ASSESSMENT OF THE PHARMACOLOGICAL INTERVENTIONS IN PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) OF HIV/AIDS IN NASARA TREATMENT AND CARE CENTRE, AHMADU BELLO UNIVERSITY TEACHING HOSPITAL, ZARIA-NIGERIA

BY

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FEBRUARY, 2013

DECLARATION

I declare that the work in the thesis entitled 'Assessment of the pharmacological interventions in prevention of mother to child transmission (PMTCT) of HIV/AIDS in Nasara treatment and care centre, Ahmadu Bello University Teaching Hospital, Zaria-Nigeria' has been performed by me in the Department of Pharmacology and Therapeutics and Nasara Treatment and Care Centre (NTCC) supported by Harvard/PEPFAR ABUTH, Zaria, under the supervision of Dr. B. B. Maiha, Dr. A.U. Zezi and Dr. H. M. Muktar.

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

AMINAT ABUBAKAR February, 2013

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Name Signature Date

CERTIFICATION

This thesis entitled "*ASSESSMENT OF THE PHARMACOLOGICAL INTERVENTIONS IN PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) OF HIV/AIDS IN NASARA TREATMENT AND CARE CENTRE, AHMADU BELLO UNIVERSITY TEACHING HOSPITAL, ZARIA-NIGERIA*" by Aminat Abubakar meets the regulations governing the award of the degree of Master of Science of the Ahmadu Bello University, Zaria and is approved for its contribution to knowledge and literary presentation.

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DEAN, SCHOOL OF POSTGRADUATE STUDIES

DEDICATION

To my beloved husband, Saleh A. Muhammad who supported me and my children for their understanding during my program by Allah's leave. My supervisors Dr. B.B. Maiha, Dr. A.U. Zezi and Dr. H.M. Muktar, for their support and encouragement. To Prof. A.I. Mamman whose contributions have helped me all through this work.

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ABSTRACT

This study was undertaken in Nasara Treatment and Care Centre ABUTH Zaria, to assess the effect of pharmacological interventions in prevention of mother to child transmission (PMTCT) of HIV/AIDS. It is a combined prospective and retrospective study. The prospective component consists of participants interview which was transcribed into a structured questionnaire and retrieval of the Clients' clinical data, forms the retrospective component. Female clients who have had at least one delivery since infection with HIV were randomly selected by convenient sampling and the seven Pharmacists working in the Centre as at the time of study were involved in the research. Of the 104 Clients interviewed, 4 were lost to follow-up. Out of the 100 Clients that participated in the study, 98% went through pharmacological intervention with anti-retroviral drugs (ART). Drug combinations prescribed for participants depended on laboratory test results and clinical examination. Therapy for PMTCT was individualised and the commonly prescribed ART for PMTCT treatment in Nasara Treatment and Care Centre was found to be Zidovudine/Lamivudine/Nevirapine (AZT/3TC/NVP) while Zidovudine/Lamivudine/Efavirenz (AZT/3TC/EFV) was used as PMTCT prophylaxis. The number of pregnancies since HIV was diagnosed in participants ranged from 1 to 6 with a mean of 2. The total number of children born by 78 out of 100 HIV positive women were determined to be 120 (22 participants have no child but were pregnant at the time of study), out of which 16 of them were HIV positive. Of these HIV positive children, 13 (11%) were delivered without PMTCT intervention while the remaining 3 (2.5%) were delivered with PMTCT intervention. The above results indicated a statistically significant reduction in vertical transmission of HIV/AIDS as shown by chi-square analysis at $P<0.05$, 95% confidence interval using SPSS version 16. The pharmacological interventions adopted by the clinic has reduced vertical transmission from 11% to 2.5%. The attitude and practice of the Pharmacists in NTCC centre ABUTH Zaria, was not satisfactory as

reported by the participants, though issues like job satisfaction and security need to be addressed by the management of the clinic. The Pharmacists need to improve their ability in the language commonly understood by majority of the clients (Hausa) to bridge communication gap. The quality of service delivery to participants was satisfactory but long waiting time (4 hours) was the major complain which also need to be addressed by the management of the clinic.

The pharmacological interventions adopted by Nasara Treatment and Care Centre ABUTH, Zaria were found to be effective in reducing vertical transmission of HIV with a statistically significant difference in the serostatus of the participants' children. With this, the null hypothesis that the pharmacological interventions in Nasara Treatment and Care Centre ABUTH, Zaria is inadequate was rejected.

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List of Abbreviations

3TC	Lamivudine
ABUTH	Ahmadu Bello University Teaching Hospital
ANC	Antenatal clinic
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AVERT	Artificial Value Endocarditis Reduction Trial
AZT	Zidovudine
bd	*bis indi*
CDC	Centre for Disease Control
CNS	Central Nervous System
C-section	Caesarian Section
DHHS	Department of Health and Human Services
EFV	Efavirenz
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Administration
F M H	Federal Ministry of Health
FTC	Emtricitabine
GIT	Gastrointestinal Tract
Gp	Glycoprotein
HBV	Hepatitis B virus
HIV/AIDS	Human Immunodeficiency Virus /Acquired Immune Deficiency Syndrome
ICTV	International Committee on Taxonomy
IFA	Immunofluorescence Assay

IPF	International Pharmaceutical Federation
INH	Isoniazid
IV	Intravenous
LPV/r	Lopinavir/Ritonavir
MTCT	Mother to Child Transmission
NACA	National Agency for the Control of AIDS
NIAID	National Institute of Allergy Infections Disease
NNRTI	Non Nucletide Reverse Transcriptase Inhibitors
NRTI	Nucletide Reverse Transcriptase Inhibitors
NTCC	Nasara Treatment and Care Centre
NVP	Nevirapine
O I	Opportunistic Infection
PCP	*Pneumocystic jirovecii*
PCR	Polymerase Chain Reaction
PCV	Packed Cell Volume
PEPFAR	U.S President's Emergency Plan for AIDS Relief
PHSTF	Public Health Service Task Force
PI	Protease Inhibitors
PLWHA	People Living with HIV/AIDS
PMTCT	Prevention of Mother to Child Transmission
PrEP	Pre-Exposure Prophylaxis
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
STD	Sexually Transmitted Disease
STI	Sexual Transmitted Infections
Tb	Tuberculosis

TDF	Tenofovir
TTA	Transfusion Transmissible HIV/AIDS
UNAIDS	United Nations Acquired Immunodeficiency Syndrome
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Special Session on HIV and AIDS
UNICEF	United Nations Children's Fund
USA	United State of America
USFDA	United State Food and Drug Administration
WHO	World Health Organisation

CHARPTER ONE

1.0 INTRODUCTION

1.1 Mother- to- Child- Transmission of HIV/AIDS

The vertical transmission of Human Immunodeficiency Virus (HIV) from an infected woman to her baby is called Mother-to-child transmission (MTCT). The virus is passed to the baby during pregnancy, labour, delivery, and/or breast feeding (De Cock *et al.,* 2000). Without treatment, about 15-30% of babies born to HIV positive women will become infected with HIV during pregnancy and delivery, and a further 5-20% will become infected through breast (De Cock *et al.,* 2000). MTCT is an issue that directly affects women as it increases the spread of HIV. Prevention of mother to child transmission (PMTCT) is a clinical approach for preventing the transmission of HIV from an infected mother to her child. HIV presents an increasing health risk to pregnant women, their infants and their families (Richter *et al.,* 2009). Research has shown that PMTCT interventions can reduce the risk of HIV transmission from mother to child from about 40% to less than 2% (UNAIDS, 2012). At the end of 2009, globally, there was an estimated 2.5 million children (under the age of 15 years) living with HIV, most of who were infected by their mothers, and without treatment, a large number of them will not live to adulthood (UNAIDS, 2011).

1.2 Statement of Research Problem

Globally, HIV/AIDS is a leading cause of death among women of reproductive age (WHO, 2009). At the end of 2010, it was estimated that out of the 34 million adults worldwide living with HIV/AIDS, nearly 60% were women (UNAIDS, 2011). UNAIDS, (2012) reported that the percentage of women living with HIV/AIDS varies significantly between different regions of the

world. In areas such as Western and Central Europe, Eastern Europe and Oceania, women account for relatively low percentage of HIV infection. However, in regions such as sub-Saharan Africa and the Caribbean, the percentage is significantly higher (UNAIDS, 2012). Factors such as poverty, restriction of women's right in spousal choice, sexual options and so forth, contribute to high female HIV burden (WHO, 2006). The overwhelming majority of people with HIV live in low- and middle- income countries. Sub-Saharan Africa is by far the region most affected. The region has just over 10% of the world's population, but is the home to 69% of all HIV cases and 70% of all deaths in 2011 (UNAIDS, 2012). Although South Africa has the largest population of people with HIV of any country in the world at 5.9 million, it accounts for around 45% of the global total of women living with HIV whereas 59% of all women with HIV live in sub-Saharan Africa (UNAIDS, 2012). Due in part to its large population size (152.6 million) (NACA, 2011), Nigeria has the second largest HIV disease burden in the world (3.3 million), with a prevalence of 3.6% and also has the highest burden of mother-to-child transmission in the world (UNAIDS, 2011). Each year, around 57,000 babies in Nigeria are born with HIV (UNGASS, 2010). It was estimated that 360,000 children are living with HIV in the country, most of who became infected by their mothers (UNAIDS, 2011). Marriage does not always protect a woman from becoming infected with HIV. UNAIDS, (2012) reported that married women have higher rates of HIV than unmarried sexually active women, often because their husbands have several partners and bring the infection home. Male to female HIV transmission is also twice as likely as female -to- male transmission. Factors that contribute to the rapid spread of HIV in Nigeria include: polygamy, a high prevalence of untreated sexually transmitted infections (STIs), low condom use, poverty, poor health status, low literacy, low status of women and stigmatization (UNAIDS, 2012).

Heterosexual transmission is the predominant means of HIV spread globally. In the USA, this mode of transmission accounts for around 72% of female infection, as intravenous drug use accounts for 26% of female HIV infections (CDC, 2007). In Nigeria, heterosexual transmission accounts for nearly 80%, as 10% is due to MTCT; while the use of unsterilized sharps, infected blood and blood products account for the remaining 10% (FMH, 2010).

Since 10% of Nigeria's HIV burden is due to MTCT, there is a need to assess the impact of currently available Pharmacological PMTCT interventions; hence the need for this study as it will provide a basis for developing measures that will prevent vertical transmission of HIV/AIDS resulting in HIV/AIDS free generation.

1.3 Justification

HIV/AIDS pandemic is a serious public health challenge the world is facing today. A disproportionate burden has been placed on women and children, who in many settings continue to experience high rates of new HIV infections and of HIV related illnesses and death. Over 90% of infection in children is acquired through MTCT and as more women contract the virus, the number of children infected has been growing.

Nigeria's programme to prevent the transmission of HIV from mother to child (PMTCT) started in July 2002 (NACA, 2011). Despite effort to strengthen PMTCT interventions, by 2007 only 5.3% of HIV positive women were receiving antiretroviral drugs to reduce the risk of MTCT. This figure has risen to almost 22% by 2010, but still remains far short of Universal access target which aim for 80% coverage (WHO/UNAIDS/UNICEF, 2010). Access to other services such as counseling, infant feeding interventions, care, treatment and in particular sexual and reproductive health are limited by ignorance, bureaucratic and logistic challenges. Family planning which is a

necessary component of PMTCT is also under-utilized. Preventing unintended pregnancy among women who are already living with HIV is particularly urgent and a neglected cornerstone of PMTCT (UNFPA, 2012). Much wider, access to HIV prevention, treatment and care services is urgently needed. A package of counseling and prevention through pharmacological interventions can prevent the unborn child from HIV infection and improve the quality of life of pregnant women living with HIV (WHO, 2010).

1.4 Aim and Objectives

Aim

To assess Pharmacological interventions in PMTCT in Nasara Treatment and Care Centre (NTCC) ABUTH Zaria, supported by Harvard/PEPFAR.

Objectives

I To assess the Pharmacological PMTCT treatment coverage in Nasara clinic.

II To evaluate the pattern of drug prescription for PMTCT in Nasara clinic.

III To determine the outcome of PMTCT interventions in Nasara clinic.

IV To assess the attitude and practice of Pharmacists towards Pharmacological interventions in PMTCT in Nasara clinic.

V To assess the quality of service delivery to pregnant women and their children in Nasara clinic.

1.5 Hypothesis:

Pharmacological interventions in Prevention of Mother to Child Transmission of HIV/AIDS are inadequate in Nasara treatment and Care Centre ABUTH Zaria.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Virology of HIV/AIDS

HIV is a member of the genus *Lentivirus,* part of the family of *Retroviridae* (ICTV, 2002). Lentiviruses share many morphological and biological properties. *Lentiviruses* are pathogenic to many species, the illnesses of which have long incubation periods and courses, hence their name Lenti meaning slow or late viruses (Levy, 1993). *Lentiviruses* are single-stranded, positive-sense, enveloped RNA viruses. Upon entry into the target cell, the viral RNA genome is reverse transcribed into double-stranded DNA by a virally encoded reverse transcriptase that is transported along with the viral genome in the virus particle. The resulting viral DNA is then imported into the cell nucleus and integrated into the cellular DNA by a virally encoded integrase and host co-factors (Smith and Daniel, 2006). Once integrated, the virus may become latent, allowing the virus and its host cell to avoid detection by the immune system. Alternatively, the virus may be transcribed, producing new RNA genomes and viral proteins that are packaged and released from the cell as new virus particles that begin the replication cycle.

2.2 Structure of HIV Virus

HIV consists of a cylindrical center surrounded by a sphere-shaped lipid bilayer envelope (see plate 1). The envelope is made up of two glycoproteins with molecular weight of 120,000 and 41,000 (Gp 120 and GP 41 respectively) for HIV-1 (see plat 1) 105,000 and 36,000 (Gp105 and Gp 36) for HIV-2 (FMH, 2007). The major function of these glycoproteins is to mediate recognition of the CD4+ molecule found on the T helper cell. The co-receptors called Beta chemokine receptors (CCXR5 and CXCR4) on the T helper cell facilitate viral entry into the host

cells after attachment and penetration by the glycoproteins (FMH, 2007). The inner sphere contains two single –stranded copies of the genomic material, RNA, as well as, multiple proteins and enzymes necessary for HIV replication and maturation which include: p24, p17, reverse transcriptase, integrase and protease (FMH, 2007). HIV uses atleast 8 genes to code for the necessary proteins and enzymes. The three principal genes are gag, pol and env genes. The gag gene encodes core protein, pol genes encode the enzymes: reverse transcriptase, protease and integrase while the env gene encodes the HIV structural components (glycoproteins). The rest of the genes –rev, nef vif, tat and vpu (for HIV-1)/ Vpx (for HIV-2) are viral for replication and enhancing HIV's infectivity rate (FMH, 2007).

