DETERMINANTS OF ADHERENCE TO ANTIRETROVIRAL THERAPY AMONG PREGNANT WOMEN ACCESSING PREVENTION OF MOTHER TO CHILD TRANSMISSION SERVICES, ABAKALIKI EBONYI STATE, NIGERIA

BY

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A DISSERTATION SUBMITTED TO THE DEPARTMENT OF EPIDEMIOLOGY AND MEDICAL STATISTICS, FACULTY OF PUBLIC HEALTH, COLLEGE OF MEDICINE IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF PUBLIC HEALTH (MPH FIELD EPIDEMIOLOGY PRACTICE) OF THE UNIVERSITY OF IBADAN

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#### ABSTRACT

Globally Mother-to-child transmission (MTCT) of HIV accounts for over 90% of all pediatrics infection. High level of adherence to antiretroviral drugs is needed to achieve maximal reduction of transmission in pregnancy. The effect of poor adherence among patients is evidenced by rising numbers of HIV positive babies of mother on PMTCT Programme. The purpose of this research is to determine the level of adherence among HIV infected pregnant women on prevention of mother to child transmission (PMTCT) on antiretroviral therapy, and to establish the factors that contribute to adherence.

A cross sectional study was conducted in which (268) HIV positive pregnant women were recruited by systematic sampling method from PMTCT clinic of Federal Teaching Hospital Abakaliki. Pre tested interviewer administered questionnaire was used for data collection. Information on socio-demographic characteristics, Knowledge of PMTCT, barriers to PMTCT and obstetric characteristics were obtained. Knowledge on PMTCT was accessed and a score of <4 out of 5 indicated poor knowledge. Adherence Level was

calculated using the respondent self- report using (3 day recall) and a value < 95% indicated poor adherence. Data were analysed using descriptive statistics, Chi square and logistic regression (p  $\leq 0.05$ ).

The mean age was  $30.7\pm4.2$  years. Two hundred and nineteen (81.7%) of the respondents were married, 124 (46.3%) were traders and 141(52.6%) had secondary education. The prevalence of good adherence was 89.2% and 227(89.0%) had good knowledge of PMTCT. Fear of being identified as HIV positive(21%) pregnancy related illness (13.7%) and forgetfulness (12.5%) were the most common reasons for non adherence. Partners support (OR=.03, 95%CI=0.01-0.09, P = 0.001), and Duration of

ART (OR=4.39, 95%CI=1.3-14.5, P=0.019) were found to be significantly associated with good adherence at Bivariate analysis. However, after controlling for confounders, only Partner support (OR=0.027, 95%CI=0.01-0.09, P<0.001) retained the association with good adherence.

The study identified that stigmatization and pregnancy related illness was related to poor adherence while having Partners support improve adherence to HAART. Interventions aimed at improving ART adherence in pregnancy should focus on these factors to guide counseling and to design programmes

Keywords: Adherence, antiretroviral therapy, pregnancy, prevention of mother-to-child Transmission.

Word count: 349

#### CERTIFICATION

This is to certify that this project was carried out by Dr. Agboeze Joseph in the Department of Epidemiology and Medical Statistics, Faculty of public Health, college of Medicine, University of Ibadan.

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iv.

# DEDICATION

This dissertation is dedicated to God Almighty for His guidance.



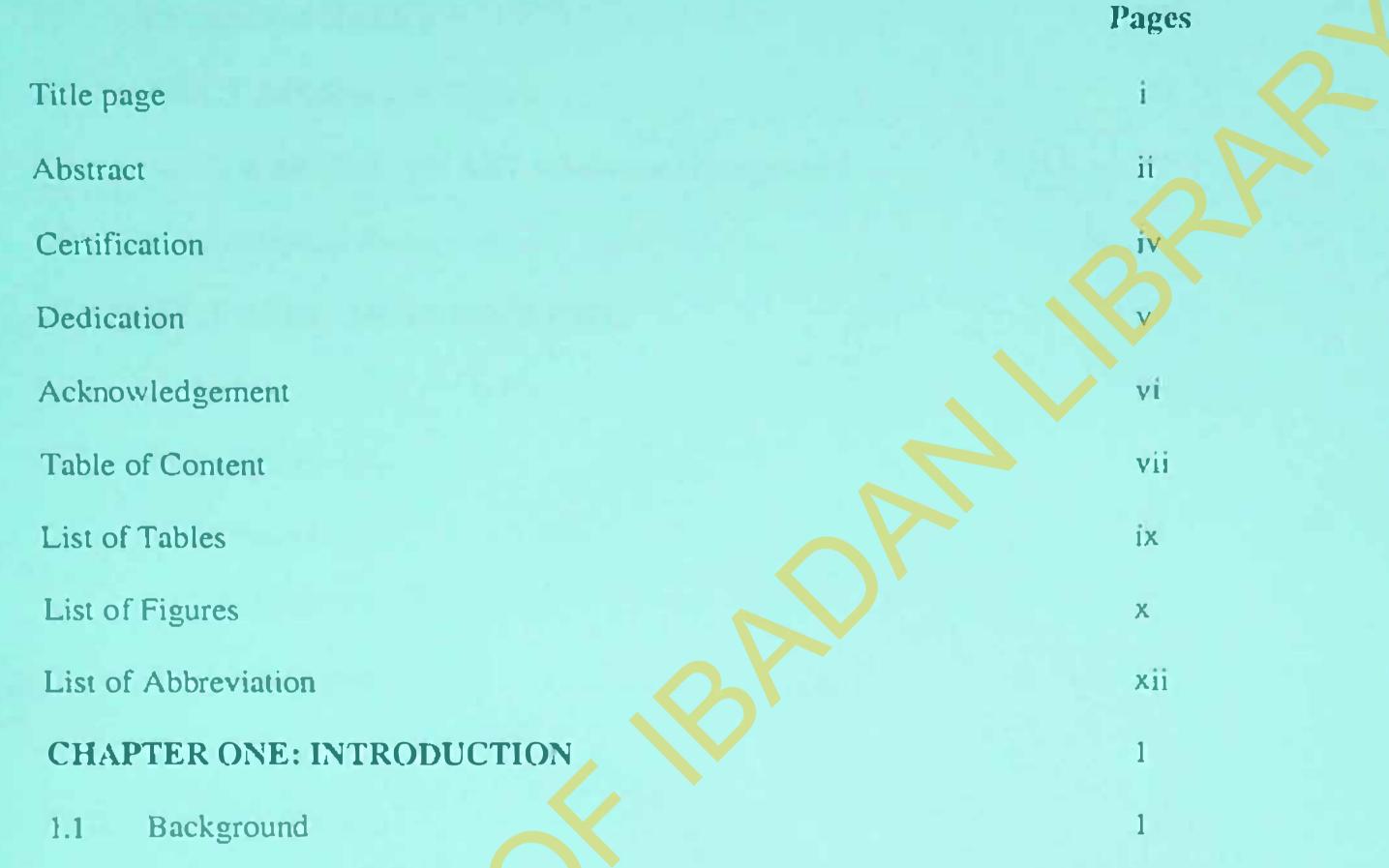
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I thank Almighty God for the strength He gave to pass through the rigors of this program. I sincerely appreciate my family for their support and understanding during this hectic period.

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# **LIST OF ABBREVIATION**

AIDS	-	Acquired Immune Deficiency Syndrome
ART	-	Antiretroviral Therapy
CASI	Ξ.	Computer-Assisted Self-Interviewing
CCCs	-	Community Care Centers
CD4	-	Cluster of Differentiation 4
CHBC	-	Community and Home-Based Care (CHBC)
DOT		Direct Observation System
D4T	-	Stavudine
ddl	-	Didanosine
EFV	-	Efavirenz
FSW		Female Sex Worker
GDP	-	Gross domestic product
HDI	-	Human Development Index

HIV/AIDS Emergency Action Plan HEAP Human Immune Deficiency Virus HIN Injection Drug Users DU Most-at-risk Population MARPs Millennium Development Goal MDG Medical Event Monitoring System MEMS Men who Have Sex with Men MISM Mother to Child Transmission MTCT National Action Committee on AIDS NACA

NHRC	-	Nigeria Health Research Council
NNRTI	-	Non-nucleoside Reverse Transcriptase Inhibitors
NsRTI	1.400	Nucleoside Reverse Transcriptase Inhibitor
NVP	-	Neverapine
PC	-	Pill Count
PIT		Pill Identification Test
PLWH	-	People Living with HIV
PMTCT	-	Prevention of Mother-to-Child Transmission
PPP	-	Purchasing power parity
SPSS	-	Statistical Package for Social Science.
TB	÷	Tuberculosis
3TC	-	Lamivudine
TDF		Тепоfovir Disoproxil Fumarat
TDM	-	Therapeutic Drug Monitoring

VAS-Visual Analogue ScaleVCT-Voluntary Counseling and TestingVDCs-Village Development CommitteesWHO-World Health Organization

ZDV

FII

Zidovudine (also known as AZT)

# CHAPTER ONE

#### INTRODUCTION

#### 1.1 Background

HIV/AIDS is a major public health problem. 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 23.5 million are in Sub-Sahara Africa and 3.1 million are in Nigeria (GHO, 2013). Nigeria 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 (FMOH, 2010).

The prevention of mother-to-child transmission (PMTCT) of HJV program is one of the health sector responses to the HIV/AIDS epidemic. Mother-to-child transmission (MTCT) is the main route of pediatrics HIV infection. It accounts for over 90% of all pediatrics (children less than 15 years) infection. The risk of transmission ranges from 25%-48% in resource limited settings (UNAIDS, 2010) In Nigeria, despite efforts to strengthen PMTCT interventions, by 2007 only 5.3 percent of HIV positive women were receiving antiretroviral drugs to reduce the risk of mother-to-child transmission (WHO, 2010). World Health Organisation recommends HAART as a key component of all effective PMTCT strategies. Without preventive intervention, about 25-40% of infants born to HIV-positive mothers will contract the virus (Abdulsalami, 2006). Adherence monitoring among large number of women on PMTCT programme in most ART centres in Nigeria is a major concern to achieving ART programme success.

Factors that affect ART adherence are known to affect PMTCT service uptake. Studies in Nigeria reveals that the average rate of vertical HIV transmission was 22.5%, but for babies whose mothers had PMTCT service the rate was 9.6% (Joseph Afe et al., 2011) and 2.8 (Ikechebelu et al., 2011). Higher transmission rates were associated with vaginal delivery, breastfeeding and lack of PMTCT services to the mothers. Adherence to ART is one of the very important factors which determine treatment success and occurrence of viral resistance (Mannheimer at el., 2005). Previous research findings showed adherence rates of 78.3% (Igwegbe et al., 2010) and 90.6% (Ekama et al., 2012) and identified factors such as high pill-burden, high cost of transport fares, religion, medical sideeffects, stigma and discrimination, attitude and poor education as some of the factors associated with poor adherence to ARV drugs among patients (Olowookere et al., 2008; Igwegbe et al., 2010 and Ekama et al., 2012) 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 (Weiser et al., 2006). The transmissibility of the antiretroviral resistant viruses from person to person further compounds the problem of mother to child transmission of HIV. It is a clinical and public health challenge (Oku et al., 2013). This study is aimed at determining the level of adherence to PMTCT among women on PMTCT antiretroviral therapy, and to identify the factors that contribute to poor adherence. The knowledge shall be useful in designing effective strategies to improve the evel of adherence and ultimately minimize the mother to child transmission of HIV.

