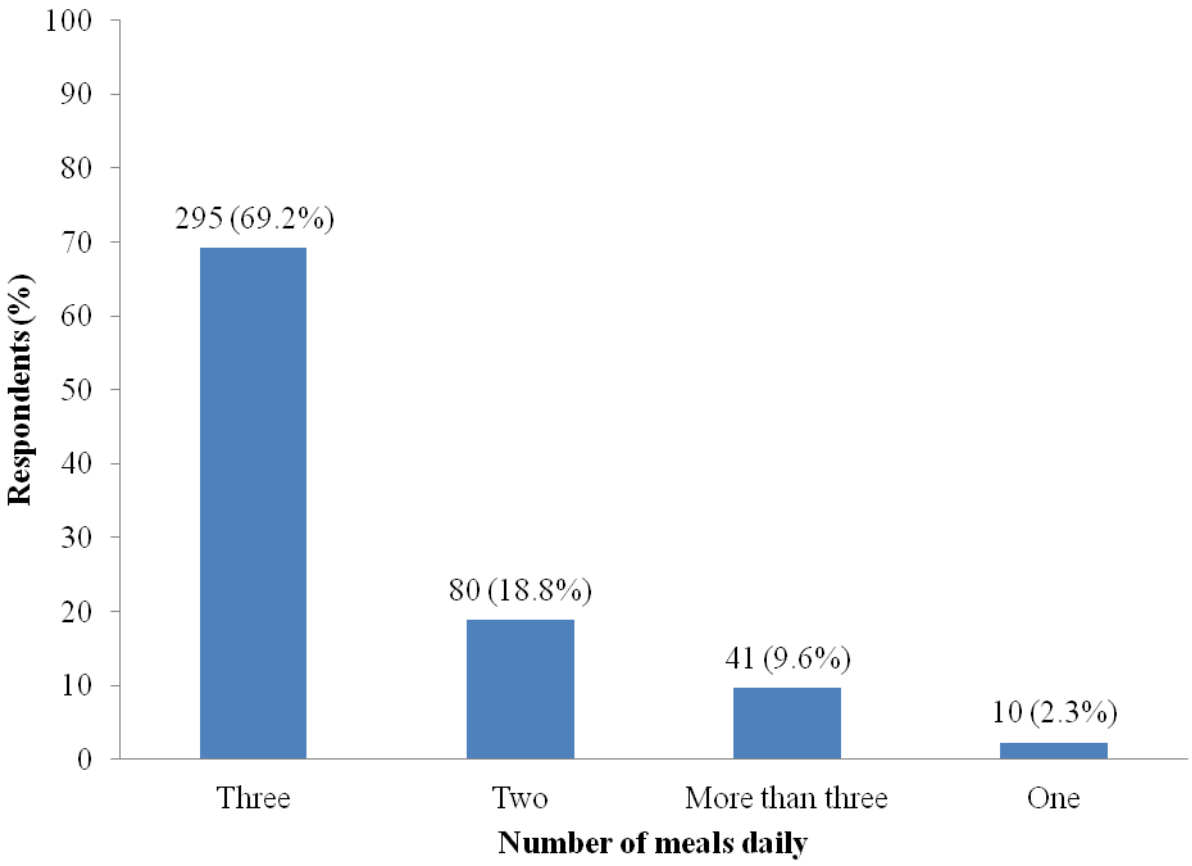


Figure 4.2: Daily number of meals respondents could afford (n=426), NIMR, Lagos ART Adherence study, 2014

The majority (69.2%) of the respondents could afford three meals per day, 80 (18.8%) could afford two meals daily and 10 (2.3%) could only afford a meal in a day. Out of 426 respondents, only 41 (9.6%) could afford more than three meals daily.

Distance from house to health facility

Distance of respondents' house to health facility for drug pick- ups is shown in figure 4.3.

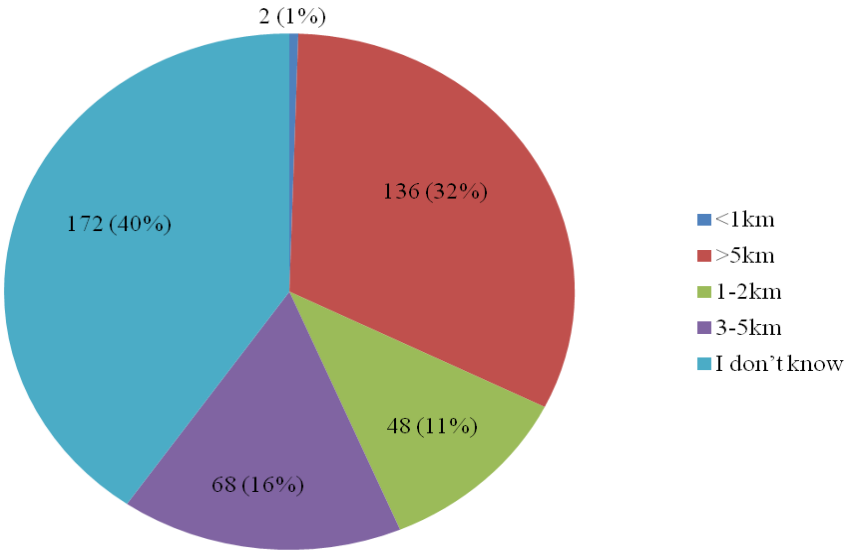


Figure 4.3: Distance of respondents' houses to health facility for drug pick-up (n=426), NIMR, Lagos ART Adherence study, 2014

Forty percent (40.0%) of respondents could not estimate the distance in Km from their houses to health facility for dug pick-ups followed by those who distance from home to health facility was greater than 5km. Sixteen percent said that the distance from their homes was between 3 to 5 km while 2 (1%) said the distance from their homes to health facility was less than one kilometre.

Time spent from home to the health facility

Duration in hour (s) respondents spent from house to health facility for drug pick- ups is shown in figure 4.4.

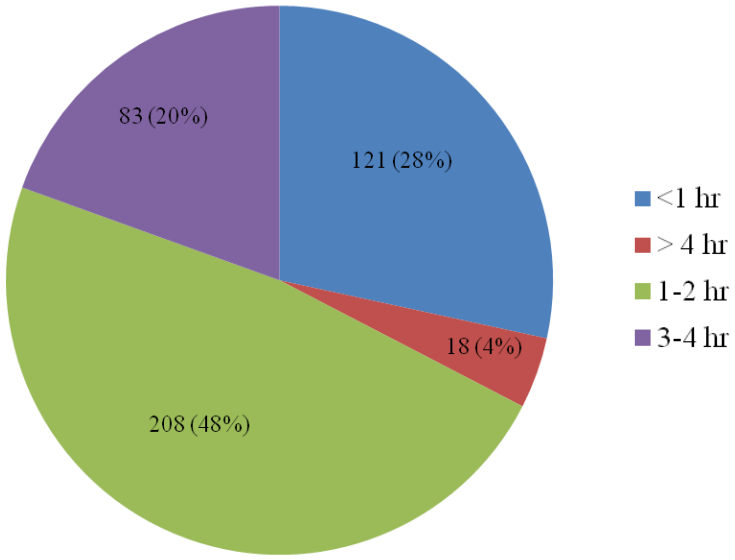


Figure 4.4: Duration in hours from respondents' houses to health facility for drug pick-up (n=426), NIMR, Lagos ART Adherence study, 2014

Forty eight (48.0%) percent of respondents usually get to the health facility within 1-2 hour for drug pick-ups, followed by 121 (28%) of respondent that said they spent less than one hour. Twenty percent said they often spent 3-4 hours before reaching the health facility from home and 18 (4%) spent more than 4 hours from home to facility for drug pick-ups.

Transport fare to and fro health facility

Table 4.3 presents the transport fares to and fro health facility for drug pick-ups of respondents

Table 4.3: Transport fare of respondents (n=381), NIMR, Lagos ART Adherence study, 2014

Transport fare (Naira)	Frequency (n=426)	Percent (%)
₦200-₦500	182	42.7
₦600-₦1,000	135	31.7
<₦200	43	10.1
₦1,100-₦1,500	38	8.9
>₦2000	11	2.6
Do not know	11	2.6
₦1,600-₦2,000	6	1.4

The proportion of respondents whose transport fare on every clinic was between 200 and 500 Naira were 182 (42.7%) followed by 135 (31.7%) whose transport fare were between 600 and 1,000 Naira. Ten percent of respondents spend less than 200 Naira on every clinic visit while 11 (2.6) spend above 2000 Naira.

Average number of clinic visit in a month

Distribution of respondents based on average number of clinic visit in a month shown in figure 4.5.

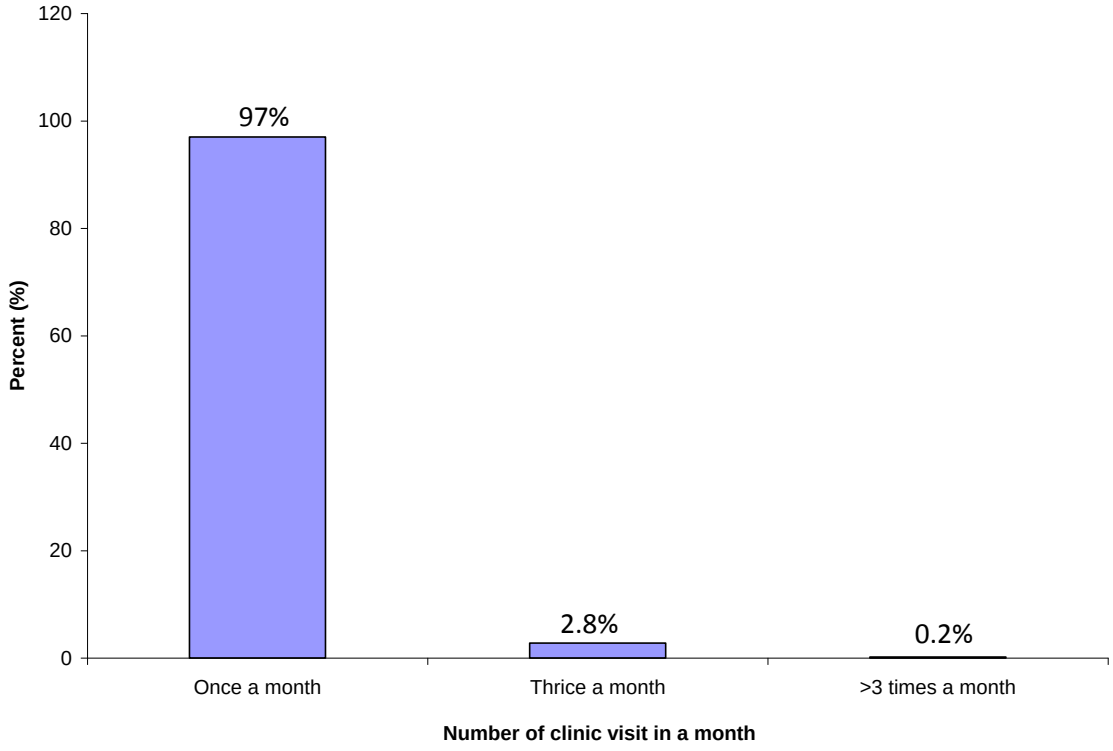


Figure 4.5: Average numbers of clinic visit in a month by respondents' for drug pick-ups and follow up (n=426), NIMR, Lagos ART Adherence study, 2014

Of the 426 respondents, 413 (97.0%) made once a month clinic visit for drug pick-ups and follow up, 12 (2.8%) visited the clinic three (3) times and only 1(0.2%) had more than three (3) visits.

Waiting time for drug pick-up on each clinic visit

Waiting time experienced by respondents for drug pick up on each clinic visit shown in figure 4.6.

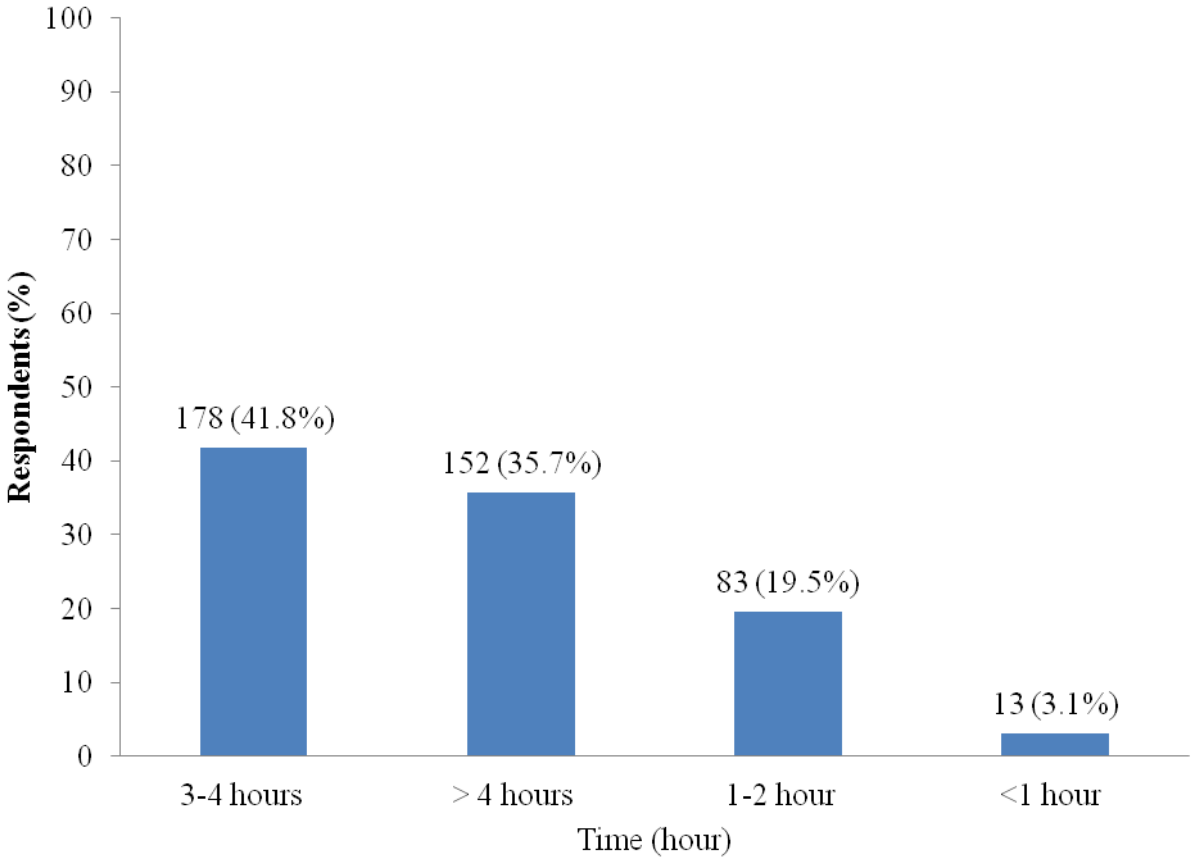


Figure 4.6: Average waiting time of respondents for drug pick up during clinic visit (n=426), NIMR, Lagos ART Adherence study, 2014

The majority (41.8%) of the respondents complained of always staying between 3-4 hours for drug pick-up on every clinic visit, 152 (35.7%) said they spent more than 4 hours, 83 (19.5%) said 1-2 hours and only 13 (3.1%) said they spent less than one hour to pick their drugs on each clinic visit.