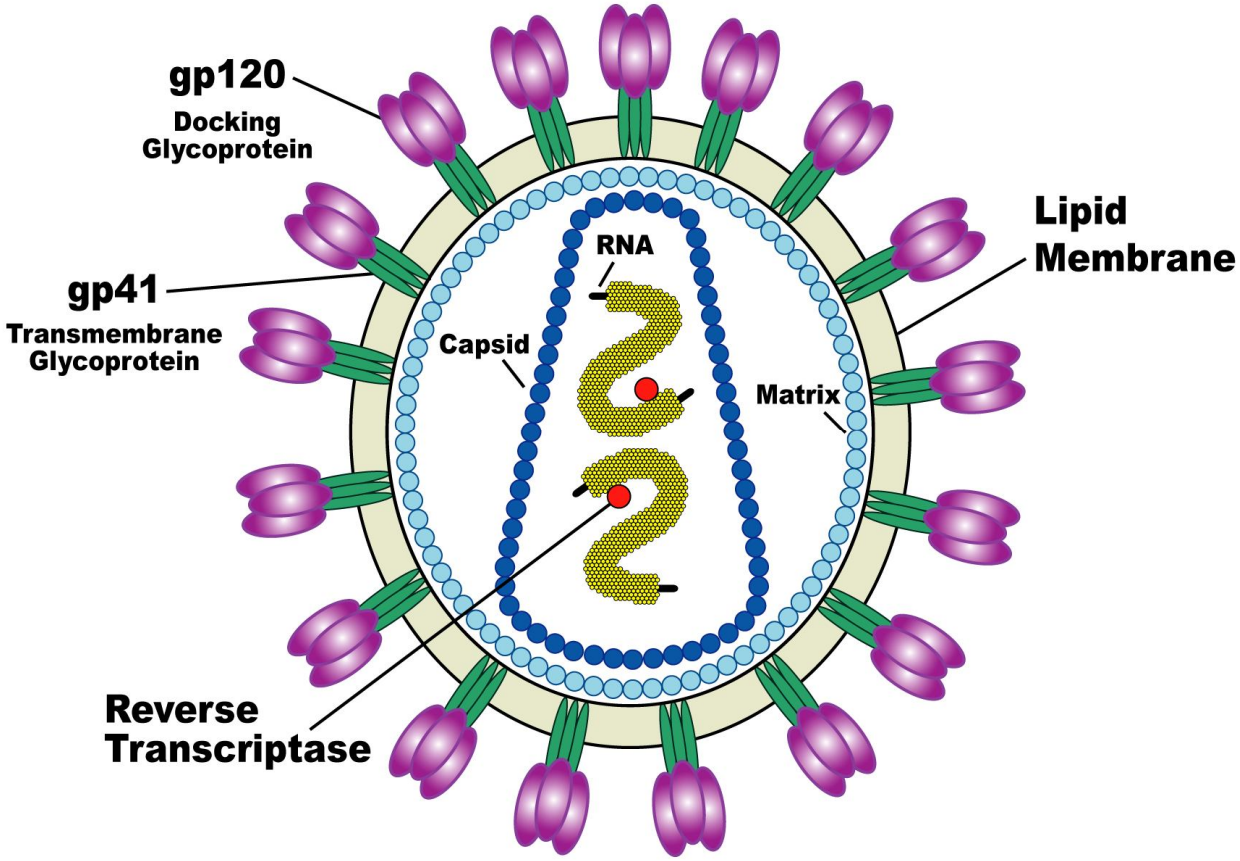


Plate 2.1: Structure of HIV Virus

Source: Structure and genome of HIV, *Wikipedia, the free encyclopedia* 26 December 2012

2.3 Pathophysiology of HIV/AIDS

HIV infects vital cells in the human immune system such as helper T cells (specifically CD4+ T cells), macrophages, microglial cell and dendritic cells (Cunningham *et al.,* 2010). Macrophages and microglial cells are the cells infected by HIV in the central nervous system. In tonsils and adenoids of HIV-infected patients, macrophages fuse into multinucleated giant cells that produce huge amounts of virus. HIV enters macrophages and CD4+ T cells by the adsorption of glycoproteins/ transmembrane protein (gp120 and gp41) on its surface to receptors on the target cell followed by fusion of the viral envelope with the cell membrane and the release of the HIV capsid into the cell (Chan and Kim, 1998). HIV infection leads to low levels of CD4+ T cells through three main mechanisms: direct viral killing of infected cells, increased rates of apoptosis in infected cells and killing of infected CD4+ T cells by CD8 cytotoxic lymphocytes that recognize infected cells. When CD4+ T cell numbers decline below a critical level, cell-mediated immunity is lost, and the body becomes progressively more susceptible to opportunistic infections (like tuberculosis, fungi, and viruses) and the emergence of malignancies which is as a result of destruction of Natural Killer cells, a reduced production of interferon, and tumour necrosis factor (Guiguet *et al.,* 2009). The common HIV related malignancies include *Kaposi sarcoma,* lymphomas (Hodgkin's and Non-Hodgkin's), and Carcinoma of the Cervix to mention a few (Engels *et al.,* 2008; Bower *et al.,* 2009). The pathogenesis of HIV infection and its sequelae is basically a struggle between HIV replication and the immune responses of the patient via cell-mediated and immune- mediated reactions. The HIV viral burden directly and indirectly mediates CD4+ T-cell destruction. There is destruction of mature CD4+ cells; CD4+ progenitor cells in the bone marrow, the thymus and peripheral lymphoid organs; as well as CD4+ cells within the nervous system, such as microglia (Cunningham *et al.,* 2010). The result of this

destruction is failure of T-cell production and eventual immune suppression. HIV is a ubiquitous virus that affects many types of organ systems like lymphoid organs, brain, spinal cord, lung, colon, liver, skin and kidney usually infection occur as illnesses. The immune systems of HIV infected children undergo changes that are similar to those in adults. Children infected with HIV often have severe disease when first evaluated, or they may develop AIDS over time, much like adults infected with HIV (Nancy *et al.,* 2012). Infants and young children normally have higher CD4 counts than those of adults. The normal CD4 count in children varies with age, but it is equal to that of adult value by the time the child is 6 years old (Nancy *et al.,* 2012).

2.4 Clinical Presentation of HIV/AIDS

Compared to HIV negative patients, the severity, frequency and duration of the presentations are increased in HIV disease. They include: Dermatologic presentations such as herpex simplex (oral/anogenital), herpex zoster, tinea nail infections, *Kaposi's sarcoma*; Oropharyngeal such as oral candidiasis, oral hair leukoplakia, *Kaposi's sarcoma* of the gums or palate, gingivitis, warts; constitutional presentations which include: fatigue, fever, chronic diarrhea, weight loss; others include: active tuberculosis (Tb), non-Hodgkin's lymphoma, unexplained leucopenia, anemia myopathy and so forth (Paul *et al.,* 2010). Immunologic and clinical categories are used to evaluate the HIV disease status and to make treatment decisions.

2.5 Laboratory Diagnosis of HIV/AIDS

2.5.1 Antibody detection

Antibodies are not detected until atleast 6 weeks after exposure to the virus. This creates a window period during which the individual tests negative despite the presence of the virus. Most

people develop detectable antibodies approximately 30 days after infection, although some seroconvert later. The vast majority of people (97%) have detectable antibodies by three months after HIV infection; a six-month window is extremely rare with modern antibody testing (CDC, 2007). During the window period, an infected person can transmit HIV to others although their HIV infection may not be detectable with an antibody test. This creates a dilemma especially in transfusion services in financially deprived nations where voluntary blood donors are scarce, coupled with a high prevalence of intravenous drug usage and other high risk factors.

An enzyme-linked immunosorbent assay (ELISA) is then used to detect antibodies to HIV-1. Specimens with a nonreactive result from the initial ELISA are considered HIV-negative unless new exposure to an infected partner or partner of unknown HIV status has occurred. Specimens with a reactive ELISA result are retested in duplicate (Kleinman *et al.,* 2004). If the result of either duplicate test is reactive, the specimen is reported as repeatedly reactive and undergoes confirmatory testing with a more specific supplemental test (e.g., Western blot or, less commonly, an immunofluorescence assay (IFA)). Only specimens that are repeatedly reactive by ELISA and positive by IFA or reactive by Western blot are considered HIV-positive and indicative of HIV infection. Specimens that are repeatedly ELISA-reactive occasionally provide an indeterminate Western blot result, which may be either an incomplete antibody response to HIV in an infected person or nonspecific reactions in an uninfected person (CDC, 2001).

2.5.2 Antigen based diagnosis

Antigen detection aims at either identifying detecting antigen like P24 or detecting viral RNA which forms the crops of the nucleic acid testing (WHO, 2007).

2.5.3 PCR based diagnosis

It is a nucleic acid-based test that looks directly for HIV in blood. It has the shortest potential window period and can be used from 3 days to 4 weeks after an exposure. It consists of DNA Polymerase Chain Reaction (DNA PCR) and reverse transcriptase polymerase Chain Reaction (RT- PCR). This test is not routinely used for laboratory diagnosis of adults and adolescents but preferred for infants less than 18 months of age. It involves the amplification of specific DNA sequences in the host cell using antibodies as its gold standard (Papadopulos *et al.,* 1993) (WHO, 2007).

2.5.4 Prognostic test

This test helps to determine the severity of HIV infection and help to determine its effect on the immune system and provide a basis for classification. The CD4 count is the hallmark for immunological characterization of HIV infection (see table 2.1). The severity of clinical presentation is inversely proportional to CD4 cell count. The normal CD4 count in a healthy, HIV-negative adult can vary but is usually between 600 and 1200 CD4 cells/mm^3 (though it may be lower in some people) (Michael and Greta, 2012). Therefore, lower CD4 count is more likely to be associated with opportunistic infections (e.g. Tb, mycosis, PCP) and malignancies.

Table 2.1: WHO Clinical and Immunologic Categories of HIV/AIDS (WHO, 2007).

WHO Clinical stages/CD4 Counts	Signs and symptoms
Stage 1 □500 cells/μL	Asymptomatic, although generalized lymph node enlargement is common.
Stage 2 350-499 cells/μL	Mild symptoms which may include minor mucocutaneous manifestations and recurrent upper respiratory tract infections.
Stages 3 200-349 cells/μL	Advanced symptoms which may include unexplained chronic diarrhea for longer than a month, severe bacterial infections including tuberculosis of the lung.
Stage 4 <200 cells/μL	Severe symptoms which includes toxoplasmosis of the brain, candidiasis of the esophagus, trachea, bronchi or lungs and *Kaposi's sarcoma*.

2.5.5 Haematological tests

A drop in haemoglobin or PCV is an indication of HIV related bone marrow failure, side effect of ARTs and cytotoxic agents, emergence of antibody mediated haemolysis or in some cases haematologic malignancies such as lymphoma. The total white blood cell is reduced in parallel with CD4 cell count (Akanmu *et al.,* 2001).

2.5.6 Chemical pathology tests

Test of renal function are preserved till very late in HIV infection. HIV nephropathy may be due to nephrotoxic effect of therapeutic agents or renal Tb. Abnormal liver function test may be due to co-existence of hepatitis B or C virus infection, hepatotoxic effect of therapy. Lipid profile is adversely affected by drugs. Stavudine, zidovudine and efavirenz causes lipoatrophy (fat loss) while, Nucleotide reverse transcriptase inhibitors (NRTIs), protease inhibitors and integrase inhibitors causes lipodystrophy (fat accumulation) (Martin *et al.,* 2004).

2.5.7 Ancillary tests

This include chest x- ray for detection of pulmonary Tb, stool and urine microscopy for the detection of endemic parasites like *Ascaris lumbricoides, Strongyloides stercoralis* and *Schistosoma spp.* Histological diagnosis is relevant for the diagnosis of cancers, deep located mycoses and extrapulmonary Tb.

2.6 Transmission of HIV

HIV is spread by parenteral modes which can be horizontal or vertical spread. Unsafe sex, transfusion of infected blood and blood products, injury with contaminated sharps; form the horizontal spread, as transmission from an infected mother to her baby in pregnancy, at birth (perinatal transmission), and breast milk constitute the vertical transmission (De Cock *et al.,* 2000).

2.6.1 Sexual transmission

The majority of HIV infections are acquired through unprotected sexual relations (Markowitz *et al.,* 2007). This can occur when infected sexual secretions of one partner come into contact with the genital, oral, or rectal mucous membranes of another. In the USA, this mode of transmission account for around 72% of female HIV infections while the other common transmission route amongst women is intravenous drug use, which accounts for 26% of HIV infections (CDC, 2007). Approximately 80% of HIV infections in Nigeria are as a result of heterosexual act (UNGASS, 2010). In high-income countries, the risk of female-to-male transmission is 0.04% per act and male-to-female transmission is 0.08% per act (Boily *et al.,* 2009). For various reasons, these rates are 4 to 10 times higher in low-income countries and the rate for receptive anal intercourse is much higher, 1.7% per act (Boily *et. al.,* 2009). Studies have shown that the consistent use of latex condoms reduces the risk of sexual transmission of HIV by about 85% (NIAID, 2001). However the use of spermicides may actually increase the transmission rate (USFDA, 2009).

2.6.2. Body fluids

The second most frequent mode of HIV transmission is via blood and blood products (Markowitz *et al.,* 2007). Blood-borne transmission can be through needle-sharing during intravenous drug use, needle stick injury, transfusion of contaminated blood or blood product, or medical injections with unsterilised equipment. The risk from sharing a needle during drug injection is between 0.63 and 2.4% per act, with an average of 0.8% (Baggaley *et al.,* 2006). The risk of acquiring HIV from a needle stick from an HIV-infected person was estimated as 0.3% (about 1 in 333) per act and the risk following mucus membrane exposure to infected blood as

0.09% (about 1 in 1000) per act (Kripke, 2007). In the United States intravenous drug users made up 12% of all new cases of HIV in 2009 (CDC, 2012) and in some areas more than 80% of people who inject drugs are HIV positive (Markowitz *et al.,* 2007). Blood transfusions with infected blood result in transmission of HIV infection in about 93% of cases (Baggaley *et al.,* 2006). In developed countries the risk of acquiring HIV from a blood transfusion is extremely low (less than one in half a million) where improved donor selection and HIV screening is performed (Markowitz *et al.,* 2007). In the UK the risk was reported at one in five million (NHS, 2011). However, as at 2008, in low income countries only half of the blood used for transfusions may be appropriately screened (UNAIDS, 2011). It was estimated that up to 15% of HIV infections in these areas come from transfusion of infected blood and blood products, representing between 5% and 10% of global HIV infections (Markowitz *et al.,* 2007). Unsafe medical injections play a significant role in HIV spread in sub-Saharan Africa. In 2007, between 12 and 17% of infections in this region were attributed to medical syringe use (Reid, 2009). The World Health Organisation estimated the risk of transmission as a result of a medical injection in Africa at 1.2% (Reid, 2009). Significant risks are also associated with invasive procedures, assisted delivery, and dental care in this area of the world (Reid, 2009). It is not possible for mosquitoes to transmit HIV (Lifson, 1998).

2.6.3 Vertical transmission

Transmission of HIV from an infected mother to her child can occur in utero (during pregnancy), intrapartum (at childbirth), or via breast feeding (De Cock *et al.,* 2000). In most cases, HIV will not cross through the placenta from mother to baby. If the mother is healthy, the placenta helps provide protection for the developing infant by strengthening the epithelial integrity of the

placenta and the genital tract (Michele and Wafaie, 2002). Factors that could reduce the protective ability of the placenta include in-uterine infections, a recent HIV infection, advanced HIV infection or malnutrition (Mofenson *et al.,* 1999). Vertical transmission is a significant cause of new infections among paediatric population. In 2010, about 390 000 children globally were newly infected with HIV down from 560 000 at their peak in 2002 (UNAIDS, 2011). More than 350 000 new HIV infections in children have been averted since 1995 by providing antiretroviral prophylaxis to pregnant women living with HIV (UNAIDS, 2011).

2.7 Epidemiology of HIV in MTCT Settings

2.7.1 Prevalence of HIV in women and children

Over the past 30 years, since the first cases of HIV infection were identified in 1981, the number of children infected with HIV has increased dramatically in developing countries because the number of HIV-infected women of childbearing age has risen (Ronald and Russell, 2012). In sub-Saharan Africa, an estimated 59% of people living with HIV are women, mostly in the reproductive age group and each year 1.4 million of these women become pregnant (UNAIDS, 2011). In 2011, globally about 330,000 children under 15 became infected with HIV, mainly through mother-to-child transmission (UNAIDS, 2012). In 2008, for every one child living with HIV in North America, Western and Central Europe, there were nearly 800 children infected with HIV in sub-Saharan Africa (UNFP, WHO, UNAIDS, 2011). About 90% of children living with HIV reside in sub-Saharan Africa where, in the context of a high child mortality rate, AIDS accounts for 8% of all under-five deaths in the region (UNAIDS, 2011) (see table 2.2).