#### **1.2 Problem Statement**

Nigeria, with about 3.1 million people living with HIV remained second highest burdened country with HIV pandemic in the world with likelihood of becoming the leading country with the disease burden if not adequately treated and properly monitored. An estimated 60,000 new HIV infections occurred among infants in Nigeria making her the country with the largest number of children acquiring HIV through MTCT (UNAIDS, 2013). Without preventive intervention, about 25-40% of infants born to HIV-positive mothers will contract the virus (Abdulsalami 2006). Studies in Nigeria reveals that the average rate of vertical HIV transmission was 22.5%, but for babies whose mothers had PMTCT service the rate was 9.6% (Joseph Afe et al., 2011) and 2.8 (Ikechebelu et.al.,2011). There have been progressive increases in PMTCT sites to 250 in 2006, 640 in 2009 and 1,320 by the end of 2012(FMOH,2012). With an estimated pool of about 228,800 infected pregnant women and 57,000 children infected principally through MTCT in 2012, Nigeria accounts for over 30% of the global PMTCT gap (FMOH, 2012) and IATT, 2012) The persistently high burden of HIV and MTCT are indications that the national PMTCT program has only made modest impact. The morbidity, mortality and socio-economic loss associated with HIV infection is a major treat to future survival of the country over the past decade of program implementation, the infant HIV transmission rate has not fallen to below 2% as portrayed possible by the WHO (WHO, 2007). It is estimated that without effective interventions, between 67,500 and 125,000 infants will be infected in a year in the country (FMOH, 2005). The reason for this may be related to medication adherence

Previous studies revealed that adherence among PLHIV in Nigeria and other Africa countries ranges from 55-85%, (Mills et al., 2011) 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 (Asekomeh et al., 2010). A research finding in Nigeria among pregnant women on PMTCT showed non adherence rates of 21.7% (Igwegbc et al., 2010)

Since 2010, Nigeria has adopted the WHO option 'B' that requires the administration of triple HAART to all HIV infected pregnant women, majority of the pregnant women and their infants do not ingest the drugs according to recommendation (Mirkuzie et al, 2011). It then implies that large missed opportunities occur within the health system despite PMTCT guidelines.

#### **1.3 Justification**

Despite the huge amount of resources expended to prevent mother to child transmission

of HIV pregnant women on HAART have continued to infect their babies partly due to inadequate adherence to ART medication. The effect of poor adherence among patients is evidenced by rising numbers of HIV positive babies of mother on PMTCT Program (Mofesen.2010 and FMOH, 2005). Without an urgent action in Nigeria, the global target of eliminating new HIV infections among children is unlikely to be reached (UNAIDS, 2013).

For about 10 years of commencing PMTCT in the state the current level of adherence to HAART among these pregnant women has not been determined and little is known about factor that impact either negatively or positively upon their adherence levels. This study

will determine the proportion of those who adhere poorly and factors associated with poor adherence to ART.

Being one of the earliest studies in the PMTCT clinic in Abakaliki Ebonyi state, it will provide baseline for further research and guide towards formulating evidence based policy and guidelines that will address adherence challenges for program planners, Most of the studies conducted on antiretroviral treatment adherence focuses on Adult patients with few concentrating on pregnant women and their adherence particularly to PMTCT. It is therefore important to determine the level of adherence to PMTCT antiretroviral therapy, and to establish the factors that contribute to poor adherence in order to develop adherence intervention strategies that can further improve the impact of the PMTCT program.

#### **1.4 Research Question**

The following are the questions this research intended to answer:

- - 1. What is the level of adherence to PMTCT antiretroviral therapy among pregnant women in Federal Teaching Hospital Abakaliki Nigeria?
  - 2. What is the level of knowledge of PMTCT antiretroviral therapy among pregnant women in Federal Teaching Hospital Abakaliki Nigeria?
  - 3. What are the factors responsible for adherence to antiretroviral treatment in pregnancy?

#### 1.5 Objectives of the Study

#### **1.5.1 General Objective**

To determine the level of adherence to PMTCT among HIV infected pregnant women on PMTCT antiretroviral therapy, and to establish the factors that contribute to poor adherence.

## 1.5.2 Specific Objectives

- I. To determine the level of ART medication adherence of pregnant women on antiretroviral PMTCT therapy in Abakaliki Nigeria.
- 2. To determine the level of knowledge of PMTCT antiretroviral therapy among the pregnant women.
- 3 To identify the factors responsible for adherence in this population.



# CHAPTER TWO LITERATURE REVIEW

#### 2.1 Overview of HIV and AIDs

Globally, an estimated 35.3 (32.2-38.8) million people were living with HIV in 2012, an increase from previous years as more people are receiving the life-saving antiretroviral therapy. There were 2.3 (1.9-2.7) million new HIV infections globally, showing a 33% decline in the number of new infections from 3.4 (3.1-3.7) million in 2001. At the same time the number of AIDS deaths is also declining with 1.6 (1.4-1.9) million AIDS deaths in 2012, down from 2.3 (2.1-2.6) million in 2005 (UNAIDS, 2013).

Sub-Saharan Africa has the most serious HIV and AIDS epidemic in the world. In 2013, an estimated 24.7 million people were living with HIV, accounting for 71% of the global total. In the same year, there were an estimated 1.5 million new HIV infections and 1.1 million AIDS-related deaths (UNAIDS, 2014).HIV prevalence for the region is 4.7% but varies greatly between regions within sub-Saharan Africa as well as individual countries. For example, Southern Africa is the worst affected region and is widely regarded as the 'epicenter' of the global HIV epidemic. Swaziland\_has the highest HIV prevalence of any country worldwide (27.4%) while South\_Africa has the largest epidemic of any country -5.9 million people are living with HIV. By comparison, HIV prevalence in West and East Africa is low to moderate ranging from 0.5% in Senegal to 6% in Kenya(UNAIDS,2014). Nigeria, with the estimated population of 167 million (NPC, 2009) is second to South Africa in the number of people living with HIV. Of all people living with HIV globally, 9% of them live in Nigeria (UNAIDS, 2014). Since 2005, there has been no reduction in

the number of annual deaths, indicative of the fact that only 20% of people living with HIV in Nigeria are accessing antiretroviral treatment (ART). (UNAIDS, 2014) Unprotected heterosexual sex accounts for about 80% of new HIV infections in Nigeria, with the majority of remaining HIV infections among key affected populations (NACA, 2014). The epidemiology of HIV in Nigeria is mainly informed by two national surveys, the Antenatal Clinic (ANC) survey conducted among pregnant women and the National HIV/AIDS and Reproductive Health Survey (NARHS) which is a general population based survey. A review of the ANC survey data has shown that HIV prevalence has declined and stabilized in Nigeria. The ANC 2010 survey reported a national HIV prevalence of 4.1% and the States' prevalence ranged from 1% in Kebbi State to 12.7% in Benue State. NARHS 2013 reported a national HIV prevalence rate of 3.4%, lower than 3.6% reported in 2007. It is estimated that about 3,229,757 people live with HIV in Nigeria and about 220,393 new HIV infections occurred in 2013. Approximately 210,000 people died from AIDS-related illnesses in Nigeria in 2013, which is 14% of the global

total.

The development of antiretrovital (ARV) drugs has transformed HIV/AIDS to that of a chronic manageable disease. Studies have reported improved quality of life of PLWHA on ARV therapy (ART), reduced progression of the disease and declining mortality from the pandemic (Grange et al, 2002; Palella et al, 1998). The Nigerian HIV/AIDS Epidemic Appraisal report in 2014 highlighted the pattern of the HIV epidemic in Nigeria. The prevalence of HIV infection in Nigeria has steadily declined, from the peak of 5.8% in 2001. 5% in 2003 and 4.1% in 2010. According to NARHS, 2012, the current HIV prevalence in the general population in 3.4%.

#### 2.2 The Nigerian ART Program

The human immunodeficiency virus (HIV) was discovered in 1982, but treatment strategies globally were not introduced until 5 years later. Early regimens consisted of one or two drugs and often led to treatment failure. Since the advent in 1995 of highly active antiretroviral therapy (HAART), which consists of at least three agents, a dramatic improvement has been seen in the number of patients attaining undetectable viral loads, improved CD4 counts, and improved survival. However, early HAART often consisted of drugs with complex dosing schedules, strict food requirements, treatment-limiting adverse effects, and the need to take 16-20 pills/day. These treatment barriers often led to patient non adherence, with subsequent treatment failure and development of resistant strains. The CD4 count and viral load are the most important surrogate markers used to determine if treatment is indicated.

Standard antiretroviral therapy (ART) consists of the combination of antiretroviral (ARV) drugs to maximally suppress the HIV virus and stop the progression of HIV disease. ART also prevents onward transmission of HIV. Huge reductions have been seen in rates of death and infections when use is made of a potent ARV regimen, particularly in early stages of the disease. WHO recommends ART for all people with HIV as soon as possible after diagnosis without any restrictions of CD4 counts.

Almost 12.9 million people were receiving antiretroviral therapy globally at the end of 2013(U AIDS GAP report 2014), 5.6 million were added since 2010. The rapid increase in antiretroviral access has primarily occurred in a few countries. One third of the u creation in the number receiving antiretroviral therapy was in South Africa, followed by

India at 7%, Uganda 6%, and in Nigeria, Mozambique, the United Republic of Tanzania and Zimbabwe 5%. Three of four people receiving HIV treatment are living in sub-Saharan Africa, where the need is most acute (UNAIDS GAP report 2014). Twenty-two million, or three of five people living with HIV are still not accessing antiretroviral therapy. The proportions of people who do not have access to treatment are 58% [56-60%] in South Africa, 64% [55-72%] in India and 80% [79-82%] in Nigeria. [11Vtreatment coverage is only 36% in India and 20% in Nigeria(UNAIDS GAP report 2014). The Federal Government of Nigeria initiated the national ARV program in January 2002 as part of an expanded response to care and support for PLWI-IA. Under this program, 10,000 adults and 5000 children were treated with a 3-drug ARV combination; 2 NRTI (lamivudine + stavudine) and 1 NNRT (nevirapine). The program began in February 2002 involving 25 treatment centers across the 6 geopolitical zones of the country. Antiretroviral treatment (ART) provision in Nigeria is extremely low, with only 21% of adults living with HIV receiving treatment in 2013, and 12% of children. Only 19% of women who are living with HIV and breastfeeding are taking ART (UNAIDS, 2014). Although the number of antiretroviral treatment (ART) sites increased between 2012 and 2013. it is still not enough. With only 820 sites in the whole of Nigeria, it is not surprising that people living with HIV are struggling to access clinics where they can get treatment. ART administration is being decentralized from hospitals to primary health centres, and from doctors to nurses and community health workers, although there is still a huge demand for more healthcare professionals (NACA, 2014).