4.2 Proportion of Poor Adherence

This section presents information about those who had poor and good adherence to ART. Proportion of respondents with adherence is shown in figure 4.7.

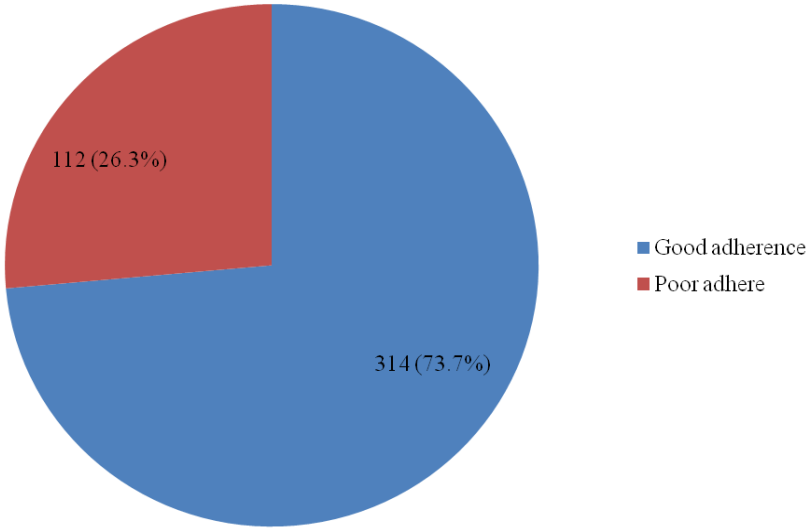


Figure 4.7: Proportion of respondents with poor adherence (n=426), NIMR, Lagos ART Adherence study, 2014

The proportion of respondents with poor adherence was 112 (26.3%) while those with good adherence were 314 (73.6%).

Distribution of adherence to ART by gender

Distribution of respondents based on level of adherence to ART by gender is shown in figure 4.8.

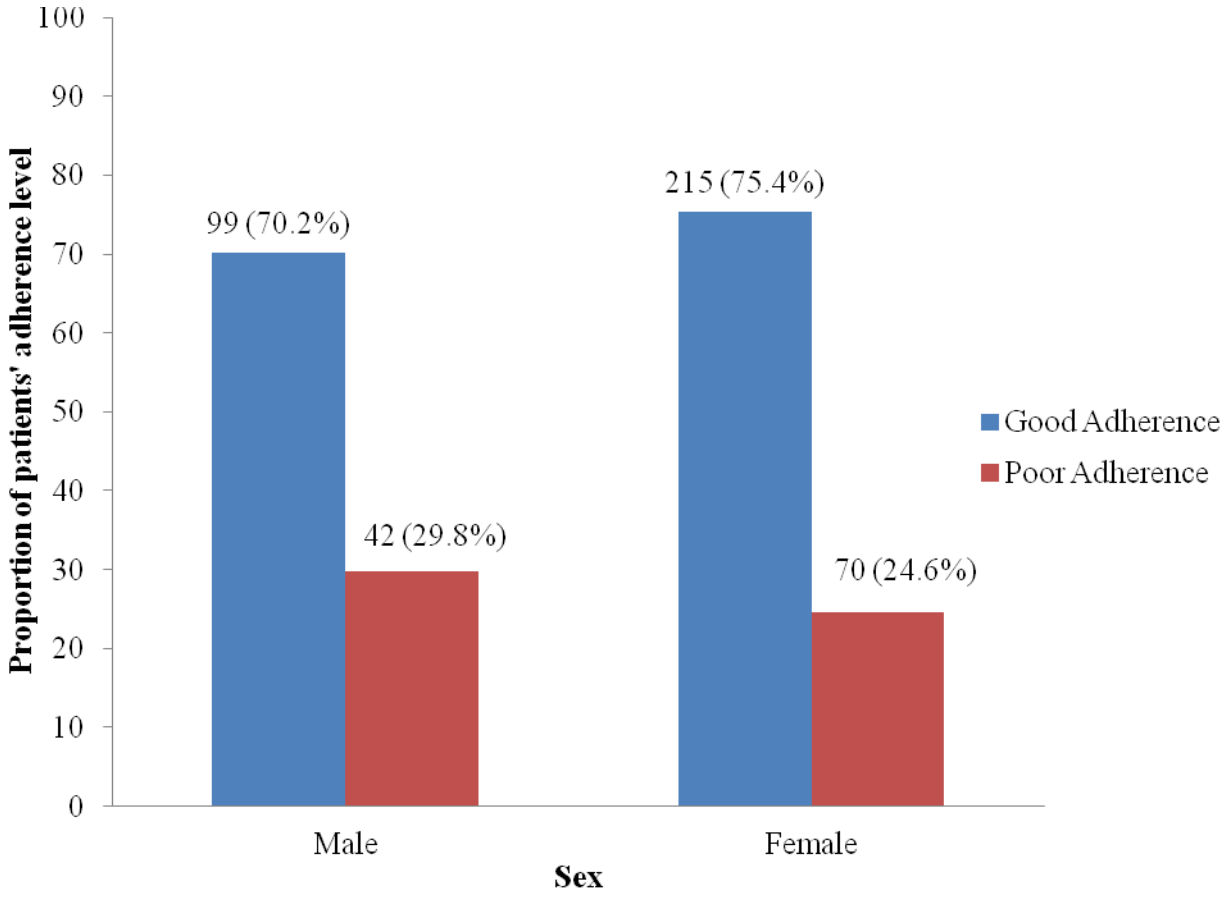


Figure 4.8: Gender distribution of respondents with their adherence status (n=426), NIMR, Lagos ART Adherence study, 2014

The majority of the respondents who had good and poor adherence were females; 215 (75.4%) and 70(24.6%) respectively, while good and poor adherence status among male respondents were 99(70.2%) and 42(29.8%) respectively.

Daily dosage of ARV drugs

Distribution of daily dosage of ARV drugs by respondents as shown in figure 4.9.

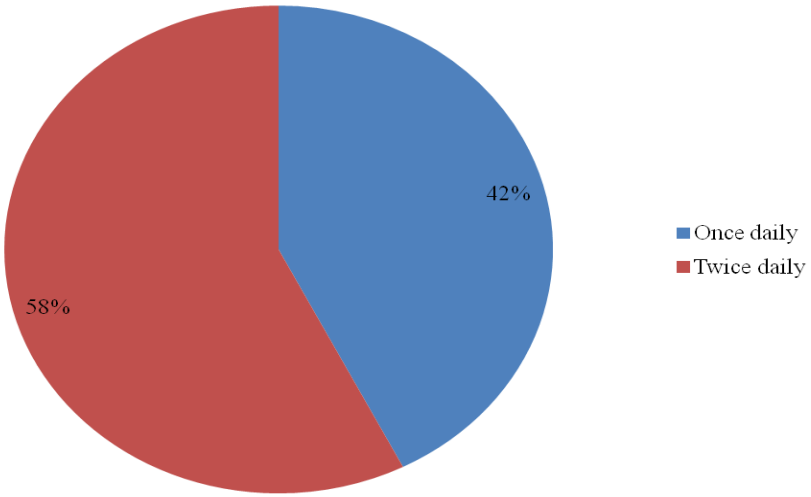


Figure 4.9: Daily dosage of ARV drugs of respondents with their adherence status (n=426), NIMR, Lagos ART Adherence study, 2014

The current available ARV drugs are either taken once daily or twice daily. Of the 426 respondents, 245(57%) take their drug two (2) times a day while 181(43%) were currently on one daily dose.

Missed doses of ARV drug combination

Proportion of respondents that missed dose (s) ARV drug combination in a month is shown in figure 4.10.

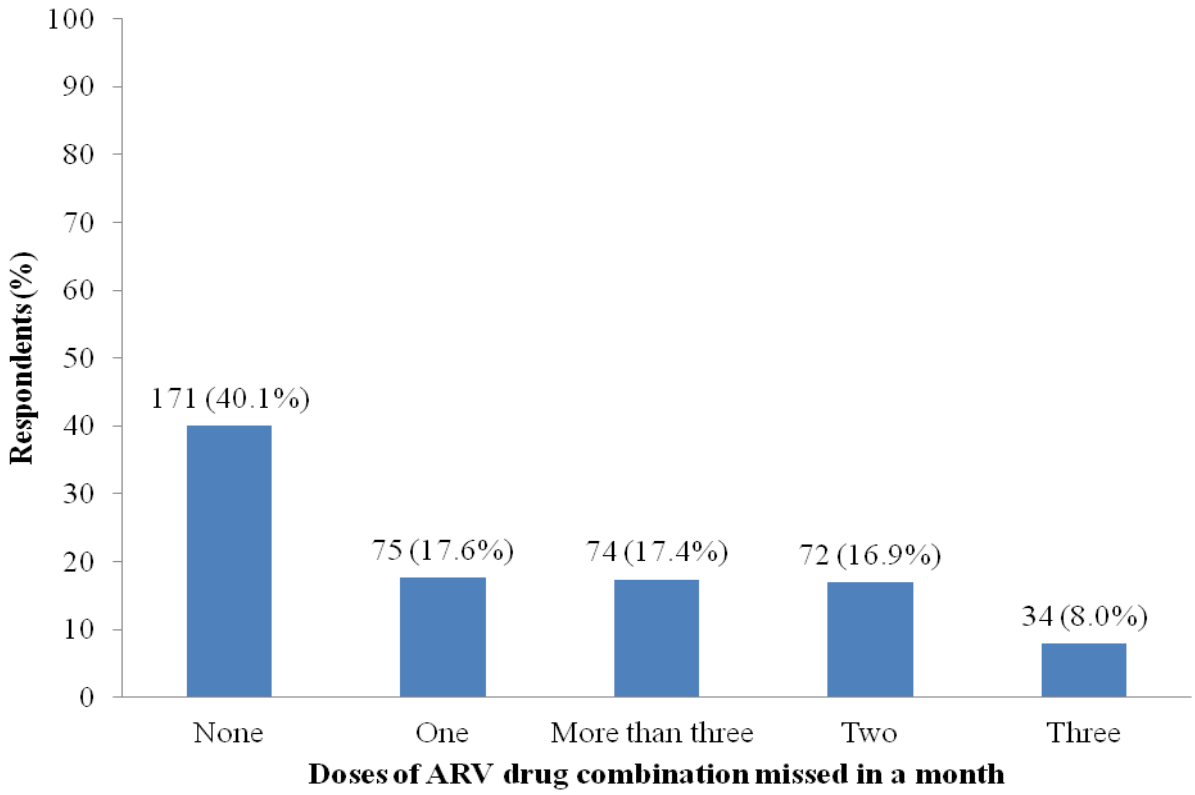


Figure 4.10: Proportion of respondents who missed dose (s) of ARV drug combination in a month (n=426), NIMR, Lagos ART Adherence study, 2014

Of the 426 respondents, 171(40.1%) did not miss a dose of ARV drug combination in a month followed by 75(17.6%) who missed one dose. Seventy percent of respondents missed two and more than three (3) doses respectively as well as 34(8.0%) who missed three doses in a month.

4.3 Knowledge on Anti-Retroviral Drugs (ART)

This section presents information about knowledge about ART including its benefits and side effects.

Knowledge about ART among respondents is shown in figure 4.11.