Table 2.2: Prevalence of PMTCT in Nigeria (NACA, 2011)

PMTCT in Nigeria (2011)	Prevalence
Indicator population	152.6 million
Births per annum	6,192,053
HIV prevalence in Ante Natal Clinic (ANC) women	4.6%
Percentage of pregnant women tested who received ARVs to prevent MTCT	32%
Estimated number of HIV exposed infants at risk of MTCT annually	85,450
Annual HIV positive births	56,681

2.7.2 Impact of HIV/AIDS on the life expectancy

The HIV/AIDS epidemic is erasing decades of progress in increasing the life expectancy of the people of sub-Saharan Africa. The vast majority of people in Africa who have HIV are between the ages of 15 and 49, and millions of adults are dying young or in early middle age (UNAIDS, 2011). AIDS-related mortality has increased among 20 to 49 year olds and this age group now accounts for 60% of all death in sub-Saharan Africa, compared to 20% between 1985 and 1990, when the epidemic was in its early stages (UNAIDS, 2006). In 2009 alone, an estimated 1.2 million adults and children died as a result of HIV/AIDS in sub-Saharan Africa (UNAIDS, 2011). Thus, by affecting this age group so heavily, HIV/AIDS is hitting adults in their most economically productive years and removing the very people who could be responding to the crisis. With HIV/AIDS claiming so many lives, Nigeria's life expectancy has declined significantly. In 1991 the average life expectancy was 54 years for women and 53 years for men (WHO, 2008). In 2009, these figures have fallen to 48 years for women and 46 years men (CIA, 2010).

2.7.3 Impact of HIV/AIDS on children

Worldwide, it is estimated that more than 16 million children less than 18 years have been orphaned by AIDS and about 14.8 million of these children live in sub-Saharan Africa (UNAIDS, 2011). In some countries which are badly affected by the epidemic a large percentage of all children, for example 16% of children in Zimbabwe and 12% in Botswana and Swaziland, are orphaned due to AIDS (UNAIDS, 2011). Nigeria has the largest burden of orphans and vulnerable children in the world with HIV/AIDS as one of the major causes of orphan hood (NACA, 2011) (see table 2.3). The age of orphans, however, is fairly consistent across countries. Surveys suggest that overall about 15% of orphans are 0-4 years old, 35% are 5-9 years old, and 50% are 10-14 years old (Monasch and Boerma, 2004). Even with the expansion of antiretroviral treatment access, it was estimated that by 2015, the number of orphaned children will still be overwhelmingly high (UNAIDS, 2008). The scale of the orphan crisis is somewhat masked by the time lag between when parents become infected and when they die. As adults continue to die from AIDS, an increasing number of orphans will grow up without parental care and love. In one study carried out in rural Uganda, high levels of psychological distress were found in children who had been orphaned by AIDS. Anxiety, depression and anger were found to be more common among AIDS orphans than other children. Twelve percent of AIDS orphans affirmed that they wished they were dead, compared to 3% of other children interviewed (Atwine *et al.,* 2005). The loss of a parent to AIDS can have serious consequences for a child's access to basic necessities such as shelter, food, clothing, health and education. The loss of a productive family member is likely to be a financial burden and might push a family into poverty, increasing the likelihood that a child orphaned by AIDS will miss out on school enrolment, have their schooling interrupted or perform poorly in school (SIRDEP, 2011). The distress and social isolation

experienced by these children, both before and after the death of their parent(s), is made worse by the shame, fear, and rejection that often surrounds people affected by HIV/AIDS because they are assumed to be HIV positive themselves, aiding to the likelihood that they will face discrimination and damage their future prospects (UNAIDS, 2012).

Table 2.3: AIDS Orphans in Africa (AVERT, 2011b)

Number of Orphans due to AIDS, alive in 2009	
Nigeria	2,500,000
South Africa	1,900,000
Tanzania	1,300,000
Uganda	1,200,000
Kenya	1,200,000
Zimbabwe	1,000,000
Zambia	690,000
Mozambique	670,000
Malawi	650,000

2.7.4 ART Coverage

ART coverage has scaled up significantly due to a 2010 change in WHO guidelines, which recommends starting treatment at an earlier stage (WHO, 2011a). From 2006 to 2010, an extra three million people in low and middle-income countries were put on treatment for HIV (WHO/UNAIDS/UNICEF 2010). In 2011 ART coverage reached 57% for PMTCT (UNAIDS, 2012). Provision of antiretroviral drugs (ARVs) for PMTCT services remain much lower in West

and Central Africa (23% coverage) compared to East and Southern Africa (68% coverage) (UNAIDS, 2011). In sub-Saharan Africa, home to 92% of pregnant women living with HIV, the percentage of pregnant women living with HIV who received antiretroviral therapy or prophylaxis is 59% (UNAIDS, 2012). Nigeria provided almost 22% treatment coverage in 2010 for HIV positive women to reduce the risk of PMTCT, a figure that rose from 5.3% treatment coverage in 2007, all of which remain far lower than that of universal access target which is aimed at 80% coverage (WHO/UNAIDS/UNICEF, 2010). Botwana, Swaziland and South Africa have reached the set target (WHO/UNAIDS/UNICEF, 2010).

2.8 Prevention and Management of HIV/AIDS

2.8.1 Preventive measures of PMTCT

Nigeria is a complex mixture of diverse ethnic groups, languages, cultures, religions and regional political groupings all of which are major challenges for HIV prevention programs (UNAIDS, 2002). Sex is traditionally a very private subject in Nigeria and the discussion of sex with teenagers is often seen as inappropriate. Attempts at providing sex education for young people have been hampered by religious and cultural objections (Odutola, 2006). In 2009, only 23% of schools were providing life skill-based HIV education, and just 25% of men and women between the ages of 15 and 24 correctly identified ways to prevent sexual transmission of HIV and rejected major misconceptions about HIV transmission (UNGASS, 2010). Finally, HIV-related stigma and discrimination in sub-Saharan Africa create major barriers to preventing infections, alleviating impact, and providing adequate care, support, and treatment. Stigma often leads to discrimination and other violations of human rights, which affect the well-being of PLWHA (UNAIDS, 2011).

Strategies for preventing HIV among children include:

1. Preventing HIV infection among prospective parents - making HIV testing and other prevention interventions available in services related to sexual health such as antenatal and postpartum care and focusing on preventing HIV in women of a child-bearing age.
2. Avoiding unwanted pregnancies among HIV positive women - providing appropriate counseling and support to women living with HIV to enable them to make informed decisions about their reproductive lives. Ensuring that contraception is available to women who want it.
3. Preventing the transmission of HIV from HIV positive mothers to their infants during pregnancy, labour, delivery and breastfeeding.
4. Integration of HIV care, treatment and support for women found to be positive and their families.

(WHO/UNAIDS/UNICEF, 2011).

2.8.1.1 *Caesarean sections (C- section)*

A C-section is an operation to deliver a baby through its mother's abdominal wall. C-section has established efficacy in reducing perinatal transmission when maternal viral load exceeds1000 c/ml (Surjushe and Maniar, 2008). A meta-analysis of 15 studies with 8,533 mother- infant pairs showed a 2-fold reduction in perinatal transmission in women giving AZT versus no ARV and a 4-fold reduction when AZT was combined with C-section (John and Joel, 2007). Also a comparative study in Europe on caesarian section and vaginal delivery shows 1.8% transmission rate for C-section as against 10.5% in vaginal delivery group (John and Joel, 2007). However, C-section confers far less benefit for pregnant women given HAART due to the substantial reduction in perinatal transmission rates with effective viral suppression (Wise, 2001). The C-

section decision is based on the risk/benefit ratio. The current DHHS guidelines (2006) recommend offering c-section to HIV infected women with viral load of >1000 c/ml at 36 weeks pregnancy but the procedure is seldom available and/or safe in resource poor settings (John and Joel, 2007). The risks for adverse outcome from C-section are: non elective C-section, malnutrition, obesity, smoking, genital infection, low socio-economic status, prolonged labour, and membrane rupture (John and Joel, 2007).

2.8.1.2 *HIV and safer infant feeding*

The breast milk of HIV-infected mothers contains proviral HIV and free virus, as well as protective factors such as HIV antibodies and a glycoprotein that inhibits HIV binding to CD4+ cells (Wise 2001; Newburg *et al.,* 1991). Despite the presence of these protective factors, a number of cases have been documented of transmission of HIV by breastfeeding (Stiehm and Vink, 1991). The rate of HIV transmission with breastfeeding is 10-16% (Nduati *et al.,* 2000). The rate appears to be much greater in the 4 to 6 months (Miotti *et al.,* 1999). The risk is increased by 2-fold with mastitis and 50-fold with a breast abscess (John and Joel, 2007). Other risk factors include: cracked nipples, infant with thrush, primary HIV infection during pregnancy and prolonged breastfeeding (John and Joel, 2007). Breastfeeding is consequently discouraged in developed world; the issue is more complex for developing countries, where breastfeeding is critical for infant nutrition and survival (Nduati *et al.,* 2000). It was established that 1.7 million babies develop HIV each year due to breastfeeding but that 1.5 million babies would die each year if not breastfed (Wise, 2001). The risk of transmission is dependent upon: whether the mother breastfeeds exclusively, the duration of breastfeeding, the mother's breast health, the mother's nutritional and immune status (John and Joel, 2007). A number of studies have shown

that the protective benefit of drugs is diminished when babies continue to be exposed to HIV through breastfeeding (John, 2004). Mothers with HIV are advised not to breastfeed whenever the use of breast milk substitutes (formula) is acceptable, feasible, affordable, sustainable and safe. However if they live in a country where safe water is not available then the risk of life-threatening conditions from formula feeding may be higher than the risk from breastfeeding. An HIV positive mother should be counseled on the risks and benefits of different infant feeding options and should be helped to select the most suitable option for her situation (Moodley, 2003). A baby fed on infant formula does not receive the special vitamins, nutrients and protective agents found in breast milk. The cost of infant formula often puts it beyond the reach of poor families in resource poor countries, even if the product is widely available. Many women also lack access to the knowledge, portable water and fuel needed to prepare replacement feeds safely, or simply have no time to prepare them. If used incorrectly, mixed with unsafe water, or over-diluted, a breast milk substitute can cause infections, malnutrition and even death. Furthermore, if a mother chooses not to breastfeed in settings where breastfeeding is the norm then this may draw attention to her HIV status and invite discrimination, violence or abandonment by her family and community. Another factor worth noting is the contraceptive effect of breastfeeding, which can help to lengthen the interval between pregnancies.

Infant feeding advice for women with regular access to antiretroviral drugs:

For HIV positive women who choose, or who are advised to breastfeed, the World Health Organization's (WHO) recommendations are based on whether a woman has access to antiretroviral drugs or not (AVERT, 2011a). If a woman has support and a regular supply of antiretroviral drugs then she should exclusively breastfeed for the first 6 months of an infant's

life and then introduced mixed feeding until the infant is able to have a safe diet without breast milk (AVERT, 2011a). Mixed feeding (breastfeeding mixed with bottle feeding of water or formula, or providing other foods) is only safe in this situation because the mother or infant is taking antiretrovirals.

Infant feeding advice for women who do not have regular access to antiretroviral drugs:

In situations where health services cannot supply women or infants with a regular supply of antiretroviral drugs for an extended period of time, women are recommended to exclusively breastfeed for the first 6 months of an infant's life and rapidly wean to avoid mixed feeding. Mixed feeding is not recommended because studies suggest it carries a higher risk than exclusive breastfeeding. Potentially this is because it damages the lining of the baby's stomach and intestines thus making it easier for HIV in breast milk to infect the baby (AVERT 2011a). If an HIV positive mother does not have access to ARVs she is strongly recommended to rapidly wean. Unfortunately, the best duration for this is not yet known and may vary according to the infant's age and/or the environment (Lallemant *et al.,* 2004).

2.8.2 Therapeutic Management for PMTCT

There are two components to treatment which include specific treatment and supportive treatment.

2.8.2.1 *Specific Treatment*

This involves the use of antiretroviral agents. The goal of ART in all HIV positive patients include: maximal and durable suppression of viral load, restoration and preservation of immunologic function, improvement of quality of life and reduction of HIV-related morbidity &

mortality (Dybul *et al.,* 2002). Pharmacological intervention in many countries has led to a positive result of PMTCT. This has led to the assumption that residual vertical HIV transmission is inversely proportional to prenatal ARV assess. This is true for Botswana where prenatal HIV screening is 95%; 93% of eligible pregnant women have access to ARVs, resulting in vertical transmission of just 4% (UNAIDS, 2011). If these interventions were used worldwide, they could save the lives of thousands of children each year.

Table 2.4: A Review of Some commonly used Anti-Retroviral Agents (ART)

Class of ARTs	Name of Drug	Mechanism of Action	Dose	Side Effect	Remarks
NRTI	Zidovudine (AZT)	Binds at the active site of reverse transcriptase enzyme to halt viral DNA synthesis.	300mg bd	Anemia and neutropenia.	A first line agent. Effective in the treatment of HIV-associated dementia and thrombocytopenia
	Lamivudine (3TC)	As above	150mg bd	Headache, insomnia and GI discomfort	A first line agent. Also use in the treatment of chronic hepatitis B infection.
	Emtricitabine (FTC)	A competitive reverse transcriptase inhibitor of HIV-1	200 mg capsule od	Headache, diarrhea, nausea, fatigue, dizziness, depression, insomnia, abnormal dreams, rash, abdominal pain, asthenia, increased cough, and rhinitis. Skin hyperpigmentation is very common	Not approved for the treatment of chronic hepatitis B virus (HBV) infection. Safety and efficacy use in HBV and HIV-1 co-infection not established.

Class of ARTs	Name of Drug	Mechanism of Action	Dose	Side Effect	Remarks
				(≥10%) in pediatric patients.	
	Tenofovir (TDF)	Inhibits HIV reverse transcriptase by competing with the natural substrate deoxyATP for incorporation into viral DNA.	300mg od	Flatulence, nausea, diarrhea, abdominal discomfort, Asthenia Acute renal insufficiency, Fanconi syndrome Chronic renal insufficiency	Active against hepatitis B virus but not FDA approved for treatment of hepatitis B. Use as a pre-exposure prophylaxis (PrEP).
NNRTI	Nevirapine (NVP)	Binds allosterically at a site distant from the active site of reverse transcriptase enzyme.	200mg od for 2 weeks then 200mg bd.	Mild or moderate rash, severe or life threatening skin reactions, toxic epidermal necrolysis and hypersensitivity reaction. Severe or life threatening liver toxicity emerging in the first six weeks of treatment.	It forms a useful component of salvage regimens after virological failure (usually in combination with one or more PIs as well a NRTI especially in those who have not previously taken an NNRTI). Resistance rates are high.
	Efavirenz (EFV)	As above	600mg od	CNS effects, skin rash. All occur in few days and resolve with continuation of	High rates of fetal abnormalities. (Teratogenic)

Class of ARTs	Name of Drug	Mechanism of Action	Dose	Side Effect	Remarks
				medication.	
Protease inhibitors (PI)	Lopinavir/ritonavir (LPV/r	They prevent HIV from being assembled and released from infected CD4+. Lopinavir inhibits the HIV-1 protease. As co-formulation, ritonavir inhibits the Cyp3A-mediated metabolism of lopinavir, thereby increase its plasma level.	400mg/100mg bd	Allergic reaction (hives, difficulty in breathing, swelling of face, lips, tongue or throat), fever, sore throat, headache, increase urination and extreme thirst, bleeding.	Contraindicated in patients previously infected with hepatitis B & C infection, TB.
	Atazanavir/ritonavir (ATZ/r)	An HIV PI with high additive activity in the presence of other ARVS and a synergic activity with other PI.	ATV/r (300/100 mg)	Mild diarrhea, hyperbilirubinemia resulting in clinical jaundice.	
Entry Inhibitors	Enfuvirtide	Bind to viral Gp41 preventing HIV from entrying the host cell.	90mg bd IV. Administered subcuteously.	Neutropenia, cysts, erythema, and nodules at injection sites.	Available only as injectable and is a reserved drug.