The National Agency for the Control of AIDS (NACA 2015) report that 747,000 HIV patients are currently receiving antiretroviral therapy treatment in over 1,050 facilities across the country

Certain weaknesses in the system exist, which mean many people who receive a positive HIV diagnosis are not referred on to treatment, or not retained in treatment for very long. Even when ART can be accessed, drug supplies are known to run out and lead to stockouts (NACA, 2014).

#### 2.3 PMTCT in Nigeria

Since the first cases of mother-to-child transmission (MTCT) of HIV were identified in the United States in the early 1980s. extensive research has led to a better understanding of the epidemiology of the global pediatric HIV epidemic, including risk factors for MTCT, potential mechanisms of transmission, and the timing of transmission. Surveillance data from the Joint United Nations Program on HIV/AIDS (UNAIDS) over the past two decades have documented the heavy burden and impact of HIV on mothers and infants living in resource-limited settings (UNAIDS, 2014).Sub-Saharan Africa carries the greatest burden of the epidemic: UNAIDS reported 150,000 pediatric infections worldwide in 2015; 110,000 new cases occurred in 21 countries in Sub-Saharan Africa (WHO, 2016) Studies of the use of antiretroviral agents to interrupt HIV transmission were initiated in the early 1990s in the United States and other resourcerich countries, Coupled with the avoidance of breastfeeding and good access to comprehensive HIV and pregnancy care services, these regimens have significantly reduced perimatal transmission in resource-rich countries to one to two percent (Neshetm

et al, 2012) in the United States, it is estimated that only 123 HIV-infected infants were born in 2012 (CDC, HIV Surveillance Supplemental Report 2015). Despite substantial barriers, efforts in resource-limited settings to introduce antiretroviral agents for perinatal prevention have also resulted in a marked decrease in perinatal HIV transmission (mother-to-child transmission [MTCT]) from over 570,000 in 2003 to an estimated 110,000 in 2015 within the 21 Global Plan priority countries in sub-Saharan Africa (WHO, 2016).

Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) is a major public health problem in Nigeria. The PMTCT services in Nigeria commenced as a pilot project in July 2002. The goal, objectives and targets of the PMTCT program have undergone some review over time in line with national realities and international demands such as the global initiative for the elimination of MTCT by the year 2015 (UNAIDS 2015). The current overall goal as documented in the 2010-2015 scale-up plan is to contribute to improved maternal health and child survival through accelerated provision of comprehensive and integrated PMTCT services. (FMOH. 2010) Since the commencement of PMTCT program. the first scale-up plan -2005-2009 was developed to direct the initial expansion of the program in the country (Wainberg, 1998). There have been progressive increases in PMTCT sites to 1,320 by the end of 2012. (FMOH, 2013). This has however not translated to effective coverage of the large population of the Nigerian society. It is estimated that in 2009 and 2012 respectively only 12% and 18% of HIV positive pregnant women received ARVs for PMICT With estimated pool of about 228,800 infected pregnant women and 57,000

children infected principally through MTCT in 2012 (UNAID, 2012; IATT, 2012), Nigeria accounts for over 30% of the global PMTCT gap (FMOH,2013). Of the 190,000 pregnant women living with HIV in 2013, only 27% of them received antiretroviral treatment to prevent the transmission of HIV to their child and 22% of all new child HIV infections globally during 2013 were in Nigeria (51,000) (UNAIDS, 2015). With only a 19% decline in child HIV infections since 2009, it is clear that Nigeria is not progressing fast enough with its PMTCT programme. The poor PMTCT coverage and uptake in Nigeria is a reflection of factors affecting the supply and demand of PMTCT services. There were 2,216 sites as at Dec 2012, a far cry from the 16,378 sites required for adequate service coverage (PCRP, 2013). Risk factors for MTCT include high maternal viral load, co-existing Sexually Transmitted Infections, Prolonged Rupture of Membrane, chorioamnionitis, hemorrhage, invasive delivery procedures, multiple gestation, prematurity and congenital malformations (WHO, 2004). Studies in Nigeria showed the average rate of vertical HIV transmission was 22.5%, but for babies whose mothers had PMTCT service the rates were 9.6%, 2.8% and 2.4% (Joseph Afe et al., 2011, Ikechebelu et. al., 2011 and Agboghoroma et al., 2015). A study in the south east Nigeria reveal that out of the 104 infants 6 of them (6%) gave a positive HIV PCR test result while 98 (94%) of them tested negative (Nwaozuzu et al.,

2014)

The main elements of the National PMTCT program are:

IN Information and counseling provided to pregnant women and their spouses.

HIV positive client, receive on-going counseling and support.

ii. Ro tine rapid HIV te ting (with an option to decline) for all women, during the

period of pregnancy and/or labor.

- iii. Antiretroviral (ARV) treatment or prophylaxis to HIV infected women. While single-dose nevirapine (sdNVP) in labor was the ARV drug intervention in the first 2-3 years of the program, a more effect combination ARV regimen in form of highly active antiretroviral therapy or zidovudine (AZT) monotherapy are now the recommended drugs.
- iv. ANC and delivery supervised by a skilled health worker to ensure safe delivery and prevent MTCT. Though the importance of cesarean section is acknowledged, its use as a public health measure was restricted with the availability of ARV and lack of access to the service in most health facilities.
- v. Infant feeding counseling on exclusive breastfeeding and breast milk substitute were the initial practice. Current guidelines emphasize only exclusive breast feeding while the mother and/or infant are on extended use of ARV drugs.
- vi. ARV prophylaxis (NVP or AZT) for the infant for 6 weeks.
- vii. Infant follow-up and HIV testing at 18 months at the early stage of the program.
   The National PMTCT program has recently introduced polymerase chain reaction services for early infant diagnosis (EID) at 6 weeks.
- viii Referral of mother. baby and other members of the family for life-long antiretroviral therapy (ART), other reproductive health services and care and support.
  - Communication activities including community dialog to improve service uptake and male involvement.
  - P 4TCF logi tics and supplies.

1X.

A How to establish new PMTCT file

xii. Monitoring and Evaluation (M and E).

The PMTCT program in Nigeria is confronted with series of challenges that have affected its success. The Nigerian PMTCT program started in tertiary institutions as a pilot program, which would be decentralized to secondary hospitals and then to PHCs. This decentralization has been slow for a variety of reasons which include: Poor buy-in at the state and local government levels, Weak health systems, human resource limitations particularly in rural areas and Low utilization of maternal and child healthcare services. Several other challenges such as high fertility rate, low contraceptive prevalence rate and a strong culture of breastfeeding with very low rates of exclusive breast feeding before 6 months have also plagued the program resulting in poor population coverage. Non-involvement of the private sector, which is a big player in the provision of health service in Nigeria, is another reason for the poor program impact. The persistently high burden of HIV and MTCT are indications that the national PMTCT program has only made modest impact. This may be attributed to the low-level

of coverage across the country and poor adherence. To address this problem, an accelerated scale-up plan 2010-2015 to rapidly decentralize PMTCT services in the country was developed and is being implemented (FMOH, 2010; FMOH, 2013).

#### 2.4 Measurement of adherence to HAART

There is no gold standard to assess the adherence, however there have been attempts to device workable adherence measurements and the most common methods are those outlined (Chesney, 2006, Edward et al. 2005).

#### a) The Direct Observation Therapy (DOT)

The DOT method requires that the health-care workers directly administer medicines to patients. This method confirms adherence since the health-care worker observes the patient taking the medicine. It cannot be used to assess patient adherence to ART in HIV care centers due to confidentiality and the huge cost that will be required for the administering of DOT in such lifelong therapy (Singh et al., 1996)

#### b) Patients' self-reports

It is the most usual, feasible, and less expensive method to assess ART adherence. In addition, it has an advantage of easy data collection, and it also help to determine why patients are non-adherence (Gao et al., 2000).Patient self-report of taking doses accurately during the past 3 days or the past week is the most practical and readily available tool for the assessment of a patient's adherence in the clinical setting and perhaps the most accurate as only that individual can report his/her actual behavior (Chesney, 2006). Abbreviated forms of questionnaires can be used, even in busy clinics, to queltly assess adherence (Lanzafame et al., 2000). Although some patients tend to overestimate their adherence in self report, several literatures have shown that this measure is associated with viral load response (Tumbu et al, 2010). Nevertheless, this method has been criticized for methodological reasons such as reliability, recall bas, social destrability, or question style (Chesney, 2000).

#### c) Pill Counts

It is an objective means of evaluating medicine adherence. It involves physical counting of patient remaining pills by physician, nurse or other health-care practitioner. Pill count adherence is usually calculated by counting the remaining doses of medication and assuming that the remaining pills in excess of what is expected to represent missed doses (Afiong et al., 2011). Adherence assessed by pill counts correlates better with adherence measured from electronic bottle caps than self-reported dose adherence(Aragones et al., 2011) However, it has some limitation: when patients remove pills from their containers but do not take them, (i.e. "pill dumping") it leads to overestimation of adherence.

#### d) Pharmacy Refill Data

Pharmacy refill adherence has become an increasingly important measure of adherence to antiretroviral medications (WHO, 2012). It can serve as an adherence measure by providing the dates on which antiretroviral medications were dispensed. In the event that refills are not obtained in a timely fashion, it is assumed that the patient is not taking medication between refills or is missing doses. It offers a simple, inexpensive, and valid

method for measuring adherence (Carrieri et al., 2006).

Other methods include, Biological Markers, Therapeutic drug monitoring (TDM), Medication Event Monitoring System (MEMS), Visual analogue scale (VAS) and Pill identification test (PIT)

#### 2.5 Adherence to HAART

#### 2.5.1 Prevalence of HAART

In the context of treatment with medications, adherence is defined as a patient's ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other medications (Wang et al., 2007). Adherence is a primary determinant of the effectiveness of treatment. (Molassiotis et al., 2002). It is also considered as a major predictor of the survival of individuals living with HIV/AIDS (Steel et al., 2007). More than 95% adherence is required in ART in order to prevent the emergence of resistant viral strains. In practice this degree of adherence requires a patient on a twice-daily regimen to not miss or substantially delay more than 3 doses of antiretroviral medications per month. 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%), (Veeman et al., 2008) while in developed countries the majority report less than 75% (range 20–100%).(Friedland et al., 2001). 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) (Mills et al. 2006). The same study revealed that poor adherence is a major concern globally despite being better in Sub-Sahara Africa. Studies among PLWH reveal non adherence rate of 37.1% (Olowookere, 2008) and 37.4% (Shaahu et al., 2008). The feeling of being healthy, forgetfulness, and unwillingness to disclose HIV status by

PLWHA were significant barriers to adherence. The adherence rate reported in a study Ugep cross River was low. 50.4% (Oku et al., 2014).