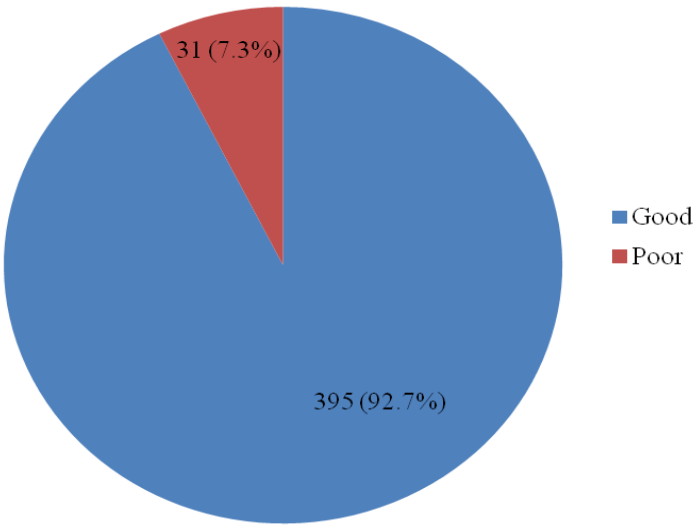


Figure 4.11: Proportion of respondents with level of knowledge about ART (n=426), NIMR, Lagos ART Adherence study, 2014

Ninety three percent of respondent had good knowledge of ART while 31 (7.3%) had poor knowledge.

Table 4.4 presents series of questions asked about knowledge about ART

Table 4.4: Series of questions and responses from respondents to assess level of knowledge about ART n=426), NIMR, Lagos ART Adherence study, 2014

Variables	n	Percent (%)
Basic laboratory tests are required before starting ART	426	98.8
Condom use by patients on ART prevent new strain of HIV	426	97.2
Failure to take ARV drugs daily can lead to treatment failure	426	96.9
3 successive adherence counselling is not required to start ART	426	93.9
Person who develop side effects of ART should stay home	426	93.2
ART can prevent progression from HIV to AIDS	426	92.5
It is not all HIV person who require ARV drug treatment	426	90.6
Person on ART cannot infect partners via sex or sharing of sharps	426	89.9
ARV drugs can lead to development of side effects	426	87.3
ARV drugs can prevent opportunistic infections like TB	426	86.4

Ninety nine percent of respondents know that a person needs to undergo series of laboratory investigation before starting ART, 414 (97.2%) know condom use by patient already on ART can prevent getting resistance strain. Ninety seven percent also that failure to take drugs daily can lead to treatment failure while 386 (90.6%) still know that despite being on ART, one can still infect partners through unprotected sexual intercourse and sharing contaminated sharps such as razor blades and needles. Ninety four percent know that minimum of three adherence counseling sessions are required before starting ART while 397 (93.2%) know that a person who develop side effects to the drugs need to see a physician for review.

4.4 Patient-Provider Related Factors

Patient related factors

This section presents information about patient related reasons for poor adherence to ART.

Table 4.5: Presents patient related reasons for poor adherence to ART (n=426), NIMR, Lagos ART Adherence study, 2014

Reasons	Frequency (n=367)	Percent (%)
Forgot to take Anti-retroviral drugs	203	47.7
Frequent trip/travelling	39	9.2
Too busy	23	5.4
Fear of stigmatization	16	3.8
Sleep off	15	3.5
Occupied with church activities	12	2.8
Getting home late due to traffic	11	2.6
Too many pills/pill burden	8	1.9
Stock was finished	8	1.9
Side effects	7	1.6
Taking time to take drugs	9	1.4
Others	5	1.2
Cost treatment	3	0.7
Felt better	3	0.7
Confusion	2	0.5
Drunk alcohol	1	0.2
Lack of transport fare	1	0.2
Too ill	1	0.2

Majority of respondents said that forgetting to take ARV dugs is one of the reasons they have poor adherence (47.7%). Other main reasons for poor adherence listed by respondents were frequent trip/travelling (9.2%), too busy (5.4%), fear of stigma (3.8%), sleeping off (3.5%), being occupied with church activities (2.8%), getting home late due to traffic (2.6%), pill burden (1.9%), stock finished (1.9%), development of side effects (1.6%), taking one's time before taking drug (1.4%), feeling better (0.7%), high cost of buying ARV drugs (0.7%), admission in hospital for other medical or surgical conditions (0.5%), confusion on whether drug has been taken or not (0.5%), too ill (0.2%) and drunk alcohol (0.2%). Approximately one percent gave other reasons such cigarette smoking, attending occasions, not responding well to ARV drugs.

Proportion of patient with reminder methods for adhering to ART

Proportion of respondents with reminder methods for adhering to ART is shown in figure 4.12.

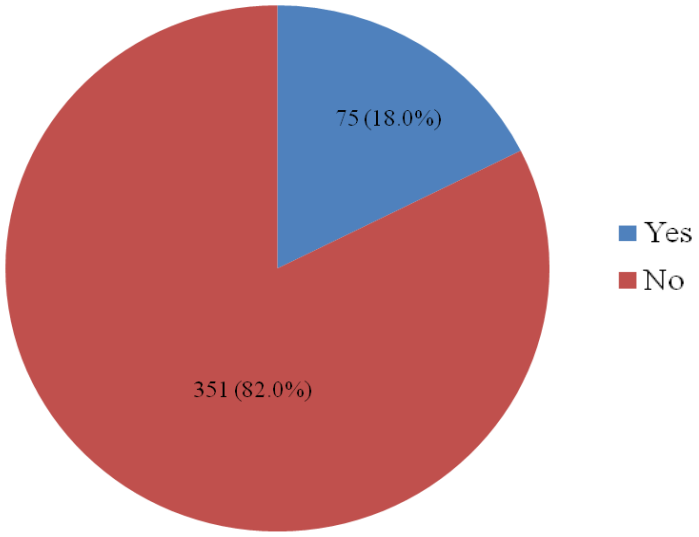


Figure 4.12: Proportion of respondents with reminder methods for adhering to ART (n=426), NIMR, Lagos ART Adherence study, 2014

Eighty two percent of respondents had reminder methods for adhering to ART while 75 (18%) had none.

Reminder methods for patients' on ART

Table 4.6: Presents patients' different reminder method for adherence to ART (n=351), NIMR, Lagos ART Adherence study, 2014

Methods	Frequency	Percent (%)
Using watch (alarm)	291	89.2
Spouse	29	8.3
Immediate family members	16	4.6
Moving with daily dose	12	3.4
Friends	2	0.6
Pharmacy	1	0.3

Of 351 respondents who had reminder method for adhering to ART as prescribed, 291(89.2%) use watch alarm as reminder, 29(8.3%) were reminded by their spouses, 16 (4.6%) were reminded by immediate family members who were their treatment supporters and 12(3.4%) move around with ARV drugs to ensure adherence. Only 2(0.6%) and 1(0.3%) were reminded by their friends and pharmacist respectively.

Adherence Counselling on ART

Proportion of respondents with adherence counselling on ART is shown in figure 4.13.

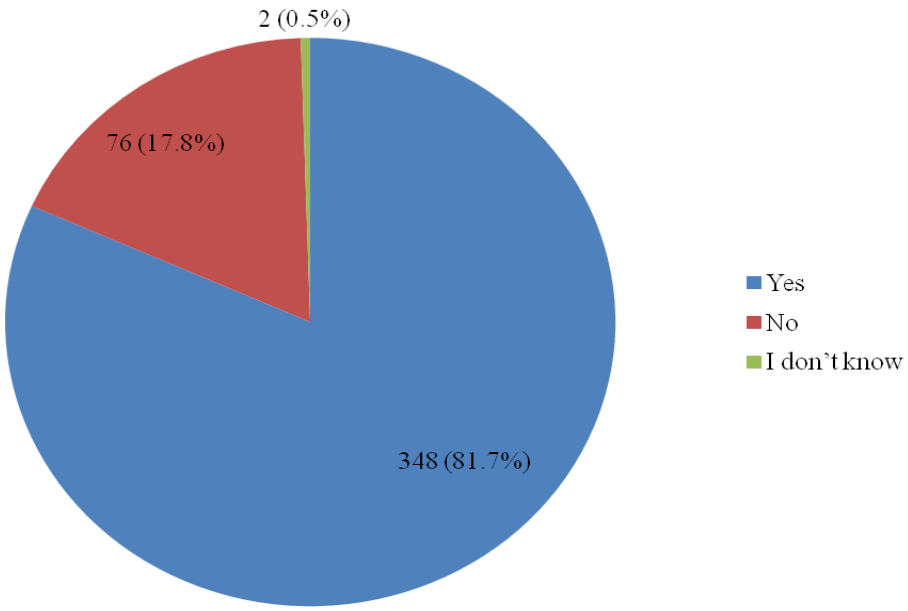


Figure 4.13: Adherence counselling on ART by respondents (n=426), NIMR, Lagos ART Adherence study, 2014

Of the 426 respondents who responded to question on whether they had adherence counselling before starting ART, 348(81.7%) said 'yes', 76(17.8%) said 'no' and 2(0.5%) said they do not know. Among the respondents, 408(95.8%) said adherence counselling was useful, 15(3.5%) said it was not useful and 3(0.7%) said they do not know.

Number of times counselled on importance of not missing doses of ART

Table 4.7: Presents number of times patients had adherence counselling sessions (n=426), NIMR, Lagos ART Adherence study, 2014

Counselling session (s)	Frequency (n=426)	Percent (%)
Three times	192	45.0
More than three times	174	40.8
Two times	28	6.6
Once	28	6.6
None	4	1.0

Of 426 respondents who were on ART, 192(45.0%) had three counselling sessions before starting treatment, 174(40.8%) had more than three times counselling sessions, 28(6.6%) had one and two counselling sessions. Only one percent of respondents never had previous counselling sessions.

Provider related factors

Adherence counselling messages from counsellors to patients.

Proportion of respondents who received important counselling messages is shown in figure 4.14.

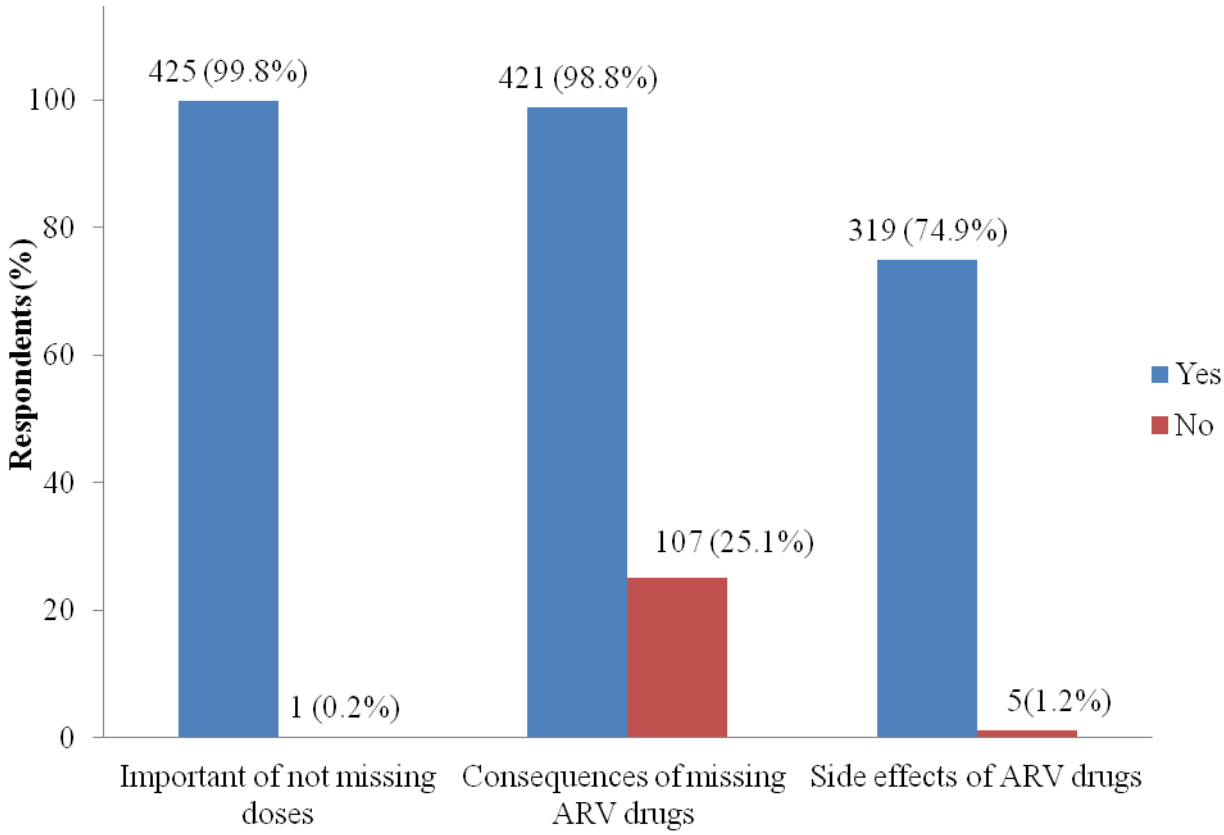


Figure 4.14: Proportion of respondents who received important counselling messages from counsellors (n=426), NIMR, Lagos ART Adherence study, 2014

Almost all respondents received counselling messages on importance of not missing doses of ART, 421(98.8%) received message on consequences of missing ARV drugs and 319 (74.9%) received information about possible side effects of ART.

Attitude of health workers to patient during clinic visits

Perception of respondents about health workers' attitude is shown in figure 4.15.