Most Common First Line Regimen:

2NRTI + 1NNRTI e.g. AZT+3TC+NVP; AZT+3TC+EFV; 3TC+TDF+NVP; FTC+ TDF+ EFV

Most Common Second Line Regimen:

2NRTI + 1PI ± BOOSTER PI e.g. 3TC+TDF+LPV/r; 3TC+AZT+ (LPV/r or ATZ/r); TDF+EFV+LPV/r;

Recommendations for the Selection of ARVS for PMTCT:

Women who require ART solely to prevent perinatal HIV transmission may wish to delay starting therapy until after week 10-12 of gestation. The commonly used regimens for PMTCT include AZT/3TC (co-formulated) + a boosted PI such as LPV/r, ATZ/r, sequinavir/ritonavir (Paul *et al*., 2010; WHO, 2011b). EFV should not be used (especially in the first trimester) due to animal data showing increased risk of CNS defects (Paul *et al.,* 2010; WHO, 2011b).

NVP may be considered only if the maternal CD4 cell count is 250 cells/mm due to the increased risk of potentially life-threatening hepatotoxicity in women with high CD4 counts, though women who enter pregnancy on NVP regimens and tolerating them well may continue therapy regardless of CD4 count as it has no teratogenic effect (Paul *et al.,* 2010; WHO, 2011b). Because of lack of data in human pregnancy and concern regarding potential fetal bone effects, TDF should be used as a component of a maternal combination regimen only after consideration of alternatives, although is the preferred NRTI of choice in conjunction with 3TC or EFV for women who are co- infected with HIV and Hepatitis B virus (US Recommendation, 2011)

Most infant HIV infections could be averted with pharmacologicl interventions. Nevirapine, given in one dose each to mother and her child, is by far the easiest type of drug for PMTCT programmes to administer but it only reduces the risk of transmission by around 50%, and it can encourage the HIV to develop drug resistance as seen in a study that drug resistance from single dose nevirapine can remain in the body for up to 12 months (Stringer, 2010). This means that if a woman starts taking antiretroviral treatment within a few months of taking single-dose nevirapine, she might not receive any benefit, and as long as PMTCT programmes supply a drug that is only 50% effective, many babies will continue to become infected (Lockman *et al.,* 2007).

The most effective way to prevent mother-to-child transmission of HIV involves a long course of antiretroviral drugs and avoidance of breastfeeding, which reduces the risk to below 2% and is less likely to cause drug resistance (WHO, 2010). In the US and Europe, aggressive prenatal HIV testing, coupled with combination antiretroviral therapy and caesarean section further reduced HIV transmission to less than 1% (Loannidis and Abrams, 2001). In industrialized settings, antiretroviral therapy (ART), with at least three potent antiretroviral (ARV) drugs is recommended to prevent mother-to-child transmission (PMTCT) of HIV, even in women with no indication for themselves. The ART is initiated, in this case, as soon as possible after the first trimester and stopped soon after delivery (PHSTF, 2006). However, in the United States, short-course regimens of one or two ARVs are still an option for women with plasma viral load <1000 copies/ml, or for those who are screened for HIV late in pregnancy or during labour (PHSTF, 2006). In resource-limited settings, ART is recommended only in pregnant women with indication of treatment for themselves, while those who do not meet clinical and immunologic eligibility criteria for ART, according to the World Health Organization (WHO) guideline, receive short-course ARV regimens as shown in table 2.5 (WHO, 2006).

In Nigeria, pregnancy is an indicator for use of ARVs as a prophylactic, with triple ARV medication (for facilities with capacity to provide and monitor ARV medication) or with one or two ARVs (for facilities with limited capacity), when the woman does not meet criteria for treatment. They include women with WHO clinical stage I & II and those with CD4 count of greater than 350 cells/ml. Those with CD4 count of less than 350 cells/ml and those with WHO clinical stage III & IV are eligible for use of ARVs for treatment (FMH, 2010).

WHO (2010) says that PMTCT programmes are "strongly encouraged" to implement the 2010 recommendations but acknowledges that this might not be possible for all countries. In this

situation, there are previous regimens that have been used and might be implemented; these options are shown in the table 2.5.

Table 2.5: WHO guidelines for PMTCT drug regimens in resource-limited settings (AVERT 2011a)

	Pregnancy	Labour	After birth: mother	After birth: infant
2010 Recommendations option A	AZT after 14 weeks	AZT continues	AZT+3TC for seven days	(If mother breastfeeds) Daily NVP syrup until 1 week after breastfeeding has finished. (If using replacement feeding) Daily NVP or AZT until 4-6 weeks of age.
2010 Recommendations option B19	Triple ARVs after 14 weeks	Triple ARVs	Triple ARVs until 1 week after breastfeeding has finished	4-6 weeks of daily NVP syrup or daily AZT syrup, regardless of feeding method.
2006 Recommendations	AZT after 28 weeks	Single dose NVP, AZT and 3TC.	AZT and 3TC for seven days	single dose NVP and AZT for seven days
	AZT after 28 weeks		AZT and 3TC for seven days	single dose NVP and AZT for seven days
Minimum (less effective)		Single dose NVP, AZT and 3TC	AZT and 3TC for seven days	single dose NVP
Minimum (less effective; higher risk of drug resistance)		Single dose NVP		Single dose NVP

2.8.3 Supportive management of HIV/AIDS

People with advanced HIV infection are vulnerable to infections and malignancies that are called opportunistic infections (OI) because they take advantage of the opportunity offered by a weakened immune system (AVERT, 2011c). Although the introduction of HAART has dramatically reduce the incidence of OI among HIV positive people by reducing the viral load and restoring the immune system, yet the prevention and treatment of OI remains essential as the efficacy of these drugs can be affected by factors like poor adherence, drug resistance etc. (AVERT, 2011a). Prevention and treatment of OI not only help HIV positive people to live longer, healthier lives but also prevent the spread of transmittable OI to others (e.g. Tb).

2.8.3.1 *Prevention and treatment of opportunistic infections (OIs)*

Co-trimoxazole is effective at preventing a number of opportunistic infections (including tuberculosis, bacterial pneumonia, malaria, septicemia and PCP) and has been shown to significantly reduce mortality among HIV-positive individuals initiating antiretroviral therapy (Walker, 2010). Although the drug is both cheap and widely available, many countries have still failed to implement policies to provide nationwide coverage of the drug (Date, 2010).

The World Health Organisation (WHO) recommends that, in resource-limited settings, the following groups of people should begin taking co-trimoxazole:

1. HIV-exposed infants and children, starting at 4-6 weeks after birth, or at first contact with health care, and continued until HIV infection is excluded
2. HIV-positive children less than 1 year old

3. HIV-positive children aged 1-4 years who have mild, advanced or severe symptoms of HIV disease, or a CD4 count below 25%
4. HIV-positive adults and adolescents who have mild, advanced or severe symptoms of HIV disease, or a CD4 count below 350 cells per ml
5. HIV-positive people with a history of treated PCP.

According to WHO guidelines, treatment of HIV-positive children should continue until at least age five. In general treatment of adults and children should continue indefinitely, though it may sometimes be stopped following successful antiretroviral treatment. Some of the worst affected countries may choose to treat all infants and children born to mothers confirmed or suspected of living with HIV, until HIV infection is excluded. They may also choose to treat everyone who is diagnosed with HIV, regardless of symptoms or CD4 count.

Drug prophylaxis is sometimes recommended even for those who have started ART if they have very weak immune systems or are otherwise considered to be especially vulnerable. They may be advised to stop taking the drugs if their immune system recovers. For people who have already contracted an OI and undergone successful treatment, secondary prophylaxis may be advisable to prevent recurrence. This applies to diseases such as Tb, salmonella, cryptococcosis and PCP.

A partial list of the world's most common HIV-related opportunistic infections, causative agents and their treatments includes:

Table 2.6: Most Common HIV-related Opportunistic Infections, Causative Agents and their Treatments

Condition	Causative agents	Prevention	Treatment
Atypical tuberculosis(Tb)	Mycobacterium	Isoniazid preventive therapy (IPT)	anti-Tb drugs
Pulmonary or renal Tb	Mycobacterium Tb/ *M. borvis*	As above	As above
Bacterial pneumonia	*Streptococus pneumonia or H influenzae, Klebsiella pneumoniae* and so forth	Co-trimozaxole	Amoxicillin±clavulanic acid, 2nd generation cephalosporins, Gentamicin 5mg/kg/ day thrice daily for 5-10 days + Ampiclox or amoxicillin ±clavulanic acid
Malaria,	*Plasmodium falciparum*	As above	Anti malarials: Atesunate + amodiaquine or Artesunate + lumefantrine.
Diarrhoea, dysentery	*Strongyloides stercoralis, Salmonella spp Campilobacter pylori* and so forth	As above	Rehydrate and treat appropriately. 1- Metronidazole 800mg orally thrice daily for 5-10 days + co-trimozaxole. 2-

Condition	Causative agents	Prevention	Treatment
			Albendazole 400mg twice daily for 5 days to treat strongyloides.
PCP	*Pneumocystis jirovecii*	As above	co-trimozaxole or Clindamycin 600mg iv 8 hourly or 300-450mg orally four times daily + oral primaquine 30mg/day for 21 days
Oral and genital herpes	*Herpes simplex virus type 1 and 2*		Acyclovir 400mg thrice daily for 7 days
Herpes zoster (shingles)	*Varicella zoster*		Acyclovir 800mg four times daily for 7 days
Kaposi's sarcoma	*Human Herpes virus type 8*		Primary treatment: HAART; 2nd line treatment: Interferon; Other adjunct therapies: Systemic Adriamycin, Bleomycin, vincristine or vinblastine

IPT: Isoniazid preventive therapy is recommended as a health-preserving measure for HIV-infected persons at risk of Tb, as well as for those with latent Tb infection.

Anti-Tb drugs: Phase 1(Induction): Isoniazid (INH) 300mg+ Rifampicin 600mg + Pyrazinnamide 1-1.5g + Ethambutol 800-1200mg orally qh for 8 weeks (56 doses)

Phase 2 (continuation): INH + Rifampicin for 18 weeks or INH + Ethambutol for 18 weeks (126 doses); Pyridoxine 25mg daily (to prevent neuropathy).

Isoniazid preventive therapy is recommended as a health-preserving measure for HIV-infected persons at risk of Tb, as well as for those with latent Tb infection.

2.8.3.2 *Anaemia*

There is need to identify and treat the cause of anaemia. Erythropoesis supporting agents e.g. iron supplement, vitamins, vitamin B (1,2,6,12), vitamin C folic acid and so forth, are used to correct anaemia (Michele and Wafaie, 2002).

2.8.3.3 *Malignancies*

People with HIV/AIDS are at high risk for developing certain cancers, such as *Kaposi's sarcoma,* non-Hodgkin lymphoma, and cervical cancer. (Robert, 2012) For people with HIV, these three cancers are often called "AIDS-defining conditions," meaning that if a person with HIV has one of these cancers it can signify the development of AIDS. The connection between HIV/AIDS and certain cancers is not completely understood, but the link likely depends on a weakened immune system (Robert, 2012). Most types of cancer begin when normal cells begin to change and grow uncontrollably, forming a mass called a tumor. A tumor can be benign (noncancerous)

or malignant (cancerous, meaning it can spread to other parts of the body). These cancers can be managed with the following therapies: (Robert, 2012) (table 2.7).

Table 2.7: Appropriate cytotoxic agents based on histologic diagnosis are:

Malignancies	Therapy
Lymphoma	Radiotherapy, immunotherapy
Kaposi sarcoma	As above
Cervical carcinoma	Surgery, chemotherapy, radiotherapy

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This is a combined prospective and retrospective based study. The prospective component consists of participant interview which was transcribed into a structured questionnaire. Female clients who have had at least one delivery since infection were randomly selected by convenient sampling and the entire Pharmacists working in the centre were involved. A retrieval of the clients' clinical data forms the retrospective component.

3.2 Scope/Area of Study

This is a hospital based research that was carried out at Nasara Treatment and Care Centre (NTCC), Ahmadu Bello University Shika, Zaria supported by Havard/ PEPFAR. The hospital serves Zaria and most parts of North –West zone of Nigeria. The consent of the Principal investigator of the clinic (NTCC) was obtained as well as a written approval from the Hospital Ethical Committee (Appendix i).

3.3 Inclusion Criteria

1 HIV/AIDs infected mothers with children of less than 15 years

2 HIV/AIDs infected mothers currently pregnant

3 HIV/AIDs infected mothers currently nursing a child/children

4 HIV/AIDs infected mothers in labour or just delivered at the time of administering the questionnaire.

5 Pharmacist staff of NTCC ABUTH Zaria involved in caregiving to HIV/AIDS infected mothers and their children.

3.4 Exclusion Criteria

1 Clients and Pharmacists that do not meet the above criteria.

2 HIV negative mothers.

3 Unwilling HIV/AIDS infected mothers.

4 Non-Pharmacist staff of NTCC ABUTH Zaria.

3.5 Sample Size

The sample size was obtained using the formula

$$n = \frac{Z^2pq}{d^2}$$ (Araoye, 2004).

Where:

n = sample size,
Z = standard deviation (1.96),
p = prevalence =0.034
q = 1-p i.e., 1- 0.034
d = degrees of freedom (0.05)

$$n = \frac{(1.96)^2 \times 0.034 \times (1- 0.034)}{(0.05)^2} = 52$$

NB: To make result more statistically significant, the sample size was increased to 104 taking into consideration 100% compliance (i.e. 52 x 2=104).

3.6 Principles of the Study

This study involves both the Clients and Pharmacists of Ahmadu Bello University Teaching Hospital PEPFAR unit. A questionnaire of 67 questions was distributed to 104 consenting Clients randomly selected by convenient sampling and also another different set of questionnaires were given to the entire Pharmacists available in the clinic involved in drug dispensing to the Clients for PMTCT. Data that cannot be responded to by the Clients were

obtained from their register. To each of the questionnaires to both the Clients and Pharmacists was attached a consent form, seeking their permission and full participation in the research assuring them of confidentiality (Appendix ii and iii). All the questions to both the Pharmacists and Clients revolve round Federal Ministry of Health Nigeria National guidelines for Prevention of Mother to Child Transmission (PMTCT) of HIV/AIDS.

3.7 Data Analysis

Information from the respondents was grouped, presented appropriately as tables and graphs. The data were analysed using the Statistical Programme for Social Science (SPSS) package version 16. Chi- square was used to determine relationship between variables.

CHAPTER FOUR

4.0 RESULTS

4.1 Participants' Bio data

Out of the 104 Participants sampled, 100 completed the study while the remaining 4 were lost to follow up.

4.1.1 Age, Ethnicity and Marital Status

The mean age of the participants was found to be 31.21±5.89 with the minimum and maximum ages of 20 and 60 years respectively. Majority of them are in the age range of 26-30 years (48%) while 2% are over the age 40 (Table 4.1). Most of them are Hausa (60%), 7% are Fulani while Yoruba and Ibo each made up 4% of the study population. Those that did not fall within the classified ethnic group were grouped as others and they account for 25%. All the participants except two (2%) were married and majority were married only once (62%) (Table 4.1).