Adherence to antiretroviral therapy (ART) has been strongly correlated with HIV durable viral suppression, reduced destruction of CD4 cells, reduced rates of resistance, increased in survival, and improved quality of life (Steel et al., 2007; Chesney, 2006). The availability of antiretroviral treatment (ART) has dramatically improved the prognosis and quality of life for HIV/AIDS patients, and reduced the rate of disease progression and death. However, increased access to ART has been accompanied by increasing unsatisfactory adherence levels and the potential risk of drug resistance. Maintaining an optimal adherence level for a long term poses a significant challenge for both patients and health care provider (Jani et al., 2004).Suboptimal treatment can lead to drug failure with the latter resulting in spread of drug resistant mutation. Consequently, it can create dangerous public health situation and decrease the success of available HIV treatment. Moreover, if people living with HIV require second-line treatment, it can be ten times more (Weidle et al., 2006) expensive than first line drugs. It also leads to increased

hospitalization rate, increased the cost of health care, effects on human resources productivity, disruption of family and communities and morbidity and mortality in developing countries (Machinger et al., 2006).

#### 2.5.2 Factors associated with HAART Adherence

Adherence to ART is a critical issue, and evidences from literature has shown that the factors that influence a patient's ability to adhere are multiple and complex. There are various factors affecting adherence, which generally are related to characteristics of the patient the regimen, the clinical setting, the society and the relationship between the

service provider and the patient (Steel et al., 2007). Presently, poor adherence to treatment regimen remains a major obstacle in the fight against HIV/AIDS (Chesney, 2006). Without proper treatment and prophylaxis, HIV/AIDS presents a significant challenge to global tuberculosis (TB) control. The main reason for skipping doses were being busy, simply forgetting to take medications and religious constraints.

2.6 PMTCT Adherence in Nigeria

#### 2.6.1 Prevalence of PMTCT Adherence

Without preventive intervention, about 25-40% of infants born to HIV-positive mothers will contract the virus (Abdulsalami, 2006). Following introduction of HAART, the rates of mother-to child transmission of HIV infection has practically crashed to less than 2 % (Homsy, 2006). However, the success of HAART, like any medication, is dependent on both the intrinsic properties of the drugs and the individual's ability to take the medication as prescribed (Hayman. 2009). This is particularly true in the prevention of

mother-to-child transmission, where the consequence of failing to achieve viral suppression is the transmission of the virus to the baby (Hayman, 2009). Adequate adherence to the prescribed antiretroviral medications is essential to achieving maximal viral suppression necessary to prevent MTCT (Igwegbe et al., 2010). As the number of pregnant mothers on PMTCT continues to increase, the PMTCT program can become more uccessful with more attention given to patient adherence to the preventive therapy. Not much research has been done on antiretroviral PMTCT adherence in Nigeria. Studies in vigera have shown a non adherence rate of 21.7 % (Igwegbe et al., 2010) and 19.4 m

(Ekama et al., 2012) to antiretroviral preventive therapy in HIV positive pregnant women, with forgetfulness and stigmatization being the most cited reason for nonadherence.

#### 2.7 Factors associated with ART Adherence in pregnancy

The factors that inhibit general antiretroviral treatment adherence also relate to adherence to PMTCT therapy alongside other peculiar pregnancy related factors such as morning sickness. GIT upsets, fear of potential effect of drug on fetus (Kartikeyan et al.,2007), and mood changes amongst others. Identified stigma, fear of knowing one's own HIV status, fear of diagnosis, disclosure, infant feeding distribution stigma, lack of male partners' support and negative attitudes of health workers, loss to follow up, inadequate care providers, lack of prenatal care, and weak health infrastructure as barriers to participation in the PMTCT program (Kebaabetswe, 2007). Some of these factors will be studied closely in this research as barriers to adherence for those already on PMTCT therapy.

Adherence to ART is a critical issue, and evidences from literature has shown that the factor; that influence a patient's ability to adhere are multiple and complex. Nigeria is one of the beneficiaries of free ARV drugs through PEPFAR however, a systematic review and meta-analysis of adherence to ART during and after pregnancy in low, middle, and high income countries reported that pregnant women achieved ART induce >80% with only 53% of women achieving this during the postpartum period (Nache ga et al., 2012).

#### 2.7.1 Socio-Demographic and Economic Factors

Important socio-economic nurturing factors for ART adherence were reported by a study in South Africa to include urban area of residence, adequate physical environment including transport and access to health services. Women initiating ART at later gestational ages have less time in HIV care and possibly less counseling than women who start ART earlier in pregnancy therefore, this suggests that women who seek antenatal care (ANC) and/or initiate ART late in pregnancy are a high-risk population that requires special attention throughout the postpartum period of breastfeeding

#### 2.7.2 Level of Education

Education empowers women to have autonomy in making important health decisions without relying on other people. Attending more antenatal care (ANC) sessions offers more opportunities for health care providers to reinforce issues such as the importance of ART adherence.

#### 2.7.3 Cultural Beliefs

Local health beliefs may result in decisions to stop ART in favour of traditional medicine. Stigma and discrimination remain an important factor against quality HIV care, as 63.6% of women in a study expressed the reason for missing their drugs as afraid of being identified as HIV positive (Ekama et al., (2012).

## 2.7.4 Patient Factors

In a Nigerian study, an active desire to remain healthy and/or to protect one's child was an enabler of ART initiation and adherence (Ekama et al., 2012). The greatest loss in the PMTCT care cascade occurs prior to infant follow up, with one-third of women being lost to follow up after receiving delivery care.

# 2.7.5 Health Service Factors.

Certain factors related to health care services have been identified as having an impact on PMTCT upsake and resention in care. Such remainders include the activability of ART services, savier access to drops and services and benefits, proclemental support, and a framely care. Enablers relies to the ability, accessibility, acceptibility and affordability of resentences that either facilitate or himler depresents and actions towards PMTCT. Beakequite and excessible velocitaty counterland and long waiting lines, further facilitate and enter actions to PMTCT service.

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2.7.6 Should's Surr (are the briefstern

Due to the contrationation of hit's cars in metaary conters in Nigeria, some bealth care processes to the terminations the opposituation to see some services in their institutions which may built perfectighted for basefit and advantages. Careently hit's and PMETCT care and

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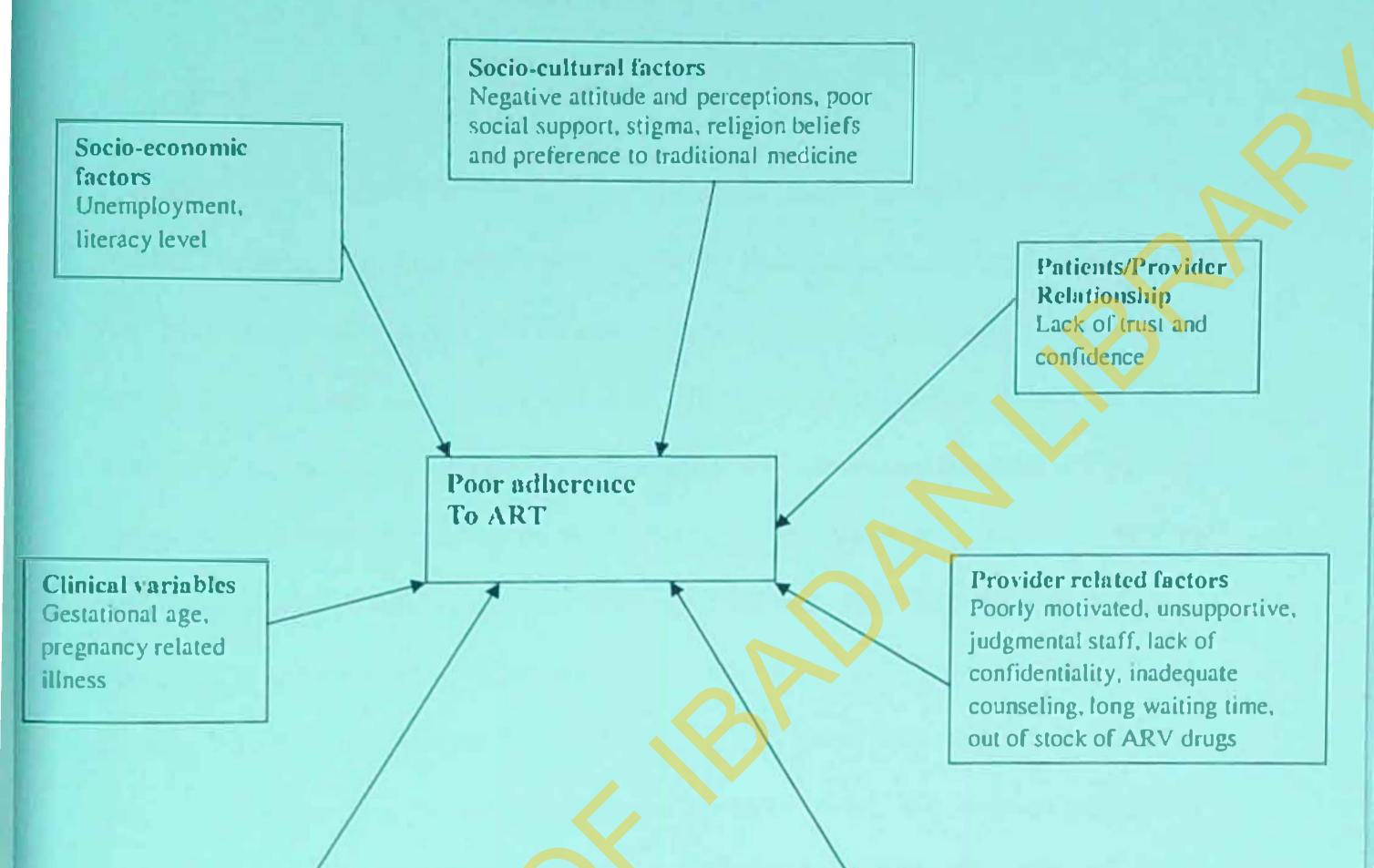
needed in order for nurses in these settings to perform the appropriate nursing practices to prevent mother-to-child transmission of HIV.