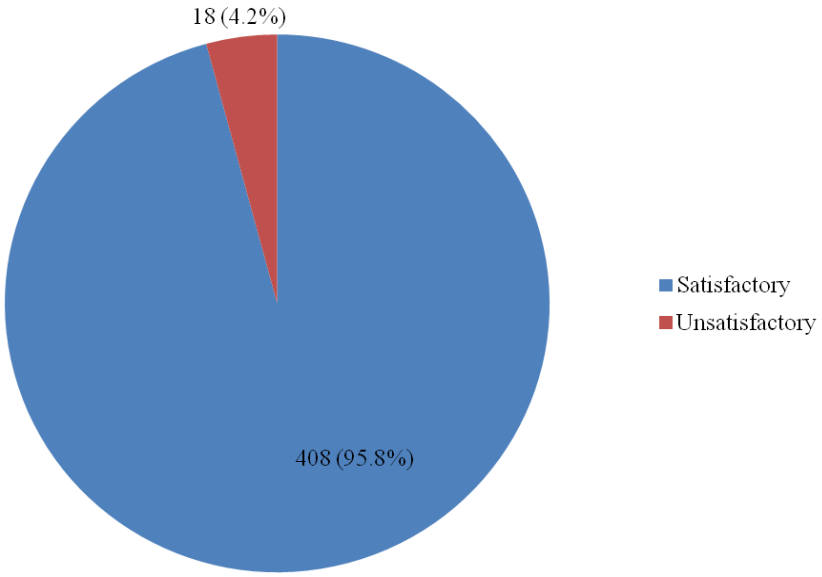


Figure 4.15: Perception of respondents about health workers' attitude (n=426), NIMR, Lagos ART Adherence study, 2014

Out of 426 respondents, 408(95.8%) were satisfied with health workers' attitude while 18(4.2%) were unsatisfied.

Perception of respondents based on adherence level

Perception of respondents about health workers' attitude based on their adherence level is shown in figure 4.16.

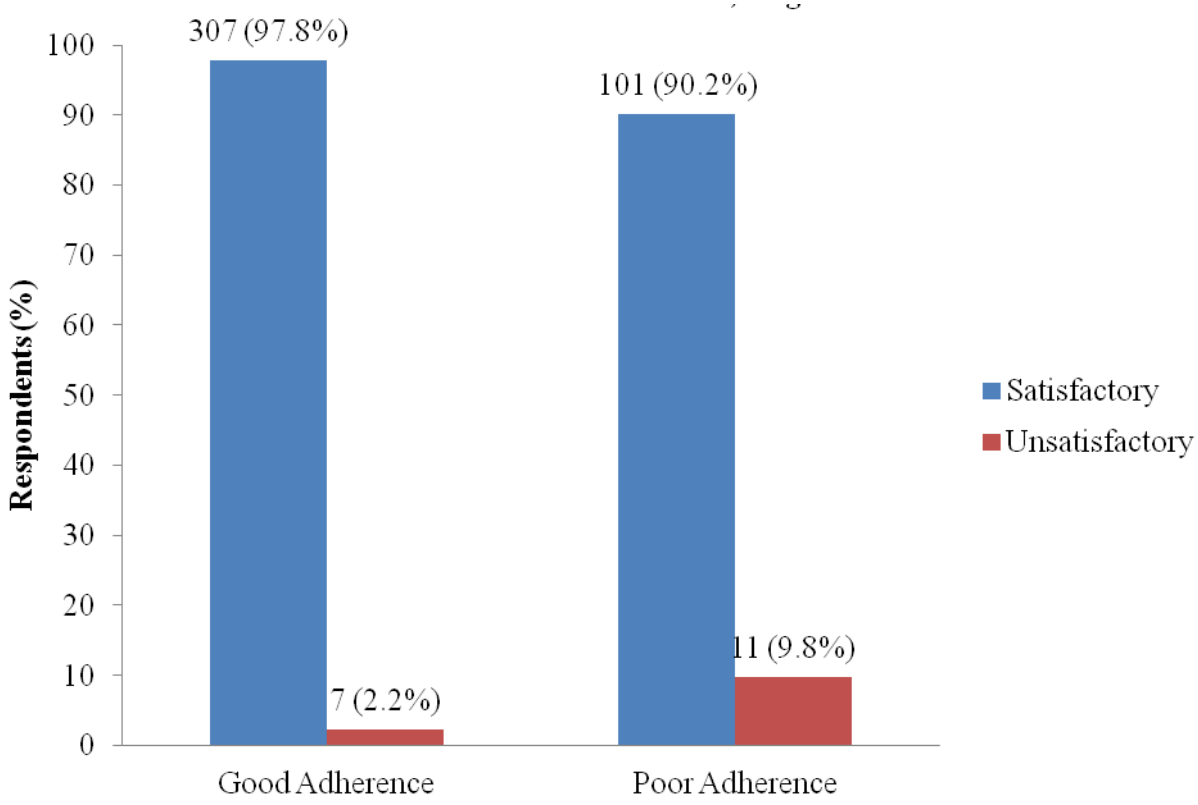


Figure 4.16: Perception of respondents about health workers' attitude based on level of adherence (n=426), NIMR, Lagos ART Adherence study, 2014

Out of 112 respondents who had poor adherence, 101(90.2%) said they were satisfied with health workers' attitude at the HIV clinic while 11(9.8%) said they were unsatisfied. Among 314 respondents who had good adherence, 307(97.8%) were satisfied with health workers' attitude while 7(2.2%) were unsatisfied.

Positive attitude of health workers

Perception of respondents about positive attitude of health workers' attitude is shown in figure 4.17.

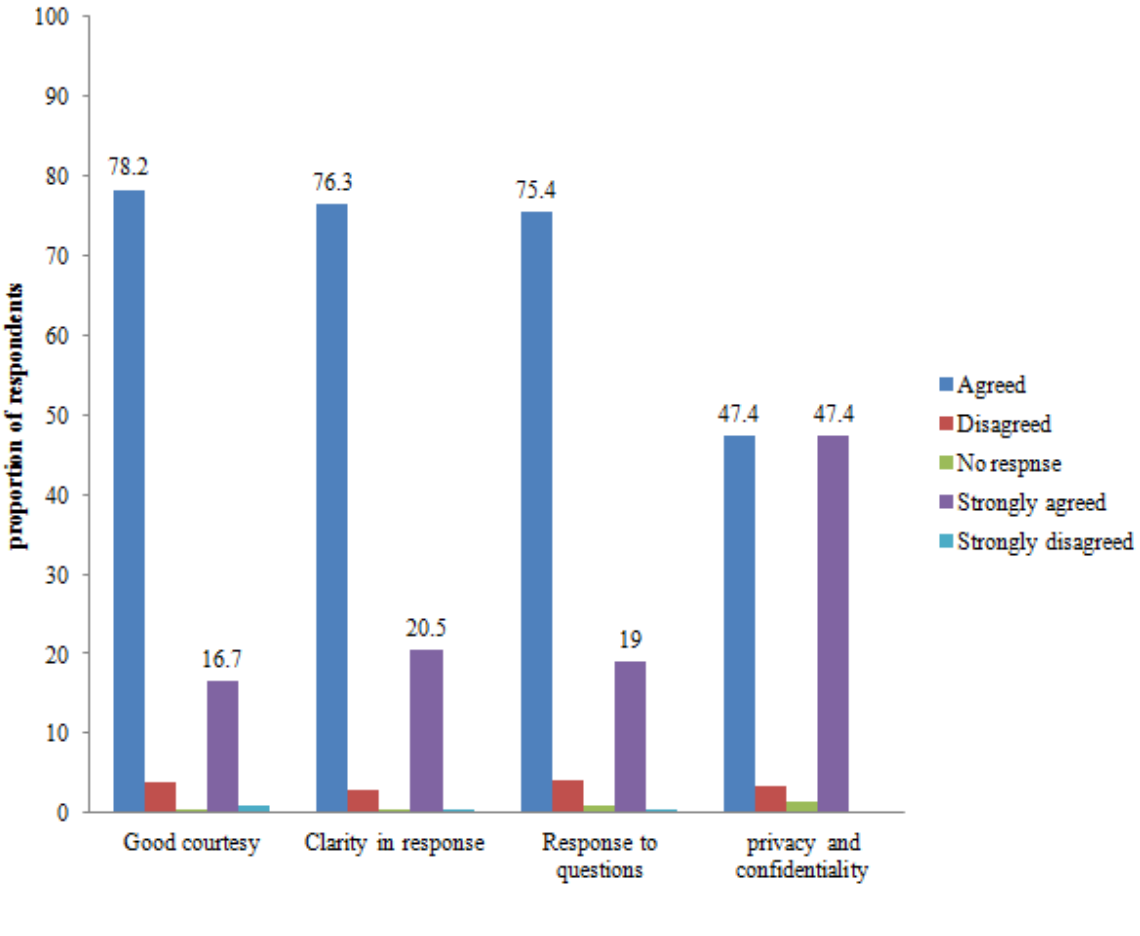


Figure 4.17: Perception of respondents about positive attitude of health workers (n=426), NIMR, Lagos ART Adherence study, 2014

For responses about all items of positive attitude of health workers, 94.9% of respondents agreed that health workers at the clinic had good courtesy, 96.8% said good clarity in response, 94.4% agreed that health workers respond well to questions and 94.8% believed that privacy and confidentiality are maintained on every visit by health workers.

Negative attitude of health workers

Perception of respondents about negative attitude of health workers' is shown in figure 4.18.

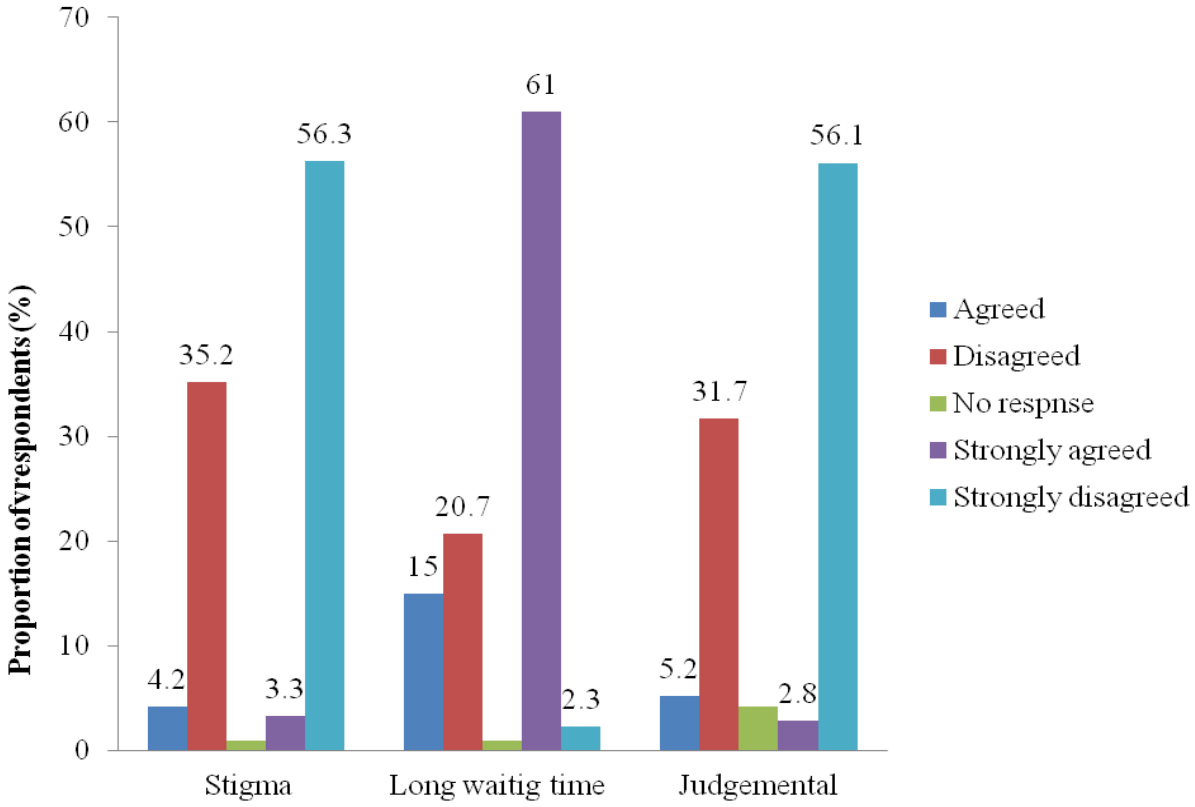


Figure 4.18: Perception of respondents about negative attitude of health workers (n=426), NIMR, Lagos ART Adherence study, 2014

For responses about all items of negative attitude of health workers, 91.5% of respondents agreed that health workers at the clinic do not stigmatize patients during clinic visits while 7.5% believed that patients were stigmatized. Seventy six percent of respondents complained of long waiting time during clinic visits while 23% did not agree. Eighty eight percent of respondents said health workers were not judgemental about their HIV status while 8% believed that health workers are often judgemental during clinic visits.