Table 4.1: Age, Ethnicity and Marital Status of the Study Population

Participants' Bio data		Frequency	Percentage
Age (years)	**≤ 25**	15	15
	26-30	48	48
	31-35	20	20
	36-40	15	15
	≥ 41	2	2
	Total	100	100
Ethnic Group	**Hausa**	60	60
	Fulani	7	7
	Yoruba	4	4
	Ibo	4	4
	Others	25	25
	Total	100	100
Marital Status	**Single**	2	2
	Married once	62	62
	Married more than once	33	33
	Separated	1	1
	Widowed	2	2
	Total	100	100

4.1.2 Occupation and Educational Status

Majority of the participants have western education; either primary (19%), secondary (27%) or tertiary (26%). 23% of them have Arabic/ Islamic education as their highest qualification, while 5% of them did not answer the question. Most of them (60%) are unemployed (i.e. house wife), 21% are self-employed, 13% are civil servants and the remaining 3% are students (table 4.2).

Table 4.2: Educational Status and Occupation of the Study Population

Participants' Bio data		**Frequency**	**Percentage**
Educational status	**Arabic School**	23	24.2
	Primary School	19	20.0
	Secondary School	27	28.4
	Tertiary Education	26	27.4
	Total	95	100
Occupation	**House Wife**	60	61.9
	Civil Servant	13	13.4
	Self Employed	21	21.6
	Student	3	3.1
	Total	97	100

Out of the 100 participants, 5 and 3 people did not answer the question on Educational status and occupation respectively.

4.2 Pharmacological PMTCT Treatment Coverage and Pattern of Drug Prescription for PMTCT in Nasara Treatment and Care Centre ABUTH, Zaria.

Out of 100 participants interviewed, 98% of them went through pharmacological intervention while the remaining 2 women were not on ART. The most commonly prescribed regimen for PMTCT in Nasara Treatment and Care Centre ABUTH, Zaria was found to be Lamivudine/ Zidovudine/ Nevirapine which make up 54% of all the regimen used (Table 4.3).

Table 4.3: Pharmacological PMTCT Treatment Coverage and Drug Regimens Used for PMTCT by the Participants at the Time of Study in Nasara Treatment and Centre ABUTH, Zaria.

Drug Regimen	Frequency	Percentage
AZT/3TC/NVP	54	54.0
TDF/3TC/LPV/r	2	2.0
AZT/3TC/EFV	16	16.0
TDF/3TC/LPV/r/AZT	2	2.0
TDF/3TC/NVP	18	18.0
TDF/FTC/EFV	4	4.0
AZT/3TC/LPV/r	2	2.0
No therapy	2	2.0
Total	100	100.0

Key:

AZT=Zidovudine

3TC=Lamivudine

NVP=Nevirapine

TDF=Tenofovir

EFV=Efavirenz

FTC=Emtricitabine

LPV=Lopinavir

r=ritonavir

4.2.1 CD4 Count of Participants at the Time of Study

The mean CD4 count of the participants was found to be 433.38±205.64 cells/µl (with minimum and maximum of 33 and 924 cell/µl respectively). 29% of them had CD4 counts in the range of ≥ 500. The CD4 counts of 24 participants could either not be retrieved or the results were not available at the time of this study (Table 4.4).

Table 4.4: CD4 Counts of Participants at the Time of Study in Nasara Treatment and Care Centre ABUTH, Zaria.

CD4	(cells/µl)	Frequency	Percentage
	< 200	9	9.0
	200-349	21	21.0
	350-499	17	17.0
	≥ 500	29	29.0
	Missing	24	24
	Total	100	100.0

4.3 The Outcome of PMTCT Interventions in the Study Population.

The total number of children delivered by 78 women out of the 100 participants was found to be 120 with a mean number of 1.54±0.83 (minimum 1 child; maximum 6 children). The remaining 22 participants were yet to deliver at the time of study. Out of these 120 children, 16 were HIV positive: 13 (11%) of whom were delivered by mothers who had no PMTCT intervention and 3 (2.5%) were delivered by mothers who had PMTCT intervention and there was a statistically significant difference ($P<0.05$) between them (Table 4.5).

Table: 4.5: The Effect of Antiretroviral Therapy on HIV Serostatus in Children Born to Participants in the Study at Nasara Treatment and Care Centre ABUTH Zaria.

PMTCT compliance by participants	HIV Positive Children	HIV Negative Children	Total no. of children
PMTCT compliant	3	97	100
Non-PMTCT compliant	13	7	20
Total	16	104	120

$\chi 2 = 55.36$, $P<0.05$, 95% Confidence interval

There is a statistically significant difference between the HIV seroprevalence outcome in relationship to PMTCT intervention.

4.4: Attitude and Practice of Pharmacists in Nasara Treatment and Care Centre ABUTH Zaria.

4.4.1: Pharmacists' Tools for Monitoring Drug Adherence

At the time of study, there are 7 Pharmacists involved in care giving to Participants in Nasara Treatment and Care Centre ABUTH Zaria, of which 6 (85.7%) monitor drug adherence using self-reporting by the Participants and 1 (14.3%) uses Pharmacy refill data (Table 4.6).

Table 4.6: Tools Used for Monitoring Drug Adherence by Pharmacists Involved in Care Giving to Participants Attending Nasara Treatment and Care Centre ABUTH Zaria.

Tools for monitoring drug adherence	Frequency	Percentage
Use of pharmacy refill data	1	14.3
Self-reporting by Clients	6	85.7
Total	7	100

4.4.2: Participants Preferred Care Giver

Most of the Participants in the study (43%) preferred relating with Doctors, followed by Nurses (22%), with the Pharmacists (4%) being the least care giver in their health matters (Figure 4.1). Others as shown on the gragh represent participants that choose relatives and friends as their preferred care giver.

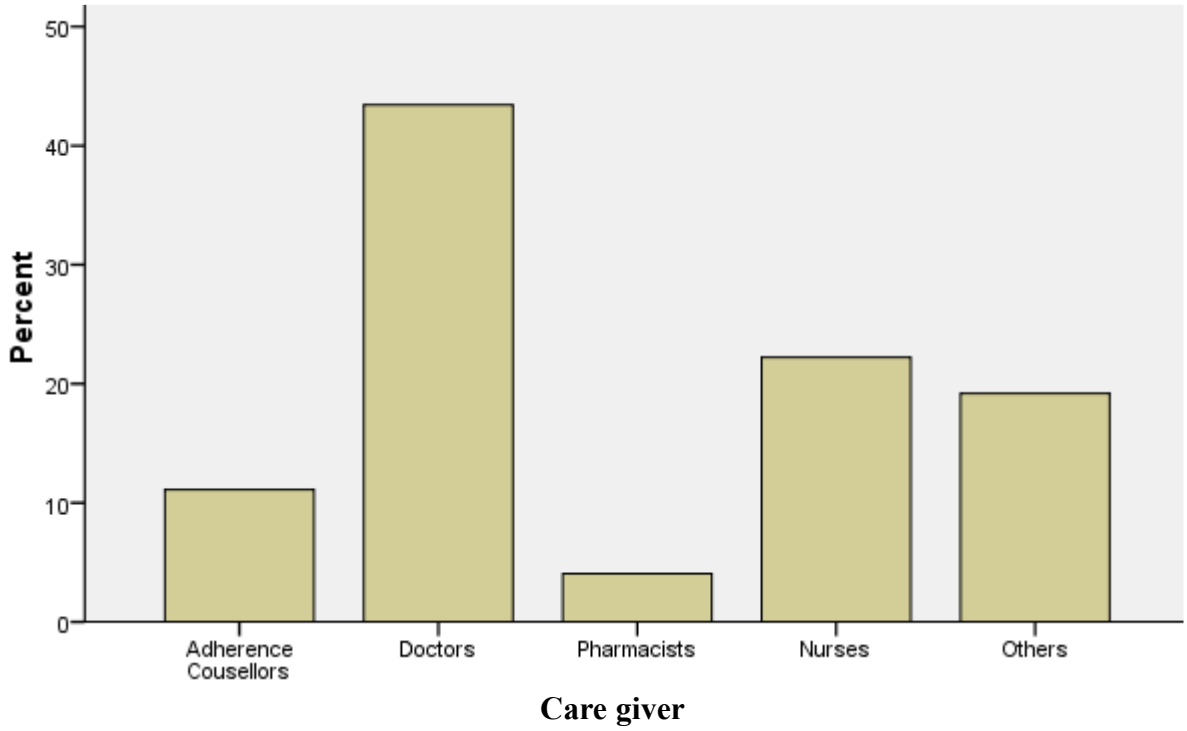


Figure 4.1: Participants' Preferred Care-Giver in the Study at Nasara Treatment and Care Centre ABUTH, Zaria

4.4.3: Participants Assessment of Knowledge levels and Information Provider in Nasara Treatment and Care Centre ABUTH Zaria.

Majority of the Participants (72-79%) do not have knowledge of basic Pharmacologic information required for their medications. The few that knew (23-25%) were educated mainly by Nurses and Doctors while Pharmacists are their least educators as reported by the participants (Table 4.7). Also, the Nurses are the main educators in counseling most of the participants (79%) on the benefit of PMTCT and method of controlling unintended pregnancy, while the Pharmacists hardly participate claiming that it is not their duty (Table 4.7).

Table 4.7: Participants Assessment of Knowledge levels and Information Provider in Nasara Treatment and Care Centre Zaria.

	Knowledge (%)			No knowledge (%)	Total
	Source of knowledge				
Criteria	**Nurses**	**Doctors**	**Pharmacists**		
Mechanism of action	19	5	1	75	100
Drug Resistance	16	9	2	75	100
Treatment Side Effects	13	14	1	72	100
Drug Interaction & food restriction	14	6	1	79	100
Duration of therapy	16	10	2	72	100
Benefit of PMTCT	79	15	1	5	100
Method of contraception	79	9	0	12	100

4.4.4: Parameters used by Pharmacists to Aid Job Efficiency

Out of the 7 Pharmacists involved in the study, 2 (28.6%) of them are not satisfied and feel insecured in their job. They also have limited understanding of Hausa which is the language spoken by majority of the participants (Table 4.8).

Table 4.8: Parameters used by the Pharmacists to Aid Job Efficiency in Nasara Treatment and Care Centre ABUTH Zaria.

Pharmacists' job efficiency aid	**Number of Pharmacists**		
	Yes	**No**	**Total**
Job satisfaction and security	5 (71.4)	2 (28.6)	7
Excellent ability in understanding and speaking the language of Participants' (majority).	5 (71.4)	2 (28.6)	7

Numbers in parenthesis are percentages

4.5 Quality of Service Delivery to Participants

4.5.1 Participants Assessment of Service Delivery

The services rendered to Participants are easy to understand by majority (93%) and complex to only 1% (Figure 4.2). Others as shown on the gragh represent participants that did not answer the question on service delivery.

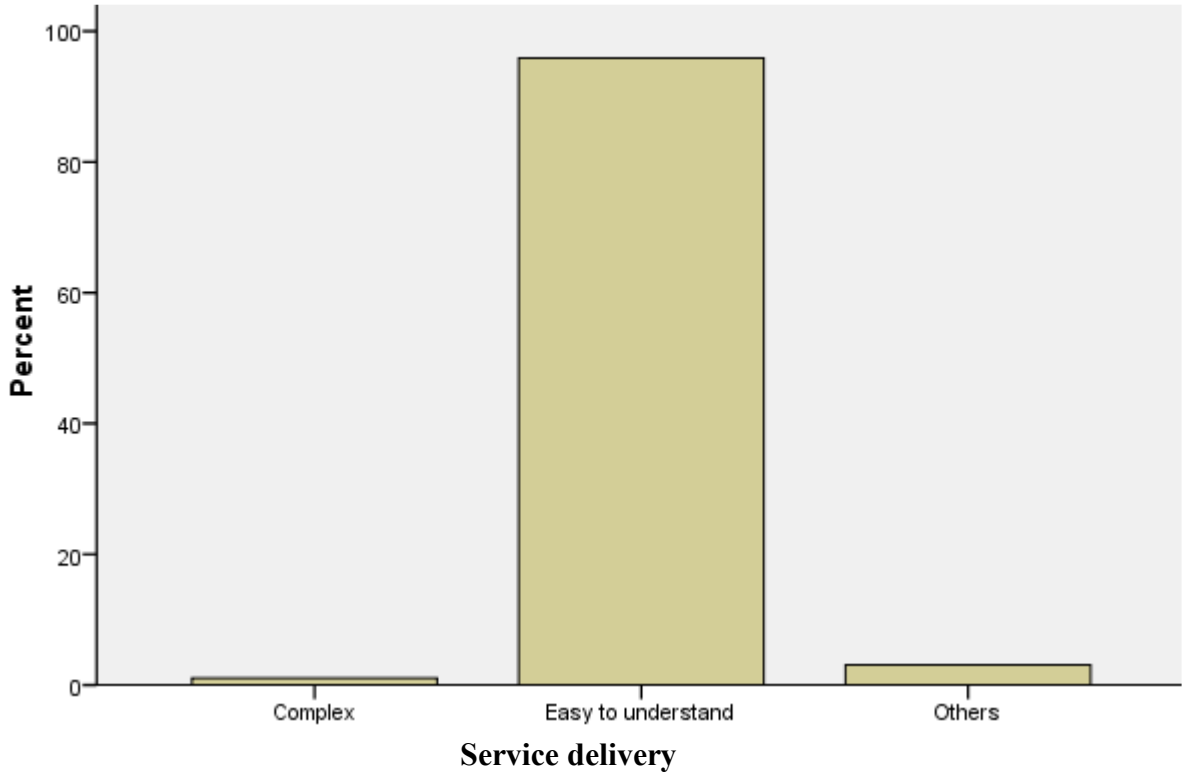


Figure 4.2: Participants Assessment of Service Delivery in Nasara Treatment and Care Centre ABUTH Zaria

4.5.2: Participants Assessment of Efficiency of PMTCT Programme

Majority of the Participants rated the efficiency of PMTCT programme in Nasara Treatment and Care Centre, ABUTH Zaria as satisfactory (57%), while 33%, 7% and 1% considered it excellent, good and fair respectively (Figure 4.3).

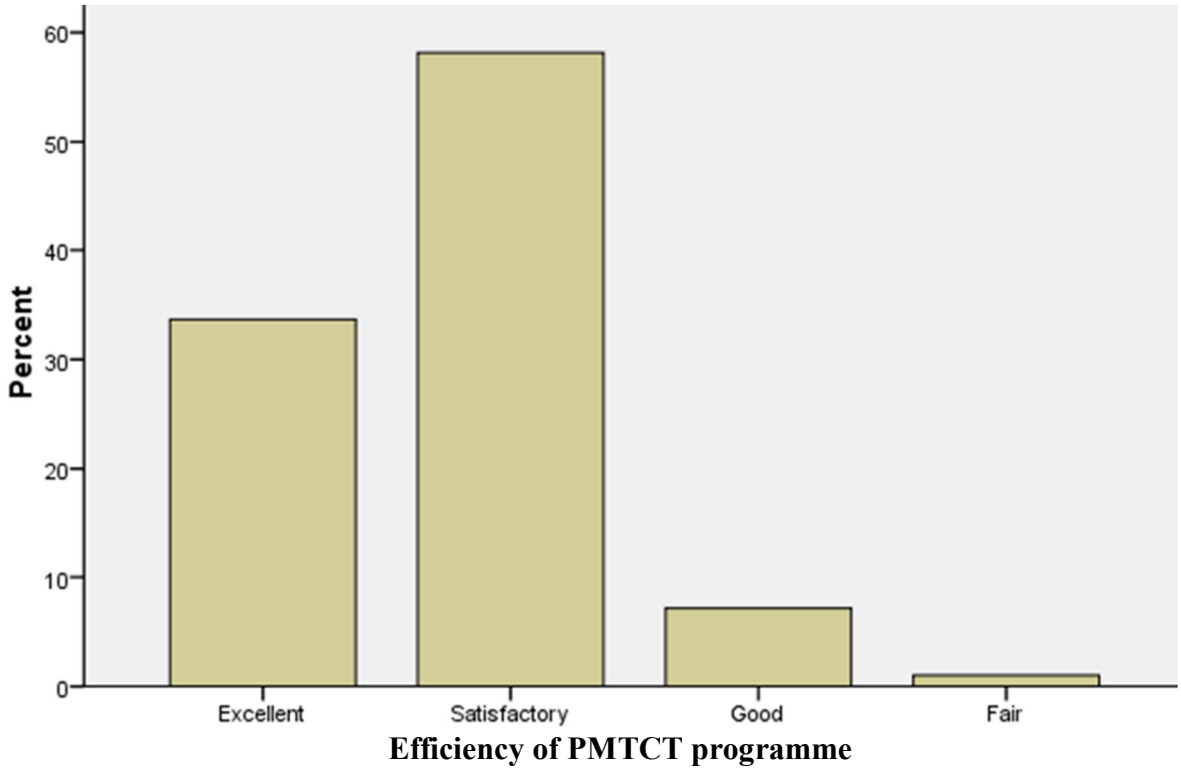


Figure 4.3: Participants Assessment of Efficiency of PMTCT Programme in Nasara Treatment and Care Centre ABUTH, Zaria.