#### 2.8 The Conceptual Framework

Figure 1 shows the conceptual frame work of possible factors contributing to poor adherence to ART. 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 forgetfulness, alcohol, side effects, religious constraints and pregnancy related illness. The provider related factors include being judgmental, 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 1: Problem analysis diagram of possible factors contributing to poor adherence to ART (Veeman et al, 2008)



Patient related factors Ran out of pill, pill burden, side effects and adverse drug reactions, alcohol, forgetfulness, Patients' variable Sex, age, Unemployment, Educational level, marital status

#### **CHAPTER THREE**

#### **METHODOLOGY**

#### 3.1 Study Area

This study was conducted at PMTCT site at Federal Teaching Hospital Abakaliki. The Federal Teaching Hospital, Abakaliki is a tertiary health care facility established in the year 2012. The hospital serves as a referral centre for both Government and private health care facilities within and outside the state. The hospital is located in the Abakaliki Metropolis, the capital of Ebonyi State of Nigeria. The inhabitants are mainly the Igbos. Ebonyi State is one of five states in the Southeast geopolitical zone of Nigeria created in 1996 from the old Abakaliki division of Enugu State and old Afikpo division of former Abia state. It has 13 local governments Areas. Ebonyi state with an estimated population of about 3 million lies between 7<sup>I</sup> 3<sup>T</sup> N Longitude 5<sup>I</sup> 4<sup>I</sup> E with a land mass approximated at 5,932 square kilometers (National Beaureau of Statistics, 2006). The state has boundaries in the North with Benue State, East with Cross River, South with Abia state and West

with Enugu State. About 75% of the populations dwell in the rural areas with farming as their major occupation (National Beaureau of Statistics, 2006).

The PMTCT clinic in the hospital is the main service provider PMTCT services in Ebonyi State. It was established in 2012 as a tertiary comprehensive HIV/AIDS health centre by the Federal Ministry of Health to provide free HIV/AIDS services to pregnant women living with HIV/AIDS in the country. It currently provides counseling and testing, treatment and care services for over 10,000 HIV/AIDS patients. The HIV clinic from received addition support from donor Agencies with about 2000 patients on

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PMTCT in 2015 The Clinic opens daily from 8:00 a.m. to 5:00 p.m. Monday through Friday, however the PMTCT clinic runs on Wednesdays. The clinic has a well-trained and motivated staff. There were few reported cases of defaulters to ART and loss to follow up.

#### 3.2 Study Design

This is a cross sectional study carried out at the PMTCT clinic of Federal Teaching Hospital, Abakaliki, Nigeria.

3.3 Study Period The period for the preparation and conclusion of the study was from January. 2016 to July, 2016. The pilot study and pre-test of study materials were conducted in March, 2016 while the main data collection was carried out in April and May, 2016.

#### 3.4 Sample Size

Sample size was calculated using the formula:  $n = (Z^2 pq/d^2)$ 

Where; p = prevalence of ART non adherence among pregnant women in Nigeria, i.e.

19.4%, (Ekama et al., 2011) d = Allowable Error (5%), and q = 100-p.

Therefore the sample size  $(n) = Z^2 pq/d^2 1.96*1.96*0.194(1-0.194)/.05*.05 = 240$ 

After adjusting for non-response rate of 10% a minimum sample size (n =240/0.9) 267

was obtained.

#### 3.5 Study population

The study population includes all HIV positive pregnant women enrolled in PMTCT at Federal Teaching Hospital Abakaliki

#### 3.5.1 Inclusion Criteria

HIV positive pregnant women with known gestational age who have received ART therapy for at least 3 month prior to the study period and are able to give informed consent.

#### 3.5.2 Exclusion Criteria

Patients who stopped ART on medical ground and Patients who were very sick.

#### 3.6 Sampling Method

Systematic random sampling technique was applied for participants" selection in the study. The sampling units were pregnant women 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 100 patients per day, a total of 25 eligible patients were recruited per clinic day using systematic random sampling method using a sampling fraction of 1:4. The first patient was randomly selected; thereafter every other fourth 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

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clinic days.

#### **3.7 Data Collection**

A pretested structured interviewer administered questionnaire was used (Appendix-1). It was pretested at the PMTCT clinic Federal Teaching Hospital Abakaliki. The questionnaire captured information on their self reported adherence levels, their socio demographic indices as well as their knowledge and perceptions towards antiretroviral therapy and other factors that may influence their adherence to treatment. Following the informed consent process, the structured questionnaire was administered by a trained research assistant who understands the local language very well. Participant specific identifiers were used to ensure that no participant will be interviewed more than once. Patticipants were interviewed in a quiet private room by the research assistant.

### 3.7.1 Assessment of adherence and Knowledge

The main outcome variable was the Adherence status of the respondents. It was measured by asking patients to recall their intake of prescribed doses in the last three days prior to the interview (Ekama et al., 2012). In an attempt to minimize recall bias patients were

asked about their adherence over the previous day, previous 3 days and previous week. ART adherence was calculated manually using the respondent's self-report. The calculated ART adherence level was derived using the following formula (Ogundahunsi et al., 2008 and Onyeonoro et al., 2013).

Adherence (%) = Number of pills (doses) taken x 100 / Number of pills prescribed, Where 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%.

General knowledge level was computed by respondents' total correct responses from the various issues posed to test for knowledge. Respondents who accepted all correct responses were grouped as having "good knowledge".

#### **3.8 Statistical Analysis**

Data analysis was performed using Epi-info software (version 7.1.4) and Microsoft Excel 2007 for univariate analysis using frequencies and proportions, Bivariate analysis of association between adherence and knowledge of ART, socio-demographic factors, Partners support and duration of ART were tested using Chi2 ( $\chi$ 2) test of statistical significance. Multivariate analysis (logistic regression) was used to identify independent predictors of poor adherence among the study group. A p- value of  $\leq 0.05$  at 95% confidence interval was taken as statistically significant.

3.8.1 Dependent Variable

Antiretroviral Therapy Adherence

#### **3.8.2 Independent variables**

Maternal age, gestational age, level of education, Obstetric history, Previous PMTCT experience and partners support

#### 3.9 Ethical consideration.

Ethical approval was obtained from Ebonyi state Ministry of Health. Ethical standards and best practice were adhered to throughout the conduct of the study

#### 3.9.1 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.

#### 3.9.2 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 counselors for appropriate counselling and other relevant interventions.

#### 3.9.3 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.

#### **CHAPTER FOUR**

#### RESULT

#### 4.1 Sociodemographic characteristics of the respondents

The sociodemographic characteristics of the respondents are shown in Table 1. The mean age was  $30.7 \pm 4.2$  years. Majority of the women were aged 30-34 years (42.9%) followed by those aged 35-39 years. Two hundred and nineteen (81.72%) of the women were married and 124(42.27%) were Traders followed by hair dressers 28 (10.45%). One hundred and forty one (52.6%) of the respondents, had secondary education followed by those with tertiary education 72 (26.7%). Fifty-six (20.90) respondents were unemployed and 20 (7.46) were civil servants.



# Table 1.The sociodemographic characteristics of HIV infected Pregnant women accessing PMTCT in Ebonyi state, Nigeria, 2016

Characteristics	Percentage (%)	
20-24	16 (5.9)	
25-29	85 (31.8)	
30-34	115 (42.9)	
35-39	52 (19.4)	
Marital status		
Married	219 (81.7)	
Single	49 (18.3)	
Occupation		
Banker	7 (2.6)	
Civil servant	20 (7.5)	
Farmer	10 (3.7)	
Hair dresser	28 (10.5)	
Tailoring	11(4.1)	
Student	12 (4.5)	
Trader	124 (46.3)	

Trader Unemployed Level of Education No formal Education Primary Secondary Tertiary

# 56 (20.9)

24 (6.9) 31 (13.8) 141 (52.6) 72 (26.7)

#### 4.2 Pregnancy and HIV-related characteristics of the Respondents.

Pregnancy and HIV-related characteristics are summarized in Table 2. Two hundred and thirty three (86.94%) had partners support and 161(60.07%) had been on ARV drugs for more than 2 years. Two hundred and twenty three (83.2%) commenced ARV drugs in their index pregnancy and 167 (62.3%) have no previous PMTCT experience. Of the two hundred and sixty eight respondents 184(68.66%) have gestational ages between 13-28 weeks followed by those whose gestational ages were above 28 weeks.



 Table 2: The distribution of pregnancy and HIV related characteristics of HIV

 infected pregnant women accessing PMTCT in Ebonyi state, Nigeria, 2016

Characteristics	Number of respondents (%)
Duration of ART	
0-2 Years	107(39.93)
>2years	161(60.07)
Partners Support	
Yes	233(86.94)
No	35 (13.06)
Gestational Age	
<13 weeks	3(1.12)
13-28 weeks	184(68.66)
>28 weeks	81(30.22)
Previous PMTCT Experience	
Ver	101 (37.7)

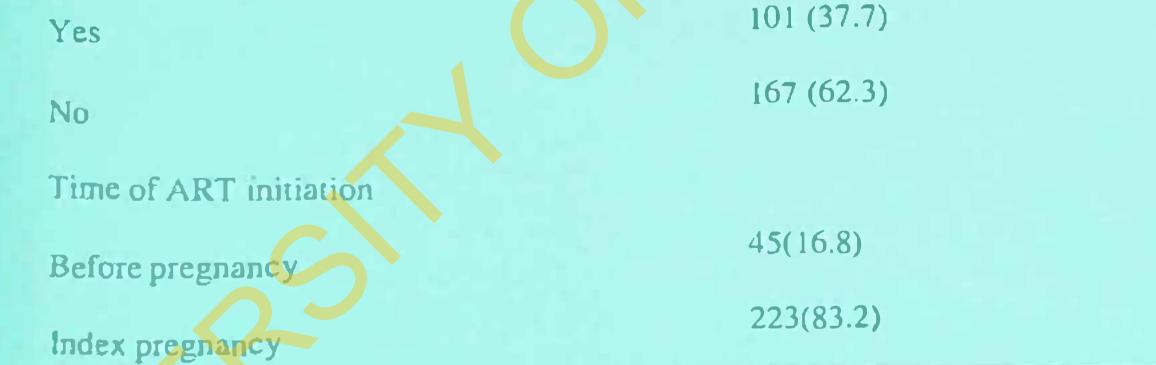


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Partners Support	
Ycs	233(86.94)
No	35 (13.06)
Gestational Age	
<13 weeks	3(1.12)
13-28 weeks	184(68.66)
>28 weeks	81(30.22)
Previous PMTCT Experience	
Yes	101 (37.7)

res

No

Time of ART initiation

Before pregnancy

Index pregnancy

167 (62.3)

4**5**(16.8) 223(83.2)

### 4.3 Prevalence of PMTCT Adherence among Respondents

During the three months study period, two hundred and sixty eight eligible HIV-positive pregnant women assessing the PMTCT services consented and were interviewed. Two hundred and thirty nine (89.2%) of the interviewed women reported achieving adherence level of greater or equal to 95% using 3 day recall method, with a non-adherent rate of 10.8% (Fig 1).