Table 4.8: Bivariate analysis of selected factors with poor adherence status, n=426) NIMR, Lagos ART Adherence study, 2014

Independent variables		Outcome Variables				
		Poor	**Good**	**OR**	**OR (95% CI)**	**p-value**
Sex	Male	42	99	1.3	0.8-2.1	0.3
	Female	70	215			
Educational status	≤ Primary	21	68	0.8	0.5-1.4	0.6
	≥Secondary	91	246			
Marital status	Single	34	73	1.4	0.9-2.3	0.2
	Married	74	222			
Occupation	Employed	103	278	1.5	0.7-3.4	0.4
	Unemployed	9	36			
Monthly salary	≤₦11,000	2	17	0.3	0.1-1.4	0.2
	>₦11,000	70	179			
Daily money for food	≤#500	18	39	1.2	0.6-2.3	0.7
	>#500	65	171			
Meals per day	≤2	26	64	1.2	0.7-2.0	0.6
	≥3	86	250			
Distance to & fro clinic	>5km	37	99	0.8	0.5-1.4	0.5
	≤5km	38	80			
Time to & fro clinic	>1 hr	83	222	1.2	0.7-1.9	0.6
	<1hr	29	91			
Transport fare to clinic	>#1,000	14	41	1.0	0.5-1.8	1.0
	≤#1,000	95	265			
No. of visit per month	≥2	3	10	0.8	0.2-3.1	1.0
	≤1	109	304			
Knowledge about ART	Poor	13	18	2.2	1.0-4.6	0.07
	Good	99	296			
Attitude of health workers	Unsatisfactory	11	7	4.8	1.8-12.7	**0.01**
	Satisfactory	101	307			
Counselling sessions	<3 times	25	35	2.1	1.2-3.9	**0.02**
	≥3 times	87	279			
Not received counselling	Yes	106	242	5.1	2.1-13.5	**0.01**
	No	6	70			
Received counselling from non-health workers	Yes	4	1	11.1	1.2-100.2	**0.03**
	No	103	285			

Being a male, single, employed, spending ≤₦500 daily on food, having ≤2meals per day, spending more than 1 hour to and fro HIV clinic and having poor knowledge of ART though no statistically significant at $p<0.05$, had odds ratios (OR) greater than one, indicating some association with poor adherence while having completed primary school or none, having a monthly salary of ≤₦11,000, travelling a distance of >5km to and fro HIV clinic and visiting clinic two or more times a month see to be protective but not significant at $p<0.05$.

However, unsatisfactory attitude of health workers at the clinic, failure to receive adherence counselling and undergoing sessions less than three times before starting ART as well as receiving adherence counselling from non-health workers were significantly associated with poor adherence.

Multivariate-Logistic regression analysis

Table 4.9 presents findings for those variables that were significantly p<0.05 which were subjected to unconditional logistic regression analysis.

Table 4.9: Multivariate analysis of the variables significant at p<0.05 with poor adherence as outcome, (n=426) NIMR, Lagos ART Adherence study, 2014

Variable	Poor Adherence AOR	p-value
Attitude of health care workers to patients		
Unsatisfactory	4.8	0.01
Satisfactory	1	
Number of counselling sessions before starting ART		
< 3 times	2.1	0.01
≥ 3 times	1	
Non-health workers giving adherence counselling		
Yes	10.9	0.03
No	1	

Poor attitude of health care workers (AOR 4.8, p-value-0.01), patients who received less than three times adherence counselling session before starting ART (AOR 2.1, p-value-0.01) and non-health workers (friends, family members, spouses e.t.c.) giving adherence counselling to patients (AOR 10.9, p-value-0.03) were significantly associated with poor adherence to ART.

Qualitative findings

Socio-demographics

The focus groups were formed to be fairly homogenous with respect to age and sex in order to minimize inhibitions in the flow of the discussions. Each FGD group comprised of 8-10 participants while the in-depth interviews had a male and female participants who were on ART for minimum of five years. The ages of the FGD participants and key informants interviewed ranged from 20 to 50 years. Most of them were married (74%) with a few who were never married (15%) while some were separated (11%). High literacy level was reported among the participants as most (78%) had a minimum of secondary education with a few others having primary education (22%). Their occupation ranged from being artisans (13%), unemployed (8%), trading (50%), formal employment (29%) in both public and private sectors as civil servants and professionals respectively. There was gender difference in the income earned per month between the male and female participants. While the income of the males ranged from ₦15,000.00K to ₦300, 000.00K per month, it ranged from ₦10, 000.00K to ₦120,000.00K among the females. A few of the female participants were however unemployed with no earned income (15%).

All the FGD participants and those interviewed were on ART medication for a duration that ranged from 6 months to 10 years having been diagnosed of having HIV overtime that ranged from 1 to 12 years. A male participant (no.10) in a focus group pointed that:

"I was diagnosed to have HIV in 2004 at the Ikeja General Hospital, I came to the Central Laboratory in Yaba to carry out a confirmatory test and I later came to NIMR

and started taking the drugs in 2005."

Adherence level

Many of those interviewed and the FGD participants could vividly describe what adherence means. It was repeatedly heard in the focus groups that drug adherence means "*…following one's normal dose of medication."* A female FGD participant (no.2) for example explained adherence as thus: "*...following your normal dose, your medication…doing as you're told to do by the doctor without failing or defaulting.*" Another female respondent interviewed described adherence to mean "*...taking the number of tablets and sticking to the time prescribed for one to be taking the drug.*"

There were mixed reactions on the extent to which the prescribed ART regimens is adhered to among the FGD participant and those interviewed. In all the group discussions and interviews, the same adherence pattern prevailed. While most participants and the interviewed had no adherence problem while had some delayed in taking their drugs.

A male participant (no.11) emphatically pointed out that, "*I've never defaulted ever since I started taking the drugs. I usually put it (a dose) in an envelope when going to the office.*" Another male participant (no.2) revealed that, "*...when it's time, since the time I started taking the drugs…whenever it's 10 o'clock, I take it and wherever I go, I go along with my drugs.*

In contrast, among those who have defaulted at one time or the other, a male participant (no.16) in a focus group pointed that, "*I guess it was on two occasions that I travelled that I missed taking my drugs. I didn't even plan not to come back that day. I thought that by 7*

p.m. I should be back at home but I couldn't, so I missed taking it that night and the following morning."

Knowledge about ART

When the participants were asked the name(s) of the ART drugs they were taking for their management, majority of them could correctly mention the name(s) of the ART drugs being taken and described the dosage. A male participant (no.4) in a focus group for example explained that, "*I take Septrin every morning, then the other one…Nevirapine, Zidovudine and Lamivudine…I take all of them around 8 o'clock in the morning and at night.*" Another participant (no.8) pointed out that, "*I'm taking Nevirapine Lamivudine and Zidovudine combine, one in the morning and one at night. Later, they (health workers) changed the regimen and I now take it only at night...once a day*" A female FGD participant (no.7) also said, "*I take Efavirenz, Tenofovir and Emtricitabine combined, one in the morning at 7 o'clock and one in the evening at 7 o'clock.*" Also, a female respondent (no.8) interviewed stated that, "*I take the Lamivudine, Zidovudine and Nevirapine twice daily…at 9 o'clock in the morning and at night.*"

In contrast, a few others could not mention the name(s) of the drug(s) they take as reflected in the response of male FGD participant (no.11) who said, "*…I'm not sure of the name...but I take one tablet twice daily with Septrin taken in the morning…once daily.*"

The FGDs and interviews revealed positive perception of the benefits of taking ART drugs. Though the participants had divergent views in their description of perceived benefits of taking ART drugs, the pattern of discussion in most of the FGDs and

interviews is similar. The majority of FGD participants and those interviewed exhibited a high knowledge of the benefits of taking the ART drugs. In his words, a male FGD participant (no.6) explained that, "*It is useful for us (HIV positive persons) taking the drugs because for someone like me, I don't usually feel sick. The only sickness that I usually experience is joint pains. Since I started taking these drugs, I no longer feel those pains. Sometimes I have this short sight…I can't see clearly and it enhances my appetite.*" Another male participant (no.7) stated that, "*…since I started taking my drugs, I've been back to my normal life. Your life is your drug…it has to become part and parcel of you.*" A female participant however emphasised that, "*…for me, the drug is like my first life. After God, it's the drug. I know how I was when I first came to this place (ART clinic)…I was so thin but since I started taking it, I've been okay. The drug is very good.*" Another female participant (no. 4) in a focus group reported that, "*What make me to take the drug is that since I started taking the drugs, it makes me feel happy. Anytime I take it, it makes me feel better because I recollect that when I started I was so sick and down.*" In another discussion, a woman (no.9) stressed the importance of staying alive to care for her family as she said, "*I want to be healthy…to be fine…I want to stay alive for my husband and my children.*" Another female participant (no.3) in a focus group revealed that, "It's helpful*…since I've been taking the medicine; I've not been admitted to the hospital for any reason. My viral load has gone down drastically going by my last laboratory test results as explained to me by the doctor during my last appointment.*"

Patient-related factors

Challenges and/or constraints to taking the ART drugs as mentioned by some of the

participants are the problems of financial challenge and drug fatigue. It was explained that some patients on ART medication are placed on some ART drugs that are most times out of stock (e.g. Abacavir) at the clinic which they would be required to buy outside at private pharmacy shops at exorbitant prices. Moreover, it was reported that there are times when the patients would have money to buy the ART drugs but such drugs will be out of stock and unavailable in the market or pharmacy shops, thereby making the patients to miss their doses throughout the period of the drug stock out. One of the FGD male participants (no.5) reported that "*...when I have money, I have where I can go buy the drugs without coming here (the ART clinic)… but there was a time I didn't have money that I missed taking the drugs for about three days. Also, there are times when I have money and kept looking for where to buy the drugs without getting it to buy.*"

In addition, the focus group discussions and interviews revealed that many patients become tired of taking the drugs as prescribed for days, weeks, months and years. Subsequently, this prolonged period of taking the drugs for months and years usually starts taking its toll on many patients' adherence pattern because they become tired of the drug routine and tend to skip some doses. This is reflected in the response of participant (no.6) in a focus group who stated that, "*...why some people default is as a result of having to take drugs every day. This may be unusual to them…taking drugs may be unusual to them right from the onset as there are some people who are not comfortable in taking drug not to mention taking it every day*."

Another constraint to ART drug adherence is the challenge of nightmares usually experienced and reported by many patients particularly those who are placed on

Efavirenz. A male FGD participant (no.8) for example pointed out that, "*…when I sleep after taking the drug, I dream a lot [laughing]. Sometimes, it could be sweet dream like finding me in the midst of white men and at times it could be horrible dream.*"

Other challenges mentioned in the focus group discussions and interviews included: nature of work; the fear of not wanting family members and relations, friends, neighbours, friends and colleagues at work becoming suspicious or knowing about the drugs they routinely take every day probably due to the problem of potential stigma that is associated with HIV/AIDS; the poor attitude of health workers attending to the patients at the ART clinic particularly the nurses; the long waiting time at the clinic when patients come to either collect drugs or see the doctor for consultation on appointment days; role conflict of being a worker and a patient which results in the problem of time management and constraint in going to work and leaving work with series of excuses to go to the ART clinic for appointment and/or pick drugs, where a whole day is spent due to long waiting time and the fear of the consequences that he/she could be sack; and habit of smoking and consuming some food (such as junk foods), drinks (such as alcohol) that cause drug interaction and compromise immunity among some patients on ART medication (15%). A female participant (no.5) in a focus group for example explained that, "*My main challenge is that I feel like I'm choking if I don't take it (the drug) with enough water…it always seemed the drug is stuck in my chest. Also, when we have visitor(s) staying with us (family) at home for many days, I always feel uncomfortable taking the drug at the prescribed time everyday with the fear of being observed by the visitor(s) who may be wondering what is this woman always taking at the same time of the day on a daily basis.*

So, the fear of raising their suspicion at times becomes challenging to me. I then tend to hide whenever I want to take it."

In order to keep to time of taking the doses of ART drugs as prescribed, many of the FGD participants suggest the need for patients on ART to use the alarm clock set at the required time to serve as reminder for them. It is believed that the use alarm clock will enhance adherence to ART regimen among patients.

Provider-related factors

A male participant (no.13) in a focus group expressed his frustration thus: "....*My own challenge is not with the drug but the clinic…the way and manner the health workers respond to us (HIV patients)…it's very bad. They (health workers) don't know who we the patients are. But just because of this illness that made us to come together here (ART clinic). They shouldn't take that advantage to talk to people the way they want. At times when I come here to pick my drugs, I usually find it very difficult because of the long time it takes to get the drugs. I wondered that if I was employed by someone, would I be able to spend so much time here on each occasion just to pick my drugs or see the doctor.*" In her response relating the constraints she experiences, a female respondent in an in-depth interview pointed out that, "*...I usually spend half of a whole day here at the clinic whenever I come to pick my drugs or see the doctor…it could be frustrating*"

In addressing the challenge of long waiting time, a female participant (no.14) opined that, "*I'd suggest that the clinic should employ more doctors and nurses to attend to patients. Those working seemed to be overwhelmed by the number patients attending the clinic.*

The doctors should also endeavour to resume work early so that they can always start attending to patients who always come to the clinic so early to the clinic in earnest."

To improve the level of adherence to ART regimens at the individual level among the patients, a male FGD participant (no.3) wondered and opined that, "*…if only there is a way in which they (drug manufacturers) can bring up the vaccine whereby one would be injected once in a month or three months…I believe this will cut down the problem of default in taking drugs among patients.*"

On the other hand, in addressing the challenge of time constraint and role conflict as worker and patient, a female participant (no.8) in a focus group suggested that, "*If there is any way they (health workers can assist us (patients) by giving us drugs that would last us up to two to three months at a time, this will help those of us who are working and always have this challenge of time constraint in leaving our offices to come to the clinic spending the whole day…this affects us at work because it's challenging at times getting approval from the office every month to come to the clinic…so if we're given drugs for three months and when we're coming after the three months, we'd be relaxed.*"

Other suggestions proffered in the focus group discussions and interviews included: establishment of more outlets where patients can easily pick up their drugs as a strategy of improving proximity to the care and reducing patient waiting time (100%); the computerization of the keeping and retrieving of medical records and the general management of patients in the clinic (70%); and the need for attitudinal change among some cadres of health workers providing health care services to patients particularly the

nurses and some doctors in the clinic (100%). In a bid to emphasise the need for change in attitude among health workers in the ART clinic towards patients, a female participant (no.8) in a focus group said that, "*...there're some doctors that are very good…if you're to see them you'd be so glad to enter their offices for consultation and there're others that not too friendly to the extent that you'd be uncomfortable to want to go see them for consultation.*"

CHAPTER FIVE

DISCUSSION

Of the 426 patients recruited for this study, only 73.7% reported good adherence in the last 30 days preceding the interview while 26.3% poor adherence in terms of missing doses and timing of dosage administration. The reported adherence to ART of 73.7% in this study is similar to reports from Lagos and Ibadan in Southern Nigeria[49,54] and among depressed HIV patients at Zaria in Northern Nigeria[42] where 78.4%, 75.4% and 73.0% were reported, respectively. Higher levels of adherence have been reported from Lagos as 89.4% by Sekoni et al. and 80.6% among pregnant women on ARV prophylaxis.[52,53] Higher adherence levels were also reported from other parts of Nigeria as 81% by Shittu et al. from Ilorin, 87.9% in Jos Nigeria by Falang et al. and 97.9% by Onyeonoro.[18,45,47] Some African countries have also reported levels higher than observed in this study.