4.5.3: Participants Waiting Time per Visit in Nasara Treatment and Care Centre ABUTH Zaria.

The minimum and maximum time spent by participants in the clinic per visit was found to be 2.48 and 4.78 hours respectively with an average of 3.63±1.34 approximately 4 hours per visit (Table 4.9). The missing data represent participants that did not respond to the question.

Table 4.9: Participants Waiting Time per Visit in Nasara Treatment and Care Centre ABUTH Zaria.

Duration (hours)	Maximum time (frequency)	Minimum time (frequency)
1	1	16
2	8	37
3	10	28
4	23	11
5	23	4
6	18	0
7	4	0
8	8	0
Missing	5	4
Total	100	100

CHAPTER FIVE

5.0 DISCUSSION

Paediatric HIV is a preventable disease. Antiretroviral drugs can decrease viral replication and viral load and significantly reduce or prevent the risk of maternal to child HIV transmission. The percentage of HIV pregnant women receiving antiretroviral (ARV) drugs for PMTCT between 2007 and 2008 as reported by WHO, (2008) increased from 47% to 54% in Latin America, 29% to 52% in the Caribbean, 74% to 94% in Europe and Central Asia. Countries have agreed to meet 80% treatment coverage by 2015 (WHO, 2011a). South Africa and Swaziland already have 88% each while Mozambique, Tanzania and Zambia have relatively high coverage rates of 70%, 70% and 69% respectively, never the less, the biggest challenge comes from Nigeria and Burundi with treatment coverage of 22% and 12% respectively (WHO/UNAIDS/UNICEF, 2010). In this study, the extent of Pharmacological intervention was found to be 98% in Nasara treatment and Care Centre, ABUTH Zaria that caters for Clients from the North-West zone of Nigeria. A similar study in South-South part of Nigeria reported an extent of pharmacological intervention of 59% (Chukwuemeka *et al.,* 2012).

Women may receive ARV drugs during pregnancy as part of potent combination regimens used to treat their HIV infection (ARV treatment) or as prophylaxis to prevent HIV infection in their children (ARV prophylaxis). ARV treatment for women benefits their health and also substantially reduces the risk of MTCT. WHO, (2006) recommended that efforts should be made to ensure that all HIV pregnant women who require ARV treatment have access to it and therapeutic decisions should be based on their need and eligibility for such treatment. However, ARV regimens for women of childbearing age should be selected considering the possibility of a

planned or unintended pregnancy considering that these drugs may be taken in the first trimester of pregnancy, before such pregnancy is recognized. In sub-Saharan Africa, 20-30% of HIV infected pregnant women are eligible for ART based on CD4 criteria (FMH, 2007). In this study, CD4 count was used as a pointer to therapy and drug regimen for PMTCT was found to be individualized according to need. This criteria for drug use is in line with the U.S Department of Health and Services guidelines (2012) that says: all HIV infected pregnant women should take a regimen (combination) of at least 3 anti-retroviral medications and the specific medication in the regimen should depend on individual need based on medication history and blood tests to assess health and stage of HIV infection. In this study, the most commonly prescribed highly active antiretroviral therapy (HAART) for ARV treatment was found to be AZT/3TC/NVP (54%) while AZT/3TC/EFV (16%) was used for ARV prophylaxis starting from the 14th week of pregnancy. Considering contraindications, side effects and treatment failure to the first line agents (AZT/3TC/NVP or EFV), second line agents (AZTorTDF/3TC/LPV/r/±AZT) were recommended for 6% of the study population. This is in line with the WHO recommendations option B19 that says: triple ARVS after 14 weeks of pregnancy can be used for PMTCT (WHO, 2010 and FMH, 2010). Following the national PMTCT guideline (FMH, 2007), a study carried out in South-South part of Nigeria by Chukuemeka *et al.,* (2012), HAART consisting of AZT/3TC/NVP or EFV was used for ARV treatment, with choice depending on individual need. ARV prophylaxis for HIV pregnant women, who did not meet the criteria for initiating HAART, comprised of zidovudine (AZT) beginning at 28 weeks and a single dose nevirapine (sdNVP) during labour, or AZT/3TC given at 33 weeks of gestation and sdNVP during labour. Women newly diagnosed for HIV during labour received sdNVP alone.

In the absence of any intervention, the risk of MTCT of HIV is 15–30% in non-breastfeeding populations, with breastfeeding by an infected mother increasing the risk by 5–20% to a total of 20–45% (De Cock *et al.,* 2000). Obervational studies in industrialised countries, where MTCT rates are below 2% have shown that pharmacological intervention with triple ARV combinations given to HIV infected women during pregnancy and labour are highly effective in reducing MTCT (Thorne and Newell, 2004). In the US and Europe, aggressive prenatal HIV testing, coupled with combination antiretroviral therapy and caesarean section reduced HIV vertical transmission to less than 1% (Loannidis and Abrams, 2001). In resource-constrained settings, elective caesarean delivery is seldom available and/or safe, and refraining from breastfeeding is often not acceptable, feasible or safe (Bueken *et al.,* 2003). In South-East of Nigeria, Mother to child HIV transmission rate was found to be 1% where 94.7% did not breastfeed, although infant formula used was associated with impaired babies' current health status (Simeon, 2012). The pharmacological interventions adopted by Nasara Treatment Care Centre ABUTH Zaria, as ascertained by this study, reduced vertical transmission of HIV from 11% (without intervention) to 2.5% (with intervention), where 89% of the babies were breastfed. These findings compare reasonably with related studies on HIV transmission rates in PMTCT program settings elsewhere. In South–South part of Nigeria, HIV transmission rate of 4.8% was observed for babies where their mothers received a pharmacological intervention for PMTCT and over 80% of the babies were breastfed and transmission rate of 20% in babies in which neither mother nor baby received ARVs (Chukwuemeka *et al.,* 2012). In Zambia, it was observed that pharmacological interventions reduced vertical transmission of HIV from 20.9% (without intervention) to 6.5% where 84% of the babies were breastfed (Stringer *et al.,* 2005; Torpey *et*

al., 2011). Vertical transmission in South Africa has been reduced to below 4% with Pharmacological interventions (Carole, 2011).

Effective antiretroviral therapy (ART) requires excellent adherence. The Pharmacy Department has a pivotal role to play in the provision of quality antiretroviral therapy (ART) care, through ensuring an efficient supply of medicines and delivering patient-oriented services to promote appropriate use. Studies in the developed world have shown that support from Pharmacists can positively affect adherence (Deschamps *et al.,* 2004). Clinical Pharmacists appear to have a strong impact on promoting positive clinical outcomes in patients starting ART, particularly in economically disadvantaged areas (Horberg *et al.,* 2007). In many developing countries, initiatives to scale up ART have focused attention on the pharmacy and on making better use of Pharmacists, whose skills and training are often underutilized (Walkowiak and Keene, 2009). Adherence to ART is measured by a variety of methods with the most commonly used methods being self-reporting by patients, pill counts, review of pharmacy records and Medication Event Monitoring System (MEMS) caps (Stone, 2001). Though some of the adherence measurement tools have been validated to be sensitive in measuring adherence, the majority of the tools currently used cannot meet all the features of an ideal tool. Hence, there is no gold standard in the measurement of adherence. This has led to the recommendation of a multi-method approach that combines feasible self-reporting and reasonable objective measures in measurement of adherence behavior. The multi-method tool can include self-report and different combinations of other tools including pill count, electronic methods, measurement of drug levels and so forth (Hirschhorn *et al.,* 2002). Majority of the Pharmacists (85.5%) in Nasara Treatment and Care Centre ABUTH Zaria said they monitor adherence to medication using self-reporting by Clients,

while the remaining 14.3% used pill count indicating that the multi-method approach is adopted by Nasara Treatment and Care Centre. Assessment by the participants however, revealed that Clients were not free relating with the Pharmacists like other members of the health care team. Two studies in Benin City and Ibadan-Nigeria by Erah and Arute (2008) and Olowookere *et al.,* (2008) respectively combined patient recall with pharmacy refill method. Even studies in advanced countries in North America and Europe where these methods are utilized more often, studies still show a large dependence on patient self-recall (Gill *et al.,* 2005). Most of the participants were educated on benefits of PMTCT and family planning related issues by the Doctors and Nurses. Majority of them don't even know the Pharmacological information related to their medications which is the duty of the Pharmacists. The key roles of the Pharmacists as given by WHO and IPF (2006), among others include: monitoring adherence to ARVs, active dissemination of drug information to patients and providers advising them on potential side effects and drug-drug interactions, report adverse drug reactions and drug interactions. This attitude and practice by the Pharmacists of Nasara Treatment and Care Centre ABUTH Zaria may be influenced by internal factors: lack of job security and satisfaction as well as language barrier as given by 28.6% of them. For effective medication counseling, Pharmacists and other health personnel need good communication and problem-solving skills to assist patients to achieve and maintain high levels of adherence (Helena and Douglas 2009). Pharmacists need to be visible, responsible, and committed to maintaining competencies in order to play a larger role in the ART health-care team. This requires changes in attitudes for all staff which includes a commitment to confidentiality and patient-oriented rather than task-oriented practices, benefits such as job satisfaction is also essential (WHO and IPF, 2006).

Adherence to the prescription instruction of HIV therapy regimens is one of the most important factors in obtaining optimal benefit from ART because it prevent the development of resistance (Bachiller *et al.,* 1998), reducing viral load and increasing the probability of survival in the majority of patients (Coetze *et al.,* 2004). This emphasizes the importance of assessing waiting times and their causes in such clinics in order to develop and institute appropriate and timely responses to the improvement of quality health care and subsequently patient satisfaction. According to Haussmann (1970), quality assessment studies often measure one of three outcomes: medical outcomes, costs and patient satisfaction. Patient satisfaction was found to include waiting and consultation time, behavior of the service provider, information given, examination, prescribed medication, cost of service and accessibility of service delivery points (Haussmann, 1970; Singh *et al.,* 1999; Aldana *et al.,* 2001). Although the services rendered to participants by the staff of Nasara Treatment and Care Centre ABUTH Zaria was easy to understand by almost 93% and their efficiency is satisfactory to majority (57%), long waiting time in the Clinic per visit (4 hours ranging from 1 to 8 hours) was their major complain. Similarly in an anti-retroviral (ARV) clinic at the Specialist Hospital Bauchi-Nigeria, waiting time was found to be 4.35 hours (Umar *et al.,* 2011). Also, in ART clinics in North East Nigeria, Inedu and Ndulue (2010), waiting time was found to be 5 hours. Patient waiting time has been defined as the time patients spend waiting for a service (Lowe, 2000). Waiting time is an important determinant of quality of services as it was noted that in health care provision 'delays are expensive, not only in terms of direct costs incurred, but also in terms of the potential costs of decreased patient satisfaction and adverse outcomes' (Haussmann, 1970). Assessment of quality health services assist managers to develop a common understanding of significant management problems. Long waiting times have been found to be one of the common problems for managers

and as such can compromise the quality of care by creating barriers that prevent much needed services reaching patients (Steel *et al.,* 2007).

CHAPTER SIX

6.0 SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 Summary

The aim of this study is to assessing the pharmacological interventions in prevention of mother to child transmission of HIV/AIDS in Nasara treatment and care Centre ABUTH Zaria. This was achieved by assessing the PMTCT treatment coverage in the clinic, their pattern of drug prescription for PMTCT, outcome of the interventions, attitude and practice of Pharmacists in the clinic toward the interventions as well as assessing the quality of service delivered to the participants.

The study was a combined prospective and retrospective study. The prospective component consists of participant interview which was transcribed into a structured questionnaire and retrieval of clients' clinical data, which formed the retrospective component. The study population includes clients of the clinic randomly selected by convenient sampling and the seven Pharmacists working in the clinic at the time of the study. The sample size for the participants was determined using the formula by Araoye (2004) and a population size of 52 was obtained which was doubled to 104 to give room for dropout and lost to follow-up. Each questionnaire to Pharmacists and the clients carried a consent form and information leaflet seeking their consent in the study assuring them of confidentiality. Participation was voluntary and participants were given the freedom to dropout without adverse consequences. Questions to the clients revolved round their physical and demographic data, medical history, knowledge level about their medications, interpersonal relationship with the pharmacists and other members of the health care team as well as, the quality of services rendered to them by the clinic. The second set of

questionnaire administered to the pharmacists includes questions on socio-demography, personal data and job performance.

Out of the 104 participants sampled, 100 completed the study while the remaining 4 were lost to follow up. The mean age of the participants was found to be 31.21±5.89 ranging from 20 to 60 years. Most of them are Hausa (60%), 7% of were Fulani while Yoruba and Ibo each made up 4% of the study population. Those that did not fall within the classified ethnic group were grouped as others and they account for 25%. All the participants except two (2%) were married and majority were married only once (62%). Western education; either primary (19%), secondary (27%) or tertiary (26%), were the highest qualification attained by the participants. 23% of them have Arabic/ Islamic education as their highest qualification, while 5% of them did not answer the question. Most of them (60%) were unemployed (i.e. house wife), 21% are self-employed, 13% are civil servants and the remaining 3% were students.

Out of the 100 Clients that participated in the study, 98% went through pharmacological intervention with anti-retroviral drugs (ART). Drug combinations prescribed for participants depended on their laboratory test results and clinical examination. Therapy for PMTCT was individualised and the commonly prescribed ART for PMTCT treatment in Nasara Treatment and Care Centre was found to be Zidovudine/Lamivudine/Nevirapine (AZT/3TC/NVP) while Zidovudine/Lamivudine/Efavirenz (AZT/3TC/EFV) was used for PMTCT prophylaxis. Considering contraindications, side effects and treatment failure to the first line agents (AZT/3TC/NVP or EFV), second line agents (AZTorTDF/3TC/LPV/r/±AZT) were recommended for 6% of the study population. The number of pregnancies since HIV was

diagnosed in the participants, ranged from 1 to 6 with a mean of 2. The total number of children born by 78 out the of 100 HIV positive women were determined to be 120 (22 participants were still pregnant at the time of the study), out of which 16 of them were HIV positive. Of these HIV positive children, 13 (11%) were delivered without PMTCT intervention while the remaining 3 (2.5%) were delivered with PMTCT intervention. The above results indicated a statistically significant reduction in vertical transmission of HIV/AIDS as shown by chi-square analysis at $P<0.05$, 95% confidence interval using SPSS version 16. The pharmacological interventions adopted by the clinic reduced vertical transmission of HIV/AID from 11% to 2.5%.