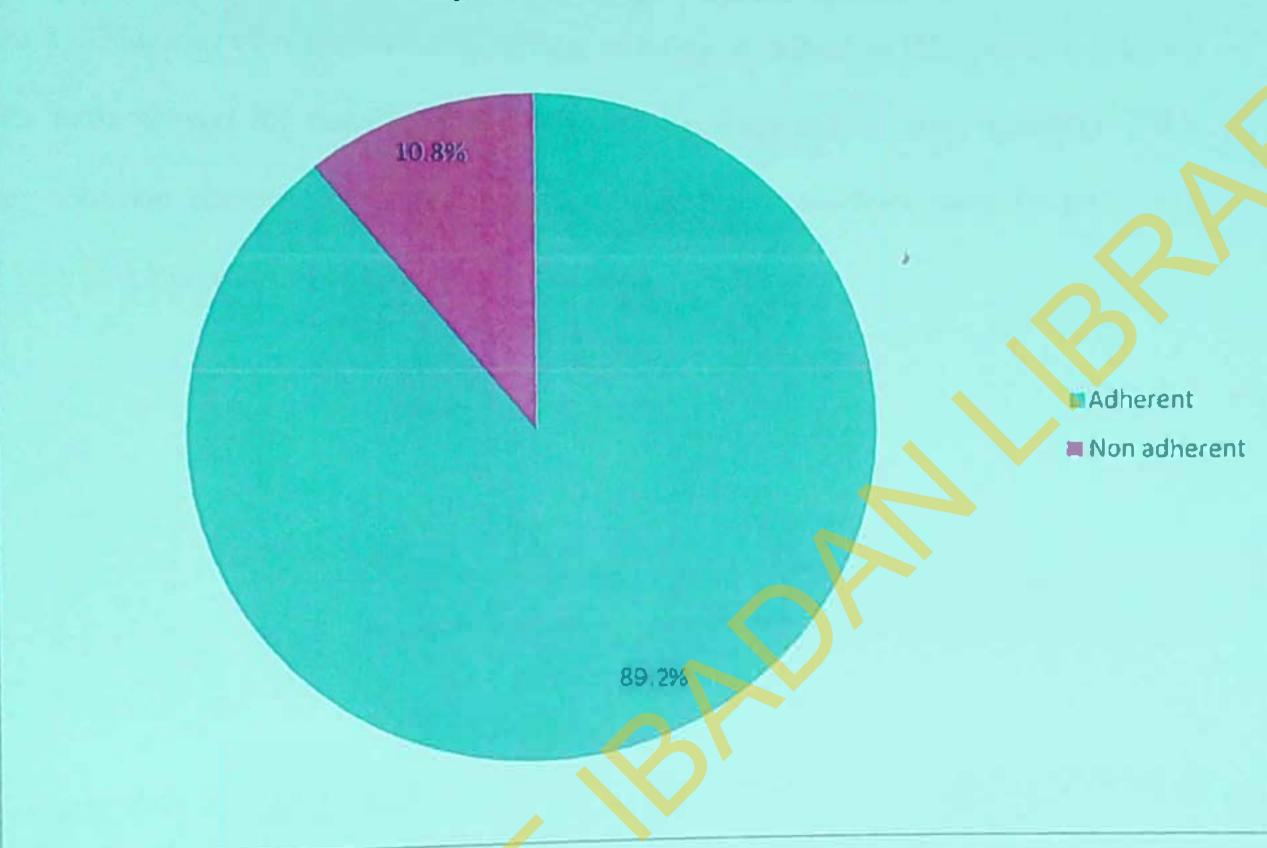


Fig 2: The adherent status of HIV infected Pregnant women accessing PMTCT in

Ebonyi state, Nigeria, 2016.

# 4.4 Barriers to ART Adherence among respondents

The reasons given by the 29 respondents for missing or skipping their drugs are shown in figure 2. Majority of respondents have Fear of being identified as HIV positive (21.0%) as the main reason for missing drugs followed by Pregnancy related illness (13.7%), Other common reasons for poor adherence listed by respondents were Forgetfulness (12.5%), and Run out of pill (9.69%).



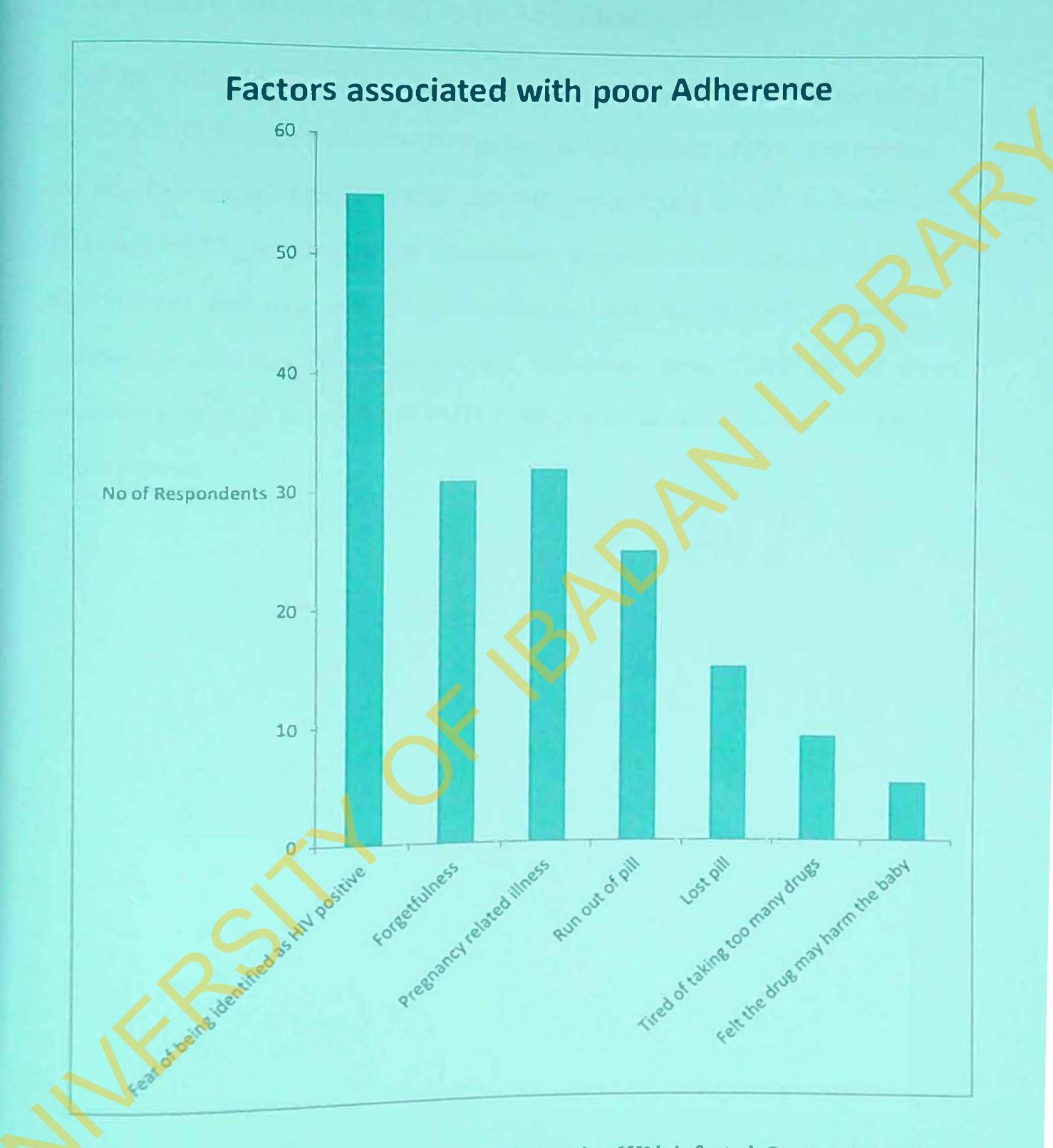


Figure 3: Reasons for missing drugs among the HIV infected Pregnant women accessing PMICT in Fbonyi state, Nigeria, 2016

#### 4.5 Knowledge of PMTCT and ART by the Respondents

All of the two hundred and sixty eight respondents knew that MTCT is possible and as high as 248 (92.5%) knew that HAART can prevent transmission of HIV. Two hundred and fifty four (94.8) respondents were sure that they will take HAART as prescribed while only 7(2.6%) do not know the consequences of not taking the drugs as prescribed. Two hundred and sixty one (97.4) respondents knew that HAART can prevent opportunistic infection (Table 3). On the Knowledge score, 255(95.2%) of the respondents had good knowledge of PMTCT. Respondent mean knowledge score was 2  $\pm$  .04 (Table 4).



 Table 3: Knowledge of PMTCT by HIV infected pregnant women accessing

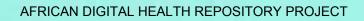
 PMTCT in Ebonyi state, Nigeria, 2016

Variables	Frequency	Percentage (%)	
HIV can be transmitted from			
mother to child during			
pregnancy			
Yes	268	100	
No	0		
HAART can prevent MTCT			
Yes	248	92.5	
No	20	7.5	
l will be able to take HAART			
as prescribed			
Very sure	254	94.8	
Not sure	14	5.2	
l know the consequences of	f		
not taking drugs			
Yes	261	97.4	
No	7	2.6	
HAART can preven			
opportunistic infections			
Yes	261	97.4	
No	7	2.6	
	41		
	AFRICAN DIGITAL HEALTH REPOSITORY PROJECT		

Table 4: Knowledge score on PMTCT by HIV infected pregnant women accessing

# PMTCT in Ebonyi state, Nigeria, 2016

Variables	Frequency	Percentage (	70)
Knowledge of PMTC	T		
Good	255	95.2	
Poor	13	4.9	