These include reports of 87.4% in Walaita Soddo, Ethiopia, 82.0% in Nairobi, Kenya and 82.0% in South Africa.[37,39,77] However, some studies in Nigeria have reported lower adherence as compared to what was reported in this study. There have been reports of 52.2%% in Sokoto, 63.6% in Keffi, 59.9%% in Calabar, 44.0% in Ile-Ife and 14.9% in Nnewi.[14,17,41,63,65] The differences in adherence levels from other studies might have been that there is no gold standard in the measurement of this parameter. For example, apart from using periods of recall time to determine adherence, there was difference in study designs and methods for measuring adherence levels. Another important factor is the difference in the quality of service delivery provided to the patients. Furthermore, most of the studies failed to state whether all services (clinical and laboratory) provided at the

facility including ART were given free of charge to patients. Ekama et al. and Shittu et al., posited that likely reasons for improved adherence level was that all the services rendered to these patients were at no cost which includes free, regular and uninterrupted supply of quality antiretroviral (ARV) drugs, medical laboratory tests and financial support.[52,45] Also, drugs for opportunistic infections and palliative care were all made free for both in and out patients. Rapid improvement in symptoms and signs that brought the patients to the hospital encouraged adherence. No food restriction, proper follow up, monthly adherence counseling were contributing factors to adherence rate.The proportion of poor adherence in this study is similar to the 24.6%, 23.3% and 23.1% reported in Ibadan, Ile-Ife and Port Harcourt respectively,[49,58,93] but higher than 10.6 and 19.4%% reported by Sekoni et al. and Ekama et al. in Lagos, Nigeria.[52,53]

The majority of the respondents had good knowledge about ART and this is similar to report from Lagos [52,53] and Ile-Ife in South-west Nigeria, Umuahia [47] and Jos [18]). Other researchers from some African countries have also reported higher level of knowledge about ART among study respondents. While Nachega et al from South Africa reported good knowledge about ART as 89.0%, Boateng et al. from Ghana reported 96.7% among pregnant women accessing PMTCT service.[55,94] However, a small proportion of the respondents had poor knowledge about ART. For example, approximately one tenth of the study group did not know that it is not all HIV infected persons who will require ARV drugs for treatment as well as person on ART can infect partners via sexual intercourse or sharing of sharps. This finding was similar to study conducted at Ile-Ife by Olowooke et al. However, as reported in Lagos, Ile-Ife and Jos by Ekama et al., Olowooke et al., and

Falang et al. respectively[18,50,52] it would be expected that high knowledge of ART among study participants would have influence adherence. There was no association between adherence and level of knowledge in this study. This finding was also in contrast to the report of Boateng et al. from Ghana.[94]

The mean age among the study participants of 39.3 (SD 8.9) corroborates with findings from study by Olowooke et al from Ile-Ife[58] but in contrast to report of study by Sekoni et al and Kasumu et al. in Lagos State.[53,54] Findings from studies from other African countries were also in contrast to result from this study as reported by Talam et al. 2008 in Kenya.[60] In this study, the proportion of female on ARV drugs is almost twice that of male counterpart. This corroborates with other studies in Lagos, Sagamu and Ile-Ife[51,54] which reported that the proportion of females was more than that of the males and Afolabi et al. Shittu et al and Erah et al from Ile-Ife, Ilorin and Benin.[45,65,68]

Findings from studies conducted Wakibi et al and Talam et al from Kenya and Peltzer at al from South Africa also reported that the proportion of female was approximately twice that of male respondents.[39,60,77] However, this finding is in contrast to report of studies conducted by Olowookere et al in Ile-Ife in South-western Nigeria where proportion of males on HIV treatment was almost that of females.58 The reasons for having higher proportion of females on treatment in this study might not be unrelated to the fact that women are less able to cope due to cultural, social and economic factors.[95]

Financial dependence makes it difficult for women to negotiate condom use, or to refuse sex if they suspect the partner is infected. Monogamy does not always protect women,

either. Available physiological data seem to indicate it's something like twice as easy for women to become infected as for men.

Findings from this study which revealed that two-third of the respondents were married which was similar to report from studies conducted in Lagos and Sagamu.[51,53,54] A similar finding was reported by Talam et al from Kenya.[60] However, this finding did not corroborate with other findings from studies conducted in Ile-Ife and Enugu[50,64] and other Africa countries as reported by Wakibi et al in Kenya.[39] This is expected since the major route of HIV transmission in Nigeria is through hetero-sexual intercourse which can easily spread among couples.[4]

This study which revealed that at least two in every five of the respondents completed secondary education was also reported by other studies conducted by Ekama et al, Sekoni et al. and Kasumu et al in Lagos State[52,53,54] while Olowookere et al from Ile-Ife reported higher proportion of respondents who completed secondary education (approximately four in every five participants).[50] This finding corroborates that of Talam et al but in contrast to that of Wakibi et al from Kenya.[39,60] One tenth of study participants were unemployed which was similar to report of a study in Lagos by Kasumu et al and Olowookere from Ile-Ife.[50,54] However, this is in contrast to report of studies conducted in Ibadan and Ile-Ife by Kayode et al and Olowookere which reported a lower proportion of respondents unemployed.[49,50] However, Afolabi et al, Oku et al and Falang et al from Ile-Ife, Calabar and Jos respectively reported higher proportion of respondents who were unemployed.[14,18,65] Reports from studies from other researcher from African countries also revealed higher and lower proportion of respondents with unemployment in Kenya

and Ethiopia by Wakibi et al and Hailesellassie et al respectively.[39,78] In addition, majority of respondents were Christian in this study. This finding corroborates with other studies carried out in Lagos, Sagamu and Ile-Ife by Kasumu et al, Ogundahunsi et al and Afolabi et al.[51,54,65] However, Sekoni et al and Erah et al from Lagos and Benin respectively reported less proportion of respondents who were Christians.[53,68] Likewise, Peltzer et al from South Africa reported lower proportion of respondents who were Christians in previous study.[77]

Most socio-demographic characteristics such as age, sex, marital status, educational attainment did not significantly affect adherence amongst study population. This corroborates the findings of other researchers from Ile-Ife and Port Harcourt[7,58,65] but in contrast to the finding of a study in Lagos, Enugu and Jos by Kasumu et al, Uzochukwu et al and Danladi et al and Falang et al respectively who reported older age was associated with good adherence.[18,54,62,64] Furthermore, a study in Ibadan, Enugu and Jos by Kayode et al, Uzochukwu et al and Danladi et al respectively found being single to be associated with good adherence[49,62,64] whereas Pennap et al from Keffi reported higher adherence level among married respondents.[17] A similar finding was reported by Sasaki et al and Bha et al from Zambia and South Africa revealed that adherence among single was higher than among married respectively.[36,61] Additionally, Uzochukwu et al from Enugu reported female respondents had higher adherence compared to males.[64] This finding was also reported by Sasaki et al and Wasti et al. from Zambia and Nepal respectively.[34,61] However, Uzochukwu et al and Falang et al reported higher adherence among males than females.[61,64] Being educated was associated with good adherence as reported in other

studies conducted in Ile-Ife, Enugu and Nnewi[63,64] while being employed was associated with good adherence as reported by studies conducted by Afolabi et al., Uzochukwu et al and Falang et al. However, Okoronkwo et al reported that being employed was associated with missing doses of ARV drugs.

Other socio-economic variables were also found not to be associated with adherence. However, other studies conducted in Ile-Ife, Enugu and Keffi reported that those who earn #5,000 or more monthly, able to afford cost of transportation to health facility, living close to health facility were associated with good adherence.[17,64,65] Sasaki et al from Zambia also opined that food sufficiency was associated with good adherence.[61]

Some of the reasons cited by study participants for missing doses included forgetting to take ARV drugs, frequent travel, too busy, fear of stigma, sleeping off, occupied with church activities, getting home late due to vehicular traffic pill burden, stock out, side effects, cost of treatment and felt better. Forgetting to take ARV drugs (47.7%) was the major reason for missing ARV medication followed by frequent travel (9.2%). This finding was consistent with report of other studies in Lagos by Sekoni et al and Kasumu et al.[53,54] While Kasumu reported being away from home as the major reason for missing ARVdrugs, Sekoni reported pill burden as the major reasons in addition to fear of stigma, travelled without medication, felt better and side effects. Other researchers from Benin, Nnewi, Enugu, Calabar and Ilorin also reported similar findings.[45,63,64,68,96]

Findings from studies by other researchers from Kenya and Ethiopia were also consistent with result of this study on patient related factors associated with adherence.[38,60] Wasti et

al from Nepal and Hansana et al from Vietnam also reported similar finding.[34,66] However, being occupied with church activities and getting home late due to vehicular traffic jam appeared to be finding which were not cited by most of the researchers who conducted other studies on adherence to ART in Nigeria and other countries outside Nigeria. This finding was expected in Lagos where vehicular traffic jam has become a common occurrence. Being occupied with church activities as reason for missing taking ARV drugs might be due to patients' full involvement in church programs which might make them forget taken their drugs or miss the timing for taking particular doses of drugs. Taken along with their medication would have address this challenge to a minimal level. Other patient related factors to poor adherence in this study were receiving adherence counselling from non-health workers and having adherence counselling sessions of less than stipulated three times. These findings were totally not in compliance with the National treatment guidelines before commencement of ART by patients. Erah et al from Benin and Pennap et al from Jos respectively reported that lack of prior or limited exposure to adherence counselling was also found to be a very important factor for poor adherence in this study.[17,68] This finding was also reported in similar studies carried out 2008 in Chad by Donato et al. Therefore, all the patient related factors need to be taken into account in planning personalized interventions, specialized counseling for patients, and training programs for health workers at the facility. It is also important to note that expertise is required for quality and effective adherence counselling as stipulated in National treatment guidelines. From finding which revealed that those counselled by non-health workers had problems with adherence as compared to health workers, it will be

highly important to allow well trained health workers counsel patients on adherence as against some patients' family members, support groups and friends who despite been trained and skilled in adherence are not regarded by other patients who are also their co-patients on treatment.

In this study, poor attitude of health workers was a significant factor for poor adherence among HIV patients on treatment. Amongst this poor attitude includes lack of courtesy, poor response and clarity to questions, long waiting time, lack of privacy and confidentiality, being judgmental, stigmatization and discrimination of patients. Some of these negative attitudes by health workers might have been influenced by patients' load, under-staffing, lack of motivation, personality issues and limited infrastructure that would require prompt intervention by head of clinical department and the institution management. Some of these this finding corroborates with a study conducted by Erah et al from Benin in Southern Nigeria where lack of confidentiality was associated with poor adherence to ART. Report of studies by other researchers from other African countries was also similar to some of the findings from this study[71] as well as other studies from Netherland, San Francisco and Brazil (Langebeek et al., Chesney et al. and Carlos et al.).[10,31,70] In addition, the low perception of quality of patient-provider interaction has been identified as one of the major factors patients miss appointment and in so doing fail to adhere to their drugs. This finding was further elaborated by Sonjobo et al, Nechega et al., Reda et al. and Skovdal et al. Hence, the importance of patient-provider interaction need to be emphasized and concerted effort be made to educate and equipped health workers with basic tools that will ensure a satisfactory atmosphere to quality service

delivery. In other words, patient-provider friendly health settings contribute immensely to patients' good adherence to ART.[69]

Findings from qualitative study also revealed that majority of interviewees had good knowledge of ART including its benefit to improving patients' health status. This is justified by high proportion of those who had no adherence challenge as compared to a relative few with poor adherence. Unsatisfactory attitude of health workers was identified by the majority of participants as impeding adherence to ART. Particularly mentioned were the long waiting time and unfriendly nature of some of the nurses and doctors during follow-up visits and drug pick-ups. This finding corroborates a study conducted by Okonkwo et al from Lagos in 2011 which similar to report by Andrew et al from South Africa.[69,72] This patient- provider factor might drastically affect adherence. Therefore, concerted effort need to be made by relevant stakeholders to address this issue so as not to discourage patronage by HIV patients on treatment and further worsen conditions of those confronted with adherence challenge.