Most of the Participants in the study (43%) preferred relating with Doctors and the Nurses (22%), with the Pharmacists (4%), being the least preferred care giver in their health matters. Majority of the Participants (72-79%) do not have knowledge of basic Pharmacologic information required for their medications. The few that knew (23-25%) were educated mainly by Nurses and Doctors while Pharmacists were their least educators as reported by the participants. Out of the 7 Pharmacists involved in the study, 6 (85.7%), said they monitor drug adherence, using self-reporting by the participants and 1 (14.3%) used Pharmacy refill data. Two (28.6%) of them were not satisfied and felt insecured in their jobs. They also have limited understanding of Hausa which is the language spoken by majority of the participants. The services rendered to Participants were easy to understand by majority (93%) and complex to only 1%. Majority of them rated the efficiency of PMTCT programme in the clinic as satisfactory (57%), while 33%, 7% and 1% considered it excellent, good and fair respectively. The minimum and maximum time spent by participants in the clinic per visit was found to be 2.48 and 4.78 hours respectively with an average waiting time of 4 hours per visit.

6.2 Conclusion

The Pharmacological interventions adopted by Nasara Treatment and Care Centre ABUTH Zaria were found to be effective in reducing vertical transmission of HIV with a statistically significant difference in the serostatus of the participants' children. With this, the null hypothesis that the pharmacological interventions in Nasara Treatment and Care Centre are inadequate was rejected. Attitude and practice of the Pharmacists in Nasara Treatment and Care Centre is inadequate as reported by the Participants. Although majority of the participants found the quality of service delivered to them satisfactory, long waiting time was their major complain.

6.3 Recommendations

1. Nasara Treatment and Care Centre ABUTH Zaria caters for Clients from the North-West zone and even beyond. Similar studies need to be done in other zones to know the progress of PMTCT and the serostatus of Nigeria children which will assist the Government in future planning.
2. Pharmacists' job satisfaction and security as well as Clients' waiting time need to be addressed by the management of Nasara Treatment and Care Centre, ABUTH, Zaria.
3. The Pharmacists need to improve their ability in learning the language commonly understood by majority of the Clients (Hausa) to bridge communication gap and strengthen their ability to impart their acquired pharmacologic knowledge to the Clients so that they will gain maximum benefit from their medications.

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Appendix ii: INFORMATION LEAFLET FOR THE CLIENTS.

TITLE OF PROJECT: Pharmacological interventions in the Prevention of Mother to Child Transmission (PMTCT) of HIV/AIDS.
INVESTIGATOR: Mrs Abubakar Aminat, M. Sc student, Department of Pharmacology and Therapuetics, ABU Zaria.
SUPERVISORS: Dr. (Mrs) B B Maiha, Dr. A U Zezi and Dr. H M Muktar

BACKGROUND INFORMATION ABOUT THE RESEARCH
Mother-to-Child Transmission (MTCT) is when a Human Immunodeficiency Virus (HIV) infected woman passes the virus to her baby which can occur during pregnancy, labour and delivery, or breast feeding. Without treatment, about 15-30 percent of babies born to HIV positive women will become infected with HIV during pregnancy and delivery, and a further 5-20 percent will become infected through breast feeding (De Cock *et al.,* 2000). MTCT is an issue that directly affects women and at the same time, increases the spread of HIV.
Prevention of Mother to Child Transmission (PMTCT) is a clinical approach for preventing the transmission of HIV from an infected mother to her child. HIV presents an increasing risk to pregnant women, their infants and their families. At the end of 2009, globally, there were an estimated 2.5 million children (under the age of 15 years) living with HIV, most of whom became infected by their mothers, and without treatment, a large number of them will not live to adulthood (UNAIDS, 2011). Research has shown that PMTCT interventions can reduce the risk of HIV transmission from mother to child from about 40 percent to less than 2 percent (UNAIDS, 2011). The most effective way to prevent mother-to-child transmission of HIV involves a long course of antiretroviral drugs and avoidance of breastfeeding, which reduces the risk to below 2% and is less likely to cause drug resistance (WHO, 2010). In the US and Europe, aggressive prenatal HIV testing, couple with combination antiretroviral therapy and caesarean section further reduced HIV transmission to less than 1% (Loannidis and Abrams, 2001). We therefore want to assess the effect of PMTCT in this North-West zone.

NATURE OF THE PROPOSED INTERVENTION
The research involves administration of questionnaires to voluntary respondents and the questions in it are not far from what they know about PMTCT and general question about the attitude of the Pharmacists and other staff toward them.

PURPOSE OF THE RESEARCH
To assess pharmacological interventions in PMTCT in Nasara Treatment and Care Centre (NTCC), supported by Harvard/PEPFAR ABUTH Zaria.

DURATION OF PARTICIPATION
All things being equal, the questionnaire is expected to be filled within 2 hours, just for a day.

PROCEDURES TO BE FOLLOWED
The questionnaire is expected to be filled by the HIV infected Client (pregnant women already with or without a child(ren), breastfeeding mothers, or those in labour at the time of administration of the questionnaire). But if the respondent cannot speak or write English language, the information will be taken in the presence of a witness.

Consent Form for the Clients

POTENTIAL RISK AND BENEFIT
Assurance of access to support through counselling, peer education and issuance of educative pamphlet on PMTCT. Confidentiality is guaranteed. Participation is voluntary and right to drop out is assured without adverse consequences to the quality of care. Information guarded will be disseminated in anonymous mode only in scientific conferences for the benefit of mankind.

SIGNATORIES
RESPONDENT

I, with participant No_____ hereby agree to participate in this research. This I do voluntarily and without force. I also understand that if I decline participation, this will NOT adversely affect the quality of care my baby and I will receive in this Centre.

Signature or thumbprint_____

TRANSLATOR
Name and signature_____

Appendix ii: TITLE: Kariya Mai Hana Jariri Daukan Cuta Maikarya Garkuwan Jiki Daga Mahaifiya

Shigan cuta daga uwa zuwa jariri yakan faru ne daliin da uwa mai dauke da kwayoyin cuta masu karya garkuwan jiki ko lokacin nakuda, haihuwa ko kuma ta wajen shayarwa.Idan har ba ayi magani ba, kashi goma shabiyar zuwa talatin (15-30%) a cikin dari na jariran da ake haihuwansu da wanar kwayoyin cuta sukan kamu da cutar ne ta samun ciki da haihuwa. Kashi ashirin (20%) cikin dari na jariran kan kamu da cutanne wajen shayarwa (De Cock *et al.,* 2000). MTCT abune da ya shafi mata kuma yakan kara musu yaduwar kwayoyin cuta masu karya garkuwan jikin.
Akan kara daukan cutar HIV daga uwa zuwa ga jarinrinta ta hanyar PMTCT. HIV yakan kara ma mata masu ciki da jariransu , harma da iyalinsu kasada. Akarshen shekara na 2009, a duniya baki daya, anyi ikrarin cewa , yara yan kasa da shekara goma shabiyar su miliyan biyu da rabi (2.5m) ne suke dauke da kwayar HIV. Mafi yawansu sun sami cutarne daga iyayensu mata. Idan har basu sami magani ba ,mafi yawansu ba za su kai munzalin balaga ba a rayuwansu (UNAIDS,2010).Bincike ya nuna cewa kariya na PMTCT yana iya ragewa jaririn kasa dan daukan wannan cutar da iyaye mata , daga arbain (40%) chikin dari ya koma kasa da biyu(2%) cikin dari (UNAIDS, 2011)
Yin anfani da wasu kwayoyin magani masu inganci tareda kauce wa shayarwa shine mafi inganci wajen kare jarirai dauken wannan cutar sida. Yin hakan kan rage hadarin daukan cutar kanan kasa da biyu chikin dari (below 2%), sa'anan, cutar ba ta fin karfin maganin (WHO, 2010). A kasashen Turai, gwaji da ake na masu juna biyu tare da daukan mahimman matakai na magani kan rage yaduwar ciwon sida har kasa da daya daga cikin dari (less than 1%) (wannidus and Abrahams,2001). Saboda hakane muke so mutabbatar da ingancin maganin da PMTCT keyi a magance Arewa shashin yamma.
YANAYIN TAMBAYOYI
A wajen binciken, takardan tambayoyi, wanda ake kira 'questionaire' a Turance , akan rabawa wayanda suka yarda zasu amsa tambayoyin. Tambayoyin dake ciki basu wuce akan PMTCT ba tare da tambayoyin akan yanayin dabiun masu basu magani da sauran ma'aikata, agaresu.
DALILIN KO KUMA MANUFAR BINCIKEN
Don tabbatan ingancin kariyan maganin PMTCT asubitin "Nasara Treatment and care centre (NTCC), tare da ba da goyon bayan Harvard /PEPFAR ABUTH zaria
LOKACIN DA AKA KEBEMA AIKIN
Ana tunanin cewa acikin awa (hour) biyune wato kwana daya kawai, za'a iya cike takardan tambayoyin.

Hanya da Za'abi Acinma Hakan
Ana tunanin mata masu ciki ko marasa yara, masu dauke da kwayoyin ciwon sida ne zasu amsa tambayoyin. Inda kuma masu amsa tambayoyin basu iya karatu ko rubutun Turanci ba, za'a rubuta bayaninsu a gaban shaidu.

Amfanin da Kasadan da aka Iya Fuskanta
Banda tarbatar da samar da kwarin gwiwa ta hanyar shawar-wari, ilmantarwa da kuma bada dan karmin littafi (pamphlet)
Wanda ke dauke da bayanai akan PMTCT. Akwai kuma garanti na sirri. Mutun zai iya ba da nashi bayanan ida yaga dama, batare da wani damuwaba. Bayanan da aka samu, daga bincike, za su yi amfani ga mutane ba tare da an ambaci sunayen mutanen dasuka taka rawan gani ba.

Yardan mai Bada Amsa
Ni, mai lamba---------- na yarda in shiga cikin wanan bincike. Na yarda dankashin kaina batareda wani ya tilastamunba. Nakuma fahinci cewa, kinshiga bazai hana jaririna samun kula a wannan asibiti.

Sa hannun mai fassara da suna ----------

Appendix ii: IWE IWIFUN ALAGBAWI

AKORI ISE IWADI: Akitiyan awon apoogun lori idaduro atagba aisan ko gboogun (HIV) lati ara iya si omo.

OLUWADI: Iyaafin Abubakar Aminat, Akekoo ni eka eko apoogun ati ilo re. (ABU Zaria).

OLUBEWO: Dokita (Iyaafin) B.B.Maiha, Dokita A.U. Zeziati Dokita H.M. Muktar.

IPILE ARIDIMU LORI IWADI

Atagba aarun ko gboogun (HIV) lati ara iya si omo (MTCT) je ni igba ti obirin ti o ni arun ko gboogun ba se atagba re si ara omo ti o bi, ti o le sele ni igba iloyun, irobi ati ibimo, tabi fifun omo lomu (Breast feeding). Laisi itoju ti o peye. Ida meedogun si ogbon ninu ida ogorun (15 – 30%) omo ti awon obirin ti o ni aarun ko gboogun (HIV) ba bi ni o n ni aarun naa ni igba iloyun tabi ti a ba bi won tan. Ida marun-un si ogun ninu ogorun (5 – 20%) sii ni o maa n ni aarun ko gboogun nipa omu mimu (De Cock *et al.,* 2000). Atagba iya si omo yii je arun ti o n doju ko obirin ju ti o si mu ki arun ko gboogun (HIV) maa gbile si.

Idaduro atagba iya si omo (PMTCT) je ona idekun itankale aarun ti ko gboogun (HIV) lati ara iya ti o ni arun naa si omo re. Arun ko gboogun mu ewu ba alaboyun, omo wewe (ikoko), ati ebi. Ni opin 2009, kaakiri agbaye ogoro omo were ti o to milionu meji abo (2.5million) ti o je omo odun meedogun si isale (Under 15) ni o ni arun ko gbogun (HIV), opo awon ti o ko arun naa nipa iya won ti ko ri itoju, opo ninu won si ni ko le di odo tabi dagba ki won to ku (UNAIDS, 2011). Iwadi ti fi han wipe "Idaduro atagab iya si omo le din ewu atagba arun ko gboogun yii ku lati ida ogoji ninu ogorun si ida meji ninu ogorun (40 to 2%) (UNAIDS, 2011).

Ona ti o ga ju fun idaduro atagba iya si omo lori arun ti ko gboogun (HIV) ni lati gba abere ajesara ati didekun fifun omo lomu; ti o le din atagba naa ku si ida meji ninu ogorun (2%) ki o si din aigboogun ku. (WHO, 2010). Ni ile alawo funfun (US ati Europe) ayewo pip, ololufe ti o n gba ajesara ati ise abe ti din atagba arun ko gboogun (HIV) ku si ida kan ninu ogorun (1%) (Loannidis and Abrams, 2001).

A few o iyorisi idaduro atagba iya si omo ni ekun ariwa (North) ati iwo oorun (East).

ABUDA ONA ABAYO SI ISORO NAA

Nipa pinpin iwe ibeere fun awon oludahun ti o fi ara won jin ni a fe lo fun iwadi ati wipe ibeere inu re ko jinna si ohun ti won mo nipa idaduro atagba arun ko gboogun (HIV) lati ara iya si omo ati iwa awon apoogun ati osise si won.

EREDI IWADI

Lati wo ipa pipo ogun lori idaduro atagba arun ko gboogun lara iya si omo ni ile iwosan Nasara (NTCC). Pelu atileyin Harvard/PEPFAR ile iwosan ABU (ABUTH) Zaria.

AKOKO ILOWOSI

Ti ohun gbogbo ba lo deede, a n fe ki a dahun ibeere naa laarin wakati meji (2Hours), lojo kan.

ONA ABAYO

A lero peki awon ti o ni arun ko gboogun dahun ibeere naa (Laboyun ti o ti bimo tabi ti koi ti bi). (Awon ti o n fun omo lomu, tabi awon ti o n robi ni asiko ti a n se ibeere naa). Sugbon ti oludahun ko ba le so tabi ka ede Geesi, a o se agbasile loju eleri kan.

IWE IJEWO OLUDAHUN

EWU ATI ANFANI TI O LAGBARA

Idaniloju atileyin nipa imoran, idanileko irosiro ati pinpin iwe ilewo lorii idaduro atagba arun iya si omo (PMTCT) pelu igbekele ati idaniloju. Ibapin atinuwa ati anfani lati ma kopa mow a lalai si ewu ti o rom o itoju ti o to. Oro ti a ba gba sile ni a o fonka lai si oruko enikeni ninu ipejopo Sayensi awon eniyan.

IFOWOSI OLUDAHUN

Emi, pelu nomba _____ gba lati lowo ninu iwadi yii. Eyi ni mo se lati inu wa lalai si ifipa mu ni. O si tun ye mi pe ti mob a yese ninu ikopa, ko le tabuku itoju ti o peye tie mi ati omo mi maa ri gba ni ibudo iwosan yii.

Ifowosi tabi Iteka_____

OGBIFO

Oruko ati Ifowosiwe _____

Appendix ii: AKWUKWO BU OKWU DI MKPA NYE NDI NKE A METUTERA

ISIOKWU IHE NCHOPUTA: Nleta anya nke ngalaba na-ahu maka ogwu e ji egbochi oria obinajaocha (HIV/AIDS) mgbochi oria na-esi na nneferenwa (PMTCT).

ONYE NCHOPUTA: ODOZIAKU Abubakar Aminat

Nwa akwukwo nke satificati di elu M.Sc. nke ngalaba a, na-amu maka agwa ogwu n'akpa n 'ogwugwo oria, na mahudun A.B.U

NDI NTUZIAKA: Dokinta na odoziaku B. B Maiha, Dokinta A. U Zezi na Dokinta H. M Muktar.

MBIDO AKUKO BANYERE IHE NCHOPUTA N'OMUMU A.