# 4.6 Factors associated with ART Adherence

## 4.6.1 Association between Socio demographic Variables and ART Adherence

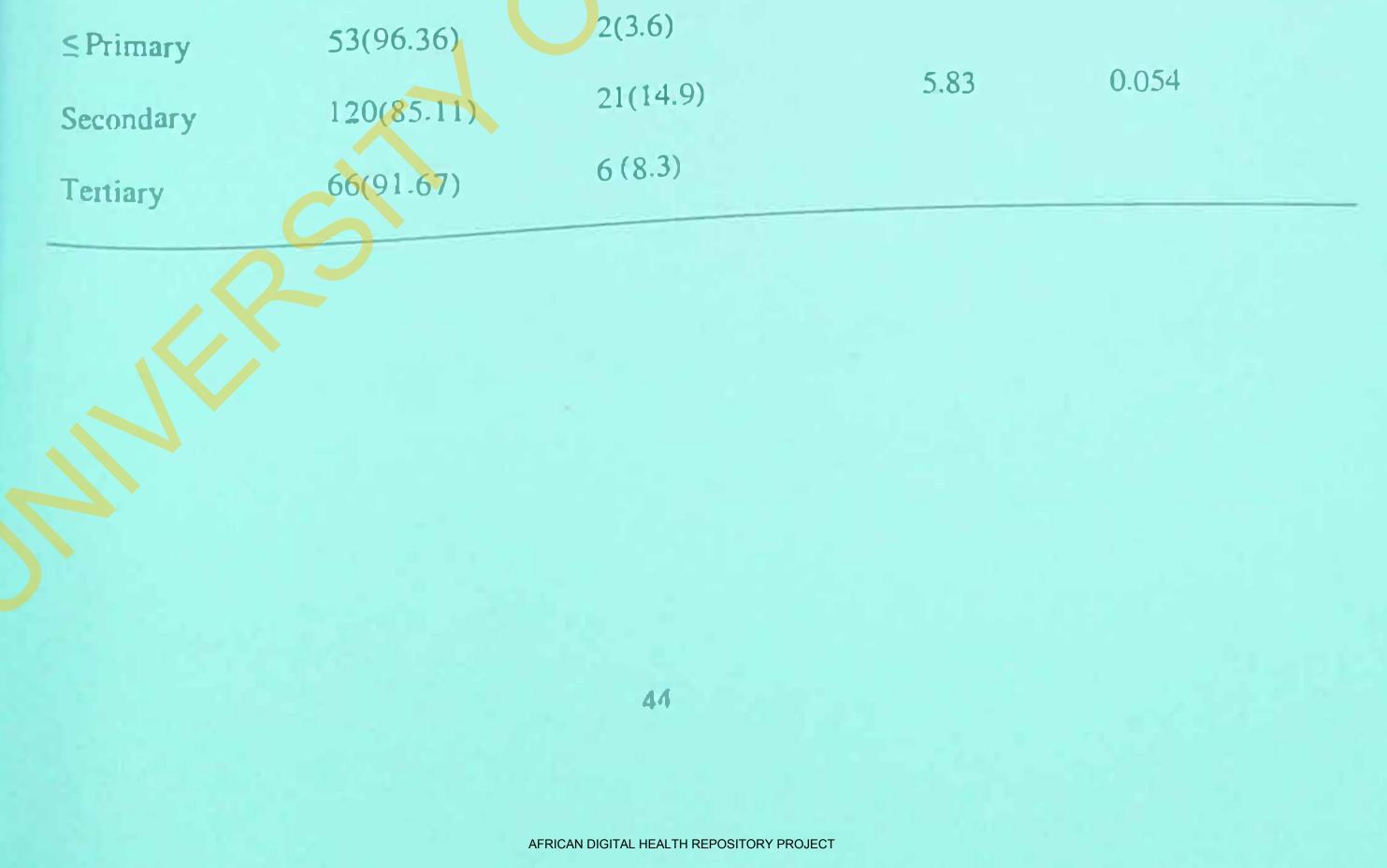
Table 5, shows the association between Socio demographic Variables and ART Adherence. Of all the variables, Age (p=0.591), Occupation (P = 0.909), marital status (P = 0.263) and Level of Education (p=0.054), none was found to be significantly associated with good adherence.



 Table 5: Association between Socio demographic Variables and ART Adherence

 HIV infected Pregnant women accessing PMTCT in Ebonyi state, Nigeria, 2016.

Factors	Adherence (%)	Non Adherence (%)	X <sup>2</sup>	P-value
Age(years)				
20-29	91 (91)	9 (9)	0.29	0.591
30-39	148 (88.1)	20 (11.9)		
Occupation				
Employed	179 (89.1)	22 (10.9)	0.01	0.909
Unemployed	60 (89.6)	7 (10.5)		
Marital status				
Married	198(90.4)	21 (9 6)	1.25	0.263
Single	41 (83.7)	8 (16.3)		
Level of				
Education				



4.6.2 Association between Knowledge of PMTCT and ART Adherence among Respondents

Table 6: shows the association between Knowledge of PMTCT among Respondents and ART Adherence. There was no significant association between Knowledge and ART Adherence (p=0.931).



 Table 6: Association between Knowledge of PMTCT and ART Adherence of HIV

 infected pregnant women accessing PMTCT in Ebonyi State, Nigeria, 2016

Variable Knowledge of	Adherence Respondents (%)	Non adherence Respondents (%)	X <sup>2</sup>	P-value
ARV/PMTCT				
Good	227(89.0)	28(10.9)	.007	0.931
Poor	12(92.3)	1(7.7)		



#### 4.6.3 Association between Obstetrics characteristics and ART Adherence

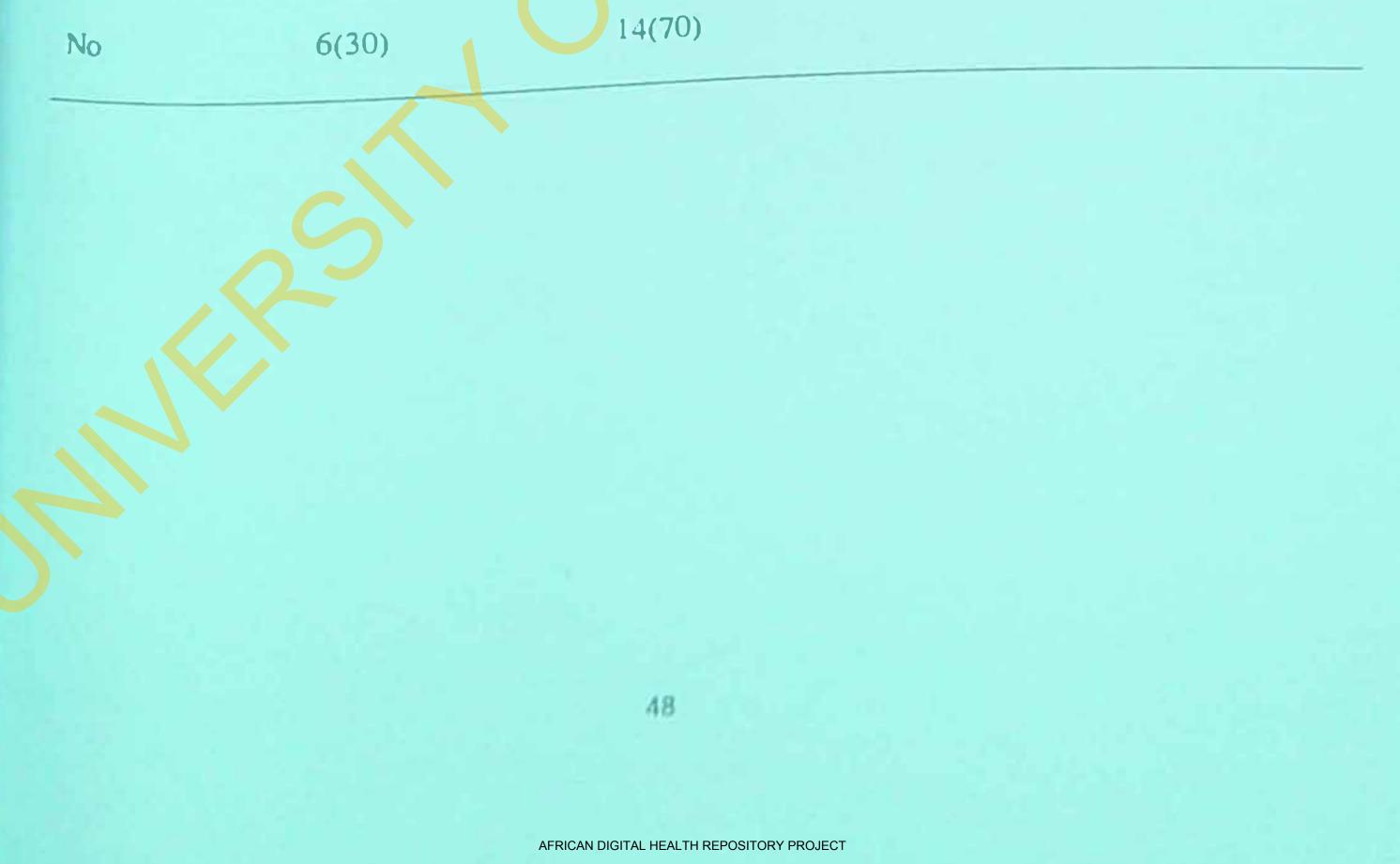
Table 7: shows the association between Obstetric characteristics and ART Adherence. Of the variables, gestational age (p=0.983) was not significantly associated with ART adherence. Duration of ART (P = 0.019) and Partners support (P = 0.001) were found to be significantly associated with good adherence.



Table 7. Association between Obstetrics characteristics and ART Adherence of HIV

infected pregnant women accessing PMTCT in Ebonyi state, Nigeria, 2016.

Factors	Adherence	Non adherence	X <sup>2</sup>	P-value
	Respondents (%)	Respondents (%)		
Gestational age				
<28 weeks	71(89.9)	8(10.1)	0.00	0.983
≥28 weeks	168 (88.9)	21 (11.1)		
Duration of				
ART				
0-2years	78 (88.6)	10 (11.3)	5.46	0.019
Above 2 years	137 (97.2)	4 (2.8)		
Partners				
Support				
Yes	218(93.6)	15(6.4)	67.2	< 0.001



4.7 Binary logistic Regression. Analysis of Factors Associated with ART Adherence during pregnancy

After subjecting the variables found to be significantly associated with good adherence to multiple logistic regressions while controlling for other potential confounders, only partners support (OR=0.027; 95%CI: 0.01-0.08,P < 0.05) retained the association with good adherence. Those that do not have partner support are three times less likely to adhere to ART in pregnancy than women with partners support



 Table 8: Binary logistic Regression Analysis of Factors Associated with ART

 Adherence during pregnancy

Variables	OR	95% confidence	Interval	P-value
		Lower	Upper	
Duration of ART				
>2	1			
≤ 2	0.3	0.06	1.92	0.219
Partners support				
Yes	1			
No	0.03	0.01	0.08	< 0.001



# CHAPTER FIVE

# **DISCUSSION, CONCLUSION AND RECOMMENDATION**

#### **5.1 DISCUSSION**

In this study, 89.2% reported good adherence. The higher adherence among HIV positive pregnant women suggests that women are always willing to protect their offspring from harm. The non-adherence rate among HIV-positive pregnant women was 10.8%. This is lower than 21.7% reported in South east Nigeria (Igwegbe et al., 2010) and comparable to 19.4% reported in south west Nigeria (Ekama et al., 2011). It is much lower than 37.1% and 37.4% reported by Olowookere et al., and Shaahu et al., respectively, from Southwestern Nigeria, among people living with HIV. Considering that our study and that of Igwegbe et al., (2010) and Ekama et al., (2011) were among pregnant women unlike the two studies by Olowookere et al., and Shaahu et al. It seems that adherence is better in pregnancy. The differences in adherence levels from other studies might have been that there is no gold standard in the measurement of this parameter and the

difference in the quality of service delivery provided to the patients. Ekama et al., 2011,

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.