Other adherence barriers raised during the interviews included fear of stigma and discrimination, fear of long time side effects of ART including frequent night mares, drug fatigue, stock out and cost of buying out of stock ARV drugs (Abacavir), fear of being sacked from current work, forgetfulness, sleeping off, confusion, smoking and alcoholism. For fear of being stigmatized and discriminated, majority of those employed failed to disclose their HIV status to their employers which poses a major challenge when seeking permission most times from their employers for follow up visits and drug pick-ups at the clinic. This is further complicated by the idea of spending a whole day at the

health facility in a bid to either see a doctor for consultation or a pharmacist and adherence counsellor for their drug pick- ups. Some even get threatened by their employer to relief them of their earned. This dilemma has continued to worsen existing adherence challenge. Therefore, as the health facility continued to support in-service and on-the-job training of her workforce, challenges and needs of patients should also be given priority and urgent attention in order to repose confidence and trust in the mind of patients receiving treatment at the facility. This will also go a long way in addressing some of these factors hindering adherence to ART.

As a way forward to addressing adherence challenge at the health facility, some of the participants in the qualitative study suggested that the use of alarm clock as a reminder for time of patients' ARV drugs administration as prescribed by physician will improve adherence as being practised by those who have never miss doses since starting ART over five years ago. Other suggestions towards reducing long waiting time at the health facility included prescription of 2-3 months dosage of ARV drugs by health care providers, development and administration of one-monthly HIV vaccine to patients, establishment of more pharmacy outlets, computerization of storing and retrieving medical records, ensuring punctuality of health workers to work by HIV clinic management and recruitment of more health workers (nurses and doctors) to attend to current large number of patients at the facility.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study documented good knowledge about ART but adherence still remains a major challenge. Unsatisfactory attitude of health workers, receiving adherence counselling from non-health workers and adherence counselling session of less than three times was associated with good adherence.

Forgetfulness, frequent travels, stigma, pill burden, side effects, stock out of some ARV drugs, fear of being sacked from workplace, long waiting time during clinic visit, confusion, smoking and alcoholism were some of the reasons patients' miss taking their ARV drugs.

Some of the suggestions made by respondents to address adherence challenge include use of alarm clock as a reminder for time of drug administration, prescription of 2-3 monthly doses, establishment of more pharmacy outlets, computerization of storing and retrieving medical records, ensuring punctuality of health workers to work by HIV clinic management and recruitment of more health workers especially nurses and doctors.

6.2 Recommendations

Health Workers (Doctors, Nurses and adherence counsellors)

- Priorities should be given to improving adherence by providing regular follow-up, increasing patients' awareness of the ART treatment, including its benefits and side-effects, eliminating problems of access and alleviating the impact of cost by making all drugs available.
- Creating awareness and health education on the use of different reminder methods especially use of alarm clock as a reminder for timely taken of appropriate doses of ART during counselling sessions This will help to address some of the patient-related adherence challenges.

Head of clinical Department NIMR

- The provider-related factor which has to do with poor attitude of doctors and nurses will require strategies targeted at attitudinal change among health workers such as institutionalizing attitudinal and behavioural change teachings into periodic departmental meetings and in-service or on-the-job training of health workers at the facility. This has to be effectively coordinated and implemented by the head of clinical service.
- Some of the health facility- related challenges such as long waiting time can be addressed by:
- Given stable patients 2-3 months dosage as supported by the treatment guidelines,
- Establishment of more pharmacy outlets for drug pick-ups
- Computerization of storing and retrieving of patients' medical records

- Sanctions/penalty for lateness to work among health workers.
- Routine supervision to monitor and ensure compliance to best practices on adherence counselling and health worker-patient interactions

Director General of NIMR

- Recruitment of more health workers especially doctors, pharmacy and nurse
- Support implementation and ensure compliance of research's recommendations.

Federal/ Lagos State Ministry of Health and Development partners

- Federal Ministry of Health and Lagos State Ministry of Health need to be aware of these key barriers to adherence so as to develop and ensure compliance to social policy which encourages patients to achieve good adherence.
- Government and Development Partners (WHO, CDC, UNICEF, UNAIDS) should support the development and provision of HIV vaccine through appropriate and adequate funding of the entire process.

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APPENDICES

Appendix 1: Questionnaire

ID no.

FACTORS ASSOCIATED WITH POOR ADHERENCE TO ANTI-RETROVIRAL DRUGS AMONG PATIENTS ACCESSING CARE AT NIGERIA INSTITUTE OF MEDICAL RESEARCH LAGOS, NIGERIA

PART B

Semi-Structured interview guide for the HIV/AIDS patients who are on treatment.

1. Date of interview:_____
2. Study site:_____

(**A) Socio-Demographic Information**

3. Sex: Male [ ] Female [ ]
4. Age as at last birthday (years):_____

5. What is your current marital status?

i) Never married [ ] ii) Married [ ] iii) divorced [ ] iv) Separated [ ] v) Widowed [ ]

8. Number of children…….

9. What is your highest level of formal education?

i) None [ ] ii) Primary completed [ ] iii) Secondary completed [ ] iv) Post-secondary [ ]

10. What is your religion? i) Islam [ ] ii) Christianity [ ] iii) Traditional [ ]

11. What is your present occupation?

i) Trader/ artisan [ ] ii) Farmer [ ] iii) Civil servant [ ] iv) Housewife / unemployed [ ] v) Others (specify)……

12. If employed, what is your monthly salary/wages in a month?

i) ≤ **#10,000** [ ] ii) **#11,000 - # 50,000** [ ] iii**) #51,000 - #90,000** [ ]

iv) **#91,000 - #130,000** [ ] v**) ≥ #130,000** [ ] vi) don't know [ ]

13. What is the main source of food for your household?

i) Purchase from market [ ] ii) Welfare/NGO support [ ] iii) Household farm/garden [ ] iv) Relatives / friends [ ] v) Other (specify)……..

14. About how much money in Naira do you usually spend on buying food for one day in your household?

i) < #200 [ ] ii) #200-#500 [ ] iii) #600-#1,000 [ ] iv) #1,100-#1,500 [ ]

v) #1,600-#2,000 [ ] vi) > #2,000 [ ] vii) Don't know [ ]

15. How many meals do you afford to take in a day?

(i) One [ ] (ii) Two [ ] (iii) Three [ ] iv) More than three

16. What is the estimated distance in Km (s) from your house to the health facility (NIMR)?

i) < 1 Km [ ] ii) 1-2Km [ ] iii) 3-5Km [ ] iv) > 5Km [ ]

17. How long in hour (s) does it take you to get to the facility to pick up your drugs from home?

i) < 1 hour [ ] ii) 1-2 hour [ ] iii) 3-4 hours [ ] iv) > 4 hours [ ]

18. How much in Naira do you spend as transport fare to and fro this facility on each visit?

i) < #200 [ ] ii) #200-#500 [ ] iii) #600-#1,000 [ ] iv) #1,100-#1,500 [ ]

v) #1,600-#2,000 [ ] vi) > #2,000 [ ] vii) Don't know [ ]

19. What is the average number of visits you make to the clinic in a month?

i) Once [ ] ii) Twice [ ] iii) Three times [ ] iv) 4 times [ ] v) > 4 times [ ]

20. How long in hour (s) does it take you to pick your drugs when you are at the clinic?

i) < 1 hour [ ] ii) 1-2 hour [ ] iii) 3-4 hours [ ] iv) > 4 hours [ ]

(B) Knowledge on Anti-retroviral drugs

(I am going to read out some statement about Anti-Retroviral drugs. For each statement, please tell me whether you think it is true, false or you don't know?)

21. Anti-retroviral drugs can prevent progression from HIV to AIDS?

i) Yes [ ] ii) No [ ] iii) don't know [ ]

22. A person on Anti-retroviral drugs cannot infect their partner (s) through unprotected sexual intercourse or sharing of sharps (razor blade, needles)?

i) Yes [ ] ii) No [ ] iii) don't know [ ]

23. Failure to take Anti-retroviral drugs everyday can lead to treatment failure?

i) Yes [ ] ii) No [ ] iii) don't know [ ]

24. Anti-retroviral drugs can lead to development of side effects by patients?

i) Yes [ ] ii) No [ ] iii) don't know [ ]

25. A person who developed side effect (s) while taken Anti-retroviral drugs is required to stay at home until he/she is better?

Yes [ ] ii) No [ ] iii) don't know [ ]

26. Three successive adherence counseling is not required to commence HIV treatment?

Yes [ ] ii) No [ ] iii) don't know [ ]

27. It is not all HIV infected persons who require Anti-retroviral drug treatment?

Yes [ ] ii) No [ ] iii) don't know [ ]

28. Basic laboratory tests are required before starting HIV infected person on Anti-retroviral drug treatment?

i) Yes [ ] ii) No [ ] iii) don't know [ ]

29. Do you know ARV drugs can prevent your chance of getting opportunistic infections like TB and skin infections?

I) Yes [ ] ii) No [ ] iii) don't know [ ]

30. Use of condom during sexual intercourse by patient on Anti-retroviral drugs is not required to prevent getting infected with another strain of HIV?

Yes [ ] ii) No [ ] iii) don't know [ ]

(C) Level of Adherence

31. What are the names of Anti-retroviral drugs you currently taken?

_____

32. How many times do you take your Anti-retroviral drugs in a day?

i) Once daily [ ] ii) Twice daily [ ] iii) Thrice daily [ ] iv) Once a week [ ]

v) Twice a week [ ] vi) Once a month [ ] vii) Others specify ……

33. In the last one (1) month how many doses of Anti-retroviral drugs have you missed?

i) One [ ] (ii) Two [ ] (iii) Three [ ] iv) More than three

33b. Adherence rate calculation: _____%

34. What things can make it difficult for you to remember your tablets?

i) Developed toxicity/ side effect [ ] ii) Forgot to take Anti-retroviral drugs [ ]

iii) Felt better [ ] iv) Too ill [ ] v) Fear of stigma/disclosure [ ] vi) Cost of treatment [ ]

vii) Stock was finished [ ] viii) Drunk alcohol [ ] ix) Too many pills/ pill burden [ ]

x) Trip/travel [ ] xi) Taking times [ ] xii) Church [ ] xiii) Other (specify)_____

35. What other drugs (besides Anti-retroviral) are you currently on (tick one as appropriate)

i) Pain killers [ ] ii) Appetitive stimulants [ ] iii) Anti-hypertensive drugs [ ]

iv) Sleeping pills [ ] v) Anti-TB drugs [ ] vi) Antibiotics (other than for TB) [ ]

vi) Anti-fungal [ ] viii) Anti-diabetic drugs [ ] Others specify……...

35b. For the ticked drug (s), how many times per day? Pain killers: _____,

Appetitive stimulants: ____, Anti-hypertensive drugs: _____,

Sleeping pills: _____, Anti-TB drugs: _____,

Antibiotics (other than for TB): _____, Antifungal: _____,

Anti-diabetic: _____, Others specify: _____

36. Do you have any own method (s) to remember time and recommendation to take your medicine? No [ ] Yes [ ]

36b. If yes, which one of these do you use? (Check one response only)

i) Spouse [ ] ii) Immediate member of family (specify) [ ] iii) Nurse [ ] iv) Doctor [ ]

v) Pharmacist [ ] vi) Social Worker/Community Health Worker [ ] vii) Friends [ ]

viii) Using watch [ ] ix) Moving with daily dose x) Others specify……..

(D) Patient-Provider related factors

37. Were you told about the importance of not missing doses? No [ ] Yes [ ]

38. How many times were you told about the importance of not missing doses before you started taken ARV drugs? i) Once [ ] ii) Twice [ ] iii) Three [ ] iv) More than three [ ] v) None [ ]

39. Were you told about the side effects of Anti-retroviral drug(s) you were given?

No [ ] Yes [ ]

39b. If yes, mention them

…….

40. Were you told of the consequences of not taking your ARV drugs as prescribed?

No [ ] Yes [ ]

40b. If yes, from whom?

i) Nurse [ ] ii) Doctor [ ] iii) Pharmacists [ ] iv) Counselor [ ] v) Parents [ ] vi) Friends [ ]

vii) Others specify …….

41. Have you received adherence counseling during your treatment?

No, [ ] Yes, [ ]

42. Do you think adherence counseling is useful for HIV patients on treatment?

No, [ ] Yes, [ ]

43. How do you rate health care providers (Clinicians, nurses, pharmacists) attitude towards you?

Attitude	**Strongly Agreed**	**Agreed**	**Disagreed**	**Strongly Disagreed**	**No response**
Good courtesy					
Good Clarity in response					
Always Stigmatized					
More waiting time					
Good response to question (s)					
Was privacy and confidentiality maintained					
Being Judgmental					

Thank you for taking time to participate in this study

Completed by:_____

Appendix 2: Patient information and consent form

PART A

A. INTRODUCTION

I am conducting a study on factors associated with poor adherence to anti-retroviral drugs among patients accessing care at Nigeria institute of medical research Lagos, Nigeria. You are invited to participate in this study and your participation is completely voluntary. Your decision to either take part or not in the study will not affect the type and quality of service that you receive.

B. PURPOSE OF STUDY

HIV/AIDS is one of the major diseases causing a lot of health problems and deaths in Nigeria. Realizing that there is no cure for the disease, government put in place a programme for the prevention and control of the disease including the provision of Anti-Retro-viral (ARV) drugs. However, it has been observed that despite free access and availability of ARV drugs, some patients do not adhere strictly to their medications, making them to always fall sick or develop complications that could lead to death. The result of this study will help identify reasons why some patients do not take their drugs as prescribed by doctors and provide solutions to these problems in Lagos State.

C. PROCEDURE TO FOLLOW

If you agree to participate in the study, you will be assigned a study unique identification number and a semi-structured questionnaire will be administered to you to collect information about your personal, socio-demographic and anti-retroviral drug history including adherence to anti-retroviral drugs. Information about your adherence status will be obtained from your pharmacy records.