De pite concerns that self-reporting, the technique used in this study, may be prone to

patient's recall bias, it has been shown in several studies to demonstrate a strong

a sociation to virologic, immunologic, and clinical outcomes in HIV treatment

(Mannheimer et al., 2004 and Nieuwkerk at el., 2001). Self-reported adherence has also

been shown to correlate with plasma concentrations of ARV drugs and quality of life (Mannheimer et al., 2004). Furthermore, the usefulness of other methods such as electronic monitoring, pill counts, medication refill rate, monitoring for an expected therapeutic outcome (such as therapeutic drug level determination and biologic markers assay), and direct observation have been flawed because most are expensive, laborious, or impractical for routine use in clinical settings (Arnsten et al., 2001).

The majority of the respondents were married and aged 30–34 years .This could be as a result of late marriage that is prevalent in this environment. Many of the respondents had at least secondary school education this could be due to poverty as majority of the inhabitants are subsistence farmers. The socio-demographic characteristics such as age, sex, and marital status in this study did not significantly affect adherence levels amongst our study population. This corroborates the findings of some other authors (Ekama et al., 2011, Mohammed., 2014, and Kleeberger., 2001), however is at variance with the findings of others who reported that older age and being single were associated with good

adherence (Uzochukwu et al. 2009) and being employed was associated with good adherence (Afolabi et al. 2009) Low educational level of the respondents, and their husbands' were associated with increased likelihood of non-adherence to therapy

(Igwegbe et al. 2010).

The majority of the respondents had good knowledge about ART/PMTCT Given that pregnant woman are generally required to attend health facilities for regular health checks, the contacts with the health care workers and the Health education which is checks, the contacts with the health care workers and the Health education which is routine during the antenatal period could have contributed to the good knowledge

recorded in this study. This finding is similar to report from Lagos (Ekama et al., 2011), Nnewi (Igwegbe et al, 2010), lle-ife (Olowookere et al., 2008), and Jos (Falang et al., 2012). Other researchers from some African countries have also reported higher level of knowledge about ART/PMTCT among study respondents. A study in Ghana reported 96.7% among pregnant women accessing PMTCT service (Boating et al., 2013). It would be expected that high knowledge of ART among study participants would have influence on adherence. There was no association between adherence and level of knowledge in this study.. This finding was similar to report from Lagos (Ekama et al., 2011) but in contrast to the report from Nnewi (Igwegbe et al. 2010) and Ghana (Boateng et al., 2013) The respondents having good knowledge of PMTCT could be partly due to the institution of counseling as part of the PMTCT programme. Patient's knowledge of PMTCT and ARTs influenced their motivation and uptake of antiretroviral for PMTCT. The main factor associated with poor adherence was Fear of being identified as HIV positive. This finding is not surprising as stigmatization and discrimination against people living with HIV are common in our society. Similar findings were documented in Nigeria (Ekama et al., 2011, Olowookere et al., 2008) and Ethiopia (Amberbir et al., 2008). Stigma and discrimination remain an important factor militating against quality HIV care. There is, therefore, the need for continued campaign against stigma and discrimination if we must improve adherence to antiretroviral drugs and uptake of other HIV-related services. The effect of pregnancy related illnesses was noticed in this study. as a major reason for missing drugs. Our findings suggest the need for Obstetricians to routinely evaluate patients who are in their first and second trimesters and advise them on what to do regarding the taking of their medications. Other reasons reported were

forgetfulness, Loss of pill, tired of taking too many drugs and feelings that the drugs will affect the baby. These findings were consistent with report of other studies in Lagos by Sekoni et al and Kasumu et al.

The finding from our study showed that women who had been on ART for up to two years were more likely to be adherent to their ARV drugs. Patients who commenced Antiretroviral therapy newly usually experience severe side effect and therefore do not comply with treatment compare to those who had been on therapy for a long time. This is consistent with a study in Zambia that reported a higher adherence rate for those on ART for a long time, and a lower non adherence rate of 16.3% (Carlucci et al., 2008) but contrast to the study in Nnewi (Igwegbe et al., 2010) that observed that women who had been on ART for up to two years and beyond were more likely to be non-adherent.

The multivariate logistic regression showed that those who have partners support were more likely to have  $\geq 95\%$  adherence to HAART. The findings of having partners

support as a factor associated with good adherence after controlling for potential confounders is in agreement with previous studies (Nachega et al., 2006). With the disclosure of HIV status to partners, who in most cases is the husband, he will not only provide support but will act as treatment partner for the spouse. We, therefore, need to encourage these women, to disclose their status to get the maximal benefit of disclosure. It is important, however, to note that women should not be forced to disclose their status, it is important, however, to note that women should not be forced to disclose their status, as HIV status disclosure has been reported to be accompanied by partner violence (Ezechi et al., 2009). Instead women who decline to disclose should be counseled and cricouraged until they feel safe to disclose, Encouraging the women to come along with a

treatment supporter for the counseling sessions prior to initiation of antiretroviral therapy preferably the partners would help in educating the partners appropriately and improving adherence in the long run.

The data collected from the study was not representative of the general population and findings might not be generalized as the study was facility based. There is no gold standard for measuring adherence and each measure of adherence has its unique limitations Adherence was calculated using self-report, 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.

# **5.2 CONCLUSION**

A high level of adherence was found among pregnant women on HAART in this study. Partners support was found to be strongly associated with good adherence. The major reasons cited by participants for missing medications were forgetfulness, stigmatization and pregnancy related illness. There was a high knowledge of PMTCT and HIV/AIDS among the respondents. There were no significant associations between adherence and socio-economic characteristics and knowledge of PMTCT. The knowledge of these identified factors should be properly utilized and addressed during adherence counseling programmes. The adherence counseling programmes should also be regular and sustained for all patients on antiretroviral therapy for its optimal benefits.

# 5.3 RECOMMENDATIONS

- Pregnant women on PMTCT should be carefully monitored by health workers for pregnancy related illness as these have been shown to affect adherence to PMTCT therapy.
- 2. Stigma and discrimination are major stumbling blocks in antiretroviral treatment adherence; this can be reduced through family and community education by Government agencies e.g. NACA and NGOs.
- 3. Federal Ministry of Health and Ebony 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.
- Priorities should be given to improving adherence by providing Health Education
   on the need to take HAART and the benefits and side-effects of the drugs during
   Antenatal and post natal visits.
- 5. These women should be encouraged to disclose their status to their partners, as

partners support has been shown to improve adherence.

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### **APPENDIX I**

## **PMTCT ADHERENCE QUESTIONNAIRE**

To determine the level of adherence of pregnant mothers to PMTCT in Federal Teaching Hospital Abakaliki.

Participant research number

Please tick ( $\sqrt{}$ ) one box for each question where there are check boxes. If you do not wish

to answer a question, please draw a line through it.

A. Socio-demographic data

Age (years)..... On HAART because of PMTCT Yes No

Month of pregnancy

Date of initiation of PMTCT therapy.....

Date

Previously has been on HAART? Yes No
If yes. Date of initiation of HAART
Education level: No formal Education Primary Secondary Tertiary
Employment status- Yes No Occupation
Marital status-Single Married Divorced Window
Du you drink alcohol Yes No
If yes, what do you drink? Beers Wines Other

How often do you drink in a week?

- B. Knowledge of PMTCT
  - 1. How sure are you that:

### Please check one box for each question.

- a. You will be able to take all Anti-HIV medications as directed? 1)Yes 2) No
  3)don't know
  - b The anti-HIV medication will prevent HIV transmission to your baby if well taken?1)Yes 2) No 3)don't know
  - c Have you at least once got some information (advices) about the consequences of not taking your treatment regularly? 1)Yes 2) No 3)don't know
  - d Do you know ARV drugs can prevent your chance of getting opportunistic infections like TB and skin infections? I) Yes [] 2) No [] 3) don't know [] e 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 Adherence Level

3 During the last seven (07) Days have you missed to take your medicament? 1 =

Yes 2 = No

a How many time(s)? .....

b. How many tablets are not taken? .....

c. How many tablets were prescribed per day? .....

4. Did you muss any of your ARV medications last weekend?

Yes No

5.Do you have your partners support Yes/No

6. In the past month, how often have you missed taking your medications because you:

Reasons for missing drugs. Please tick Yes or No for each question.

- a. Wanted to avoid side effect?..... 1)Yes 2)No
- b. Not fully understanding how and when to take the medication? 1)Yes 2)No
- c. Lost pills? 1)Yes 2)No
- d. Did not like the attitude of the health Workers?......1)Yes 2)No
- e. Had a bad event happen that you felt was related to taking the pills? 1)Yes 2)No
- f. Forgot?1)Yes 2)No
- g. Ran out of pills? 1)Yes 2)No
- h. Tured of taking too many pills? 1)Yes 2)No
- i. Felt the drugs may harm your baby? \_\_\_\_1)Yes 2)No
- j. nausea, or some pregnancy related Health problems got in the way? 1)Yes 2)No
- k. Fear of being discovered as HIV positive 1)Yes 2)No

l. Others specify.....

Thank you very much for completing these questions

#### **APPENDIX II**

### **INFORMATION CONSENT FORM**

TITLE OF RESEARCH: Factors associated with adherence to antiretroviral drugs among pregnant women in Abakaliki South Eastern Nigeria.

### PRINCIPAL INVESTIGATOR: DR. AGBOEZE JOSEPH

Dear patient,

This is to kindly request your participation in a study that is aimed at determining the Factors associated with adherence to antirctroviral drugs in Abakaliki southeastern Nigeria. A trained interviewer will spend about 10 minutes with you to help you complete a structured questionnaire. You will be required to answer the questions as truthfully as possible.

**CONFIDENTIALITY:** You are hereby assured that the information you give and the result of the test performed on you will be treated with absolute confidentiality.

VOLUNTARINESS: Participation in this study is voluntary. You will not suffer any consequences whatsoever, or be denied any treatment that you require, should you decide not to participate in the study. If you have any questions concerning your rights as a participant, please contact the principal investigator on 08035033814. You may also contact the ethical committee of FETHA Abakaliki through the office of the Chief Medical Director (CMD). If you decide you no longer wish to participate in the research, you may withdraw your consent at any time.

AGREMENT: Your signature on this form indicate that you fully understand this study and have decided to participate.

Participant

Witness

Interviewer

Date

### **APPENDIX III**

# WORK PLAN

	February	March	April	May	June	July
Submission of	~					
proposal & Ethical						
clearance						
Training of research		~				
Assistants						
Field			~			
testing/validating						
the Questionnaire						
Collection of data					~	
Data analysis and						~
thesis submission						