D. CONFIDENTIALITY STATEMENT

The records concerning your participation are to be used for the purpose of this research project. Your name will not be used on study questionnaire or in any report resulting from the study. Any information obtained in connection with this study will be kept strictly confidential. Only members of the study group (Doctors, Nurses, Adherence counsellors, pharmacists and monitoring and evaluation officers) will have access to information linking your name with your study number.

E. VOLUNTARY PARTICIPATION

A decision not to participate or to withdraw from participation will not affect the treatment you will receive at the clinic in any way. Even if you do agree to become a study participant, you can withdraw from the study at any time (verbally).

F. BENEFITS AND RISKS

There may be no immediate benefits of your participation in the study. When the study results are known, if your adherence level is below 95%, it will immediately communicated to the relevant healthcare providers in you attending health facility for you to undergo successive adherence counselling sessions at no cost to you. You may experience some discomfort and embarrassment because some of the questions are sensitive.

G. COMPENSATION

There will be no monetary compensation for the study.

H. QUESTIONS AND FREEDOM TO WITHDRAW FROM STUDY

Your consent to withdraw from the study at any time will not affect your present or future medical care at the clinic. You may contact any member of the study group if you have questions about the research.

I. CONTACT INFORMATION

If you have any question about this study. Please contact Dr. Ganiyu Jamiyu, Principal investigator of the study, HIV/AIDS Division, Department of Public Health, Federal Ministry of Health Abuja. You can also send e-mail to jamiuganiyu@ymail.com OR call 08071027755. If you have questions regarding your right as a study participant, or you have been treated unfairly, please contact: The Secretary, Institutional Review Board (IRB), Nigeria Institute of Medical Research (NIMR) Yaba, Lagos. You can also send e-mail to: NIMR_IRB@yahoo.com.

J. RESULT PUBLICATION

Data from the study will be kept for more than one year, as it may be necessary to refer to it during the duration of treatment and beyond. When the researchers will have analyzed the data, the results and explanation of its implication will be given to the health facility and relevant stakeholders.

K. PARTICIPANT STATEMENT

I have been informed (someone has informed me) verbally and in writing about this study and understand what is involved. I know whom to contact if I need more information. I understand that I am free to withdraw from the study at any time without affecting the care I normally receive at the clinic. I agree to participate in this study as a voluntary subject.

_____	_____
Signature/Thumbprint	Date
_____	_____
Name of Participant	Name of study staff obtaining consent
_____	_____
Signature of study staff	Date

Appendix 3: Focus Group Guide

FOCUSED GROUP DISCUSSION

FACTORS ASSOCIATED WITH POOR ADHERENCE TO ANTI-RETROVIRAL DRUGS AMONG HIV/AIDS PATIENTS ACCESSING ART SERVICES AT NIGERIA INSTITUTE OF MEDICAL RESEARCH, LAGOS.

Qualitative Study with HIV patients at NIMR, Lagos: Focused Group Discussion Guide

PATIENT INFORMATION AND CONSENT FORM

My name is……., I am MPH (Field Epidemiology) student of Ahmadu Bello University Zaria. We are conducting a study on factors associated with poor adherence to anti-retroviral drugs among HIV/AIDS patients accessing ART services at Nigeria Institute of Medical Research Yaba, Lagos State.

HIV/AIDS is one of the major diseases causing a lot of health problems and deaths in Nigeria. Realizing that there is no cure for the disease, government put in place a programme for the prevention and control of the disease including the provision of Anti-Retro-viral (ARV) drugs. However, it has been observed that despite free access and availability of ARV drugs, some patients do not adhere strictly to their medications, making them to always fall sick or develop complications that could lead to death. The result of this study will help identify reasons why some patients do not take their drugs as prescribed by doctors and provide solutions to these problems in Lagos State.

You are invited to participate in this study and your participation is completely voluntary. Your decision to either take part or not in the study will not affect the type and quality of service that you receive in this HIV clinic. Even if you do agree to become a study participant, you can withdraw from the study at any time.

If you have any question about this study. Please contact Dr. Ganiyu Jamiyu, Principal investigator of the study, HIV/AIDS Division, Department of Public Health, Federal Ministry of Health Abuja. You can also send e-mail to jamiuganiyu@ymail.com OR call 08071027755. If you have questions regarding your right as a study participant, or you have been treated unfairly, please contact: The Secretary, Institutional Review Board (IRB), Nigeria Institute of Medical Research (NIMR) Yaba, Lagos. You can also send e-mail to: NIMR_IRB@yahoo.com.

What we will do

These interviews will be conducted as an informal meeting of individuals or groups of people who are identified as having a lot in common. If you do agree to take part in this meeting, a trained interviewer will ask questions to obtain some relevant information.

Your decision to either take part is voluntary. The records concerning your participation are to be used for the purpose of this research project. Your name will not be used in the study or in any report resulting from the study. Any information obtained in connection with this study will be kept strictly confidential. Only members of the study group and clinic staff (Doctors, Nurses, Adherence counsellors, pharmacists and monitoring and evaluation officers) will have access to information linking your name with your study number.

To be read to or by the participants

I have been informed about the study and am satisfied with the information given. By given a verbal consent witnessed by the interviewer, I am given my consent to participate in the focused group discussion.

Interviewer Name and Signature:……...Date……..

(Interviewer to sign only if respondent agrees to continue with the interview and gives a copy of the document to the individual/individuals).

FOCUSED GROUP DISCUSSION GUIDE

Introductions: Thank you very much for agreeing to participate in this study.

- This session will provide a better understanding of factors associated with poor adherence among patients accessing care at Nigeria Institute of Medical Research, Lagos.
- This interview session will add value to the quantitative study that has been conducted in this health facility a couple of days ago by providing in-depth explanations and significance for the information generated by the study and guide in making decisions and policy formulation.
- This study will take between 60-90minutes

Time started:

A. Socio-demographic information

1. *What is your name, age, marital status, educational level, occupation?*
2. *What is your monthly income? (Probe if on a daily income, how much is earned daily)*

B. Knowledge about HIV and AIDS

3. *Describe what you know about HIV/AIDS? Probe for transmission routes, sign/symptoms, how to prevent HIV infection and perception of the reality of HIV/AIDS?*

C. Knowledge about Anti-retroviral drugs (ART)

4. *Information about drugs: Ask name of drug, how many times it is taken per day, how many pills taken*
   Why are you taking the drugs, and has it been helpful.

D. Adherence to ART, Adherence counselling and patient-provider related factors

5. *What you think about the terms "treatment adherence," what comes to your mind?*
6. *What type of problems do you face when trying to take the medication according to prescription?*

7. *How many doses have you missed since the last time you came to collect the medication? And how many doses did you miss the past week? What is the reason for missing the dose?*
8. *What makes it easy to stick with your medications? What makes it hard to stick with your medications?*
9. *Has your doctor talked with you about adherence to your medications? Have you ever been enrolled in a program to improve treatment adherence? If yes, tell me about this/these experiences.*
10. *Do you encounter any constraints while picking up your drugs? What are the constraints?*
11. *What is poor adherence and good adherence?*
12. *What unique challenges do you think hinder patients on ART in this facility from adhering to ARV treatment?*
13. *How do you think such challenge can be address?*
14. *What role have you ever played in addressing poor adherence by patient (s) in your facility?*
15. *What are your experience and lesson learnt in addressing poor adherence by patient (s) in the last 3 years?*

Time closed:

THANK PARTICIPANT FOR TIME AND INVITE THEM TO MAKE ANY COMMENTS ON THE INTERVIEWER OR SURVEY AND ADDRESS THEM TO THE BEST OF YOUR ABILITY

Appendix 4: Key Informant Interview Guide

FACTORS ASSOCIATED WITH POOR ADHERENCE TO ANTI-RETROVIRAL DRUGS AMONG PATIENTS ACCESSING CARE AT NIGERIA INSTITUTE OF MEDICAL RESEARCH LAGOS, NIGERIA

Key Informant Interview Guide

For use with HIV patients on ART for minimum period of five (5) years

Introductions: Thank you very much for agreeing to participate in this study.

- This session will provide a better understanding of factors associated with poor adherence among patients accessing care at Nigeria Institute of Medical Research, Lagos.
- This interview session will add value to the quantitative study that has been conducted in this health facility a couple of days ago by providing in-depth explanations and significance for the information generated by the study and guide in making decisions and policy formulation.
- This study will take between 60-90minutes

Time started:

A. Socio-demographic information

16. *What is your name, age, marital status, educational level, occupation?*
17. *What is your monthly income? (Probe if on a daily income, how much is earned daily)*

B. Knowledge about HIV and AIDS

18. *Describe what you know about HIV/AIDS? Probe for transmission routes, sign/symptoms, how to prevent HIV infection and perception of the reality of HIV/AIDS?*

C. Knowledge about Anti-retroviral drugs (ART)

19. *Information about drugs: Ask name of drug, how many times it is taken per day, how many pills taken*

Why are you taking the drugs, and has it been helpful.

D. Adherence to ART, Adherence counselling and patient-provider related factors

20. *What you think about the terms "treatment adherence," what comes to your mind?*
21. *What type of problems do you face when trying to take the medication according to prescription?*
22. *How many doses have you missed since the last time you came to collect the medication? And how many doses did you miss the past week? What is the reason for missing the dose?*
23. *What makes it easy to stick with your medications? What makes it hard to stick with your medications?*
24. *Has your doctor talked with you about adherence to your medications? Have you ever been enrolled in a program to improve treatment adherence? If yes, tell me about this/these experiences.*
25. *Do you encounter any constraints while picking up your drugs? What are the constraints?*
26. *What is poor adherence and good adherence?*
27. *What unique challenges do you think hinder patients on ART in this facility from adhering to ARV treatment?*
28. *How do you think such challenge can be address?*
29. *What role have you ever played in addressing poor adherence by patient (s) in your facility?*
30. *What are your experience and lesson learnt in addressing poor adherence by patient (s) in the last 3 years?*

Time closed:

THANK PARTICIPANT FOR TIME AND INVITE THEM TO MAKE ANY COMMENTS ON THE INTERVIEWER OR SURVEY AND ADDRESS THEM TO THE BEST OF YOUR ABILITY

Appendix 5: Ethical Approval

INSTITUTIONAL REVIEW BOARD

IRB-NIMR

NIGERIAN INSTITUTE OF MEDICAL RESEARCH

6, Edmond Crescent Off Murtala Muhammed Way, P.M.B. 2013 Yaba, Lagos.
Tel: 01-4823123, 01-7744723, 08050254484, 08033460947 Fax: 01-4823123, 234-1-3425171
E-mail: nimr_irb@yahoo.com *Website:* www.nimr-nig.org
Secretariat: Room 207, Biochemistry Division, Research Block, NIMR

26th September, 2013

PROJECT TITLE: **FACTORS ASSOCIATED WITH POOR ADHERENCE TO ANTI-RETROVIRAL CARE AT SECONDARY AND TERTIARY HEALTH FACILITIES IN LAGOS, NIGERIA.**

PROJECT №: **IRB/13/220**

APPROVAL LETTER

The above named proposal has been adequately reviewed; the protocol and safety guidelines satisfy the conditions of NIMR-IRB, policies regarding experiments that use human subjects.

Therefore the study under its reviewed state is hereby approved by Institutional Review Board, NIMR.

PROF. F. E. OKONOFUA
Name of IRB Chairman

Signature of IRB Chairman & Date 26/9/13

MRS. O. A. NWOGBE
Name of IRB Secretary

Signature of IRB Secretary & Date 26/9/13

This approval is given with the investigator's Declaration as stated below;
By signing below I agree/certify that:

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.
2. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
   - I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
   - I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing

such modifications.

3. I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping; and (f) the current IRB approval status of the research study.

4. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.

5. I will submit the research study in a timely manner for IRB renewal approval.

6. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his /her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).

7. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.

8. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.

9. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.

10. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.

11. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

12. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines

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DR. GANIYU JAMIYU
Principal Investigator's Name

..... 27/09/13
Principal Investigator's Signature and Date

Appendix 6: WORKPLAN

Activity	**Resources**	**Person(s) responsible**	**Indicator**	**Means of Verification**	J	A	S	O	N	D	J	F	M	A	M	J
Study protocol	Development of proposal	Principal investigator	Study protocol developed and approved	Protocol document												
Obtain Permission from NIMR' ART treatment centres	Submission of proposal for Ethical Review	Principal Investigator		Ethical Clearance												
Training of Research assistants	Study Data instruments	Principal Investigator	No of Research assistants trained	Attendance list												
Collection of Data	Administration of questionnaires, FGD guide and audio-tape recorder, KII guide	Principal Investigator, research assistants	No of Questionnaires administered	No of Consent form signed												
Data entering and Cleaning	Daily questionnaires filled, Laptop	Principal Investigator	No of Questionnaires entered into the database	All data entered into data base												
Analysis of Data	Laptop, Filled Questionnaires	Principal Investigator	No of Questionnaires analysed and FGD notes transcribed	Report submitted on time												
Thesis writing	Laptop	Principal Investigator	Draft thesis submitted for review	Draft thesis submitted on time												
Draft thesis submitted to academic and	Thesis, laptop	Principal Investigator	Thesis reviewed	Thesis submitted on time for												

program supervisors for review				internal defense												
Corrected thesis submitted for external defense	Reviewed thesis, laptop	Principal Investigator	Corrected thesis	Thesis submitted on time for external defense												
Dissemination of study findings	Meetings, Seminars, Publications, Conferences	Principal Investigator	No of Conference Presentations, No of abstracts submitted	Submission notes,Acceptance notes												