Oria na-esi na nne fere nwa (MTCT) BU ORIA na-adi mgbe nwanyi nwere oria a bu HIV bufere nwa ya oria a , nwere ike igosiputa n'afo inne , n'oge ime omume , n'omumu nwa ma o bu n'oge inye nwa ara. E wepu nlekota anya , ihe di ka umuaka site n'iri na ise rue na iri na ato n'ima umuaka nari umuwanyi ndi nwere HIV muru na-enwe oria HIV n'oge a di ime ha na n'oge omumu nwa, n'iga n'ihu site n'ise rue n'iri abuo n'ime nari umu aka ha muru na-enweta ya site n'inye nwa ara (De Cock *et al.,* 2000). oria nne na-ebufe nwa MTCT bu okwu gbasara umunwanyi kpomkwem n'otu aka ahu na-eme ka mgbesa oria obinajaocha HIV na-abawanye. Mbochi oria na-esi na nne fere nwa (PMTCT) bu uzo ogwugwo nke mgbochi oria HIV na-esite na nne were fere nwa. HIV na-egosiputa nbawanye nzute nsogbu nye umunwanyi di ime obere umu ha na ezinaulo ha Na ngwucha afo 2009, n'uwa nule a gutara umuaka ruru otu nde na nari puku ise (2.5 million) (ndi erubeghi afo iri na ise) nwere oria HIV,nke otutu n'ime ha butere site na 'aka nne ha, na e wepu nlala anya otutu n'ime ha agaghi adi ndu ruo okenye ma obu ihe eji mmadu eme. (UNAIDS, 2011). Ihe nchoputa egosiwo na mwebata mgochi aria si na nne fere nwa (PMTCT) nwere ike ibelata mbufe oria obinajaocha bu HIV nke na-esite na nne fere na nwa ya site n'ihe dika uzo iri ano ewepuru na nari, gbaturue n'ihe na-agaghi eru uzo abuo e wepuru na Nari (2%) (UNAIDS, 2011). Uzo ka di ire iji gbochi nne ibufe nwa ya oria obinajaocha abu HIV bu inye ogwu mgbochi ogologo oge na enyeghi nwa amuru ara chacha, nke a na-eme ka nsogbu bilata hapu iru abuo e wepuru na nari 2%, ma wetue ihe ga-eme ka ogwu hara iru oru (WHO, 2010). N'obodo ndi ocha (US na EUROPE), isionwu nnyocha ndi di ime maka HIV tupu ha amuo nwa, tinyekwara inye ogwu mgbochi, na iwa afo eweputa nwa na-enye aka ebilata mbufeHIV, nke na-anaghi kwa eru otu ewepuru n'ime nari (1%) (Loannidis & Abams 2001). Site n'ihi nke a ka anyi jiri choo itule oru (mgbochi oria na-esi nan ne ferenwa). (PMTCT). Na mpaghara site nugwu gawa n'odidaanyanwu. (North-West Zone).

ODIDI IHE E ZUBERE ILEBA ANYA

I he nchoputa a gunyere ike ndi o masiri isa ajuju akwukwo nwere ajuju nchoputa, ma ajuju a juru n'ime ya agaghi adi anya n'ihe ha mabu banyere(mgbochi oria na-esi na nne ferenwa). (PMTCT) na ajuju o bula banyere agwa ndi oru ndi ozo n'ebe ha no.

IHE BUTERE IHE OMUMU NA NCHOPUTA A

Nka a bu maka itule aka oru ulo oru na enye ogwu mgbochi maka oria a na-esi na nne agafere nwa na Nasara Treatment and Care Centre (NTCC) nke Harvard/PEPFAR A.B.U Zaria na akwado.

OGE ISO MEE YA GA –ABIA NA NGWUCHA.

Ihe daba otu o kwesiri , e kwesighi iji karia awa abuo (2hrs) iji deba aziza n'akwukwo ajuju, out ubochi naani ezuola.

USORO A GA-AGBASO

Ndi a turu anya ideba aziza ajuju nchoputa a bu ndi nwere oria bu HIV na-abia maka ya (umunwanyi di ime, ndi nwere umu ntakiri nan di na enweghi,ndi na-enye nwa ara ma o bu ndi ime na-eme n'oge a na-eke akwukwo ajuju nchoputa). O buru na onye na-asa ajuju di n'akwukwo nnochaenweghi la isulut ma o bu idelite asusu bekee, aga-edeba ma obu were aziza na n'ihu onye akaebe.

AKWUKWO NA-EGOSI NKWENYE NDI A NA-ELEBA ANYA NA NSOGBU HA

NSOGBO NWERE IKE IDAPUTA NA URU YA

Ikwe nkwa inwe ike inye nkwado site na ndumodu, nkuzi ibe na ibe, inye obere akwukwo e deputara maka mgbochi oria na-esi na nnefere nwa (PMTCT). Nkwa e kwere bu na mmebo agaghi adi. Iketa oke na ya bu nkweta nke onye, inwe ike ipu na ya bu nke na-enweghi mgbagha na-agbanyeghi nsogbu o ga-ewetara ezi nleta anya a akuko a ga-achikota ka a ga-agbasa na enweghi onye a ga-akpo aha, soso na nzuko ntule okwu ndi sayinsi (scientific conferences) maka odi mma nke ndi mmadu.

NDI NTINYEAKA NAKWUKWO

NDI SARA AJUJU

Mu, ji nomba nketa oke-----n'eba a kwere n'keta oke n'ihe Omumu na nchoputa a. Nke a ka m ji obi m na-eme na-abughi na ndugide. Aghotakwara m ozo na o buru na m ju iso keta oke, nke a agaghi emetuta ezi nleta anya mu na nwa m ga-enweta n'ogige nleta anya a.

Ntinyeakan'akwukwo ma o bu mbianyeaka----------

ONYE NTUGHARI

AHA NA NTINYEAKA n' AKWUKWO: ----------

Appendix iii: PHARMACOLOGICAL INTERVENTIONS IN PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV/AIDS

Client's Questionnaire

GENERAL INFORMATION:

Hospital unit Number: _____

PART I: PHYSICAL AND SOCIO-DEMOGRAPHIC DATA

1. How old are you last birthday, in years? _____
2. How much do you weigh in kilogrammes? _____
3. What is your Nationality?

   i Nigerian ☐ ii Non-Nigerian ☐ specify country_____

4. To which ethnic group do you belong?

   i Hausa ☐ iii Yoruba ☐

   ii Fulani ☐ iv Ibo ☐

   v Others ☐ specify:_____

5. What is your religion?

   i Islam ☐

   ii Christianity ☐

   iii Traditional religion ☐

   iv others ☐ (specify)_____

6. What is your current marital status?

   i Single ☐ v Divorced ☐

   ii Married, once ☐ vi Widowed ☐

   iii Married, more than once ☐

   iv Separated ☐

7. Where do you live?

   i Area in Zaria (specify) _____

   ii Area outside Zaria (specify)_____

8. What is the highest educational level attained by you?

i Illiterate ☐

ii Arabic school ☐

iii Primary school ☐

iv Secondary school ☐

v Tertiary (i.e. higher education after secondary school) ☐

9. What is your occupation? (Please list if more than one)

i _____

ii_____

iii_____

PART II: MEDICAL HISTORY

10. How did you come to know you have HIV?

i Routine blood test at antenatal clinic ☐

ii Voluntary testing ☐

iii Others ☐ (specify)_____

11. What year and month did you first know your HIV status? _____

12. What is /was the HIV status of your husband/partner/spouse?

i Negative ☐ iii Window period ☐

ii Positive ☐ iv Don't know ☐

13. How many times have you being pregnant? _____

14. How many children do you have? _____

15. How many times have you being pregnant since you became HIV positive?_____

16. How many children did you have since you contacted HIV? _____

17. How many are alive and how many are HIV positive?

Number alive _____

Number that are HIV positive _____

Number that their status are yet to be confirmed (specify age in months)

_____

18. If yes, how did you get to know the HIV status of your children?

i Voluntary testing. ☐

ii Advised in the clinic /hospital to screen them. ☐

iii Screened without my explicit consent. ☐

iv Others ☐ (specify) _____

19. Did you attend antenatal clinic for your other pregnancies with your present status?

i Yes for all ☐

ii Yes, but not for all ☐(specify no)_____

iii No ☐

iv No, except for this present pregnancy ☐

20. Is your husband aware of you attending this clinic?

Yes ☐ No ☐

21. Do you know what Prevention of Mother to Child Transmission (PMTCT) of HIV/AIDS is?

Yes ☐ No ☐ (specify reason) _____

22. How did you get to know about PMTCT?

(Tick more than one if applicable)

i Health talk in media (TV, radio, DVD, VCD , satellite) ☐

ii Community forum in your locality ☐

iii General counseling at antenatal clinic by the health officer ☐

iv Friends of the same status (HIV positive pregnant women) ☐

v While consulting the doctor ☐

vi Prior to drug dispensing by the pharmacist ☐

viii Others ☐ (specify)_____

23. When did you get to know about PMTCT?

i Before the current pregnancy ☐ ii In the current pregnancy ☐

iii After delivery ☐ iv Others ☐ (specify)_____

24. Did you go through PMTCT intervention for your pregnancies?

i all ☐

ii Only the present pregnancy ☐

iii Others ☐ (specify)_____

25. What do you know about PMTCT?

i Is a programme that protect off springs from contracting HIV. ☐

ii Is a programme that improves my HIV status and my children. ☐

iii A normal routine ANC programme. ☐

iv is a programme that prevent transmission of HIV virus to offspring through counseling and testing as well as drug intake during the course of pregnancy, labour, delivery and thereafter. ☐

26. How do you view PMTCT programme?

i Real ☐ reason _____

ii waste of effort and resources ☐ reason _____

iii Beneficial/ advantageous ☐ reason_____

27. Which of the following health workers do you find reliable and free to relate with about your HIV status? (Tick more than one if applicable)

i Adherance cousellors ☐

ii The Doctors ☐

iii The Pharmacists ☐

iv The Nurses ☐

v The lab Scientist ☐

vi Others ☐ (specify)_____

28. How did you see their service delivery?

i Combersome ☐ ii Easy to understand ☐

iii Manageable ☐ iv Others ☐ (specify) _____

29. How will you rate the efficiency of the PMTCT Programme in this hospital?

i Excellent ☐ ii Satisfactory ☐

iii Good ☐ iv Fair ☐

v Not satisfactory ☐ vi Poor ☐

30. How old is your pregnancy in weeks? _____

31. Do you attend any other ANC clinic apart from your HIV /PMTCT clinic?

Yes ☐ No ☐

32. How frequent is your PMTCT clinic appointment?

i Every month ☐

ii Every two months ☐

iii Every three months ☐

iv Other ☐ (specify)_____

33. What is the minimum and maximum time (in hours) you do spend per visit?

Minimum time_____ Maximum time_____

34. Do you miss your appointment days?

Yes ☐ No ☐

35. If yes, how many have you missed since this pregnancy? _____

36. What are your reasons for missing appointment days?

i Waste of time (i.e number of hours spent affect daily activities) ☐

ii Lack of money for transportation ☐

iii Don't want to be seen in the clinic area (e.g due to stigmatization) ☐

iv Too sick sometimes to attend as scheduled ☐

v Poor treatment by the health workers ☐

vi Inadequate drug supply ☐

vii Others ☐ specify_____

37. Apart from HIV, which other (co-existing) illness do you have or have you had for this present pregnancy?

i Malaria ☐ ii Typhoid ☐

iii Diabetes ☐ iv Hypertension ☐

v Tuberculosis ☐ vi Asthma ☐

vii Others ☐ specify_____ viii None of the above ☐

38. Do you know how a child gets the virus from his/her mother?

Yes ☐ No ☐

39. If yes, mention the methods?

Breast feeding.	Yes ☐	No ☐
Vaccination.	Yes ☐	No ☐
Time of delivery.	Yes ☐	No ☐
Kissing.	Yes ☐	No ☐
Playing with the children.	Yes ☐	No ☐

40. Can a mother who is HIV/ AIDS positive breast feed his/her child?

Yes ☐ No ☐

41. If no to question 40 above, what measures are there to prevent your child from starvation?

Local food.	Yes ☐	No ☐
Adoption of a surrogate mother.	Yes ☐	No ☐
Infant formula.	Yes ☐	No ☐
Non-modified cow milk.	Yes ☐	No ☐
Soya beans milk.	Yes ☐	No ☐

42. Where do you normally deliver your children?

i At home alone ☐

ii At home supervised by a midwife /nurse ☐

iii At the nearby clinic /hospital other than your ANC clinic ☐

iv At your ANC clinic other than your PMTCT clinic ☐

v At your PMTCT clinic ☐

vi At a hospital with a referral note from your PMTCT clinic ☐

vii others ☐ specify _____

43. Which of the following methods of delivery did you undergo since you became HIV positive?

i Normal vaginal delivery ☐

ii Normal delivery but with induction of labour ☐

iii Normal delivery but with a tear ☐

iv Caesarean section (operation) ☐

v Others ☐ specify _____

44. Will you want the same to be done for your present pregnancy?

Yes ☐ specify reason _____

No ☐ specify reason _____

45. Did you start treatment immediately after HIV infection was discovered?

Yes ☐ No ☐

46. If no, mention the duration between HIV diagnosis and commencement of treatment?

i Less than 1 month ☐ iii 6 – 12 months ☐

ii 1 – 6 months ☐ iv Greater than 1 year ☐

v Others (specify) _____

47. At what point did you start treatment?

i Illness ☐

ii Doctor's decision ☐

iii My choice ☐

iv Pegnancy ☐

48. Were you on ARV before this pregnancy for your own HIV status?

i Yes ☐ (please list the drug combinations)_____

ii No ☐

49. If no, when were you initiated to ARV for this pregnancy?

i 1st trimester of pregnancy ☐

ii 2nd trimester of pregnancy ☐

iii 3nd trimester of pregnancy ☐

iv others ☐ (specify)_____

50. With what drug combination were you initiated?

i Lamivudine + Nevirapine + Zidovudine ☐

ii Tenofovir + Lamivudine + Nevirapine ☐

iii Tenofovir + Emtricitabine + Nevirapine ☐

iv Tenofovir + Emtricitabine + efavirenz ☐

v Others ☐ (specify)_____

51. Are you still on the above drug combination?

i Yes ☐ ii No ☐

52. If no, what drug combination are you on presently?

(Specify the gestational age)

i present drug combination_____

ii Gestational age _____

53. Why were the drugs changed?

i Presented adverse drug reaction ☐ (specify the reaction)_____

ii Change of gestational age ☐ (specify the age)_____

iii Hypersensitivity reaction ☐

iv Not responding well to medication ☐

v Don't know (change without educating you) ☐

vi Others ☐ (specify)_____

54. How is your treatment monitored in this clinic? (Select any 3)

i Weighing	☐	vi Measuring shirt size	☐
ii Measuring abdominal size	☐	vii B.p monitor	☐
iii Clinical exams	☐	viii Measuring head size	☐
iv Height	☐	ix Temperature measurement	☐
v Counseling sessions	☐	x Measuring shoe size	☐

55. Have you ever reported any side effect of your ARV medication?

i Yes ☐ (specify)_____

ii No ☐

56. If yes, which of the drugs do you feel is the cause? _____

57. What was done when such reaction was presented?

i Treat the reaction and still continue the same medications ☐

ii Told to manage with the side effect and still continue the drugs ☐

iii One or all of the drugs was substituted/changed ☐

iv others ☐ (specify)_____

58. Who do you normally report such reaction to?

i Doctor ☐

ii Pharmacist ☐

iii Nurse ☐

iv Adherence counselor ☐

v Others ☐ (specify) _____

59. Do you know the meaning of the following? (Tick Yes or No)

(Specify who educated you by referring to the options above)

i Benefit of taking your drugs on your own health and the survival of your child.

Yes ☐ No ☐ Educator(s) _____

ii Implication of not attending your clinic regularly.

Yes ☐ No ☐ Educator(s) _____

iii Consequence of omitting or missing a dose of your medications.

Yes ☐ No ☐ Educator(s) _____

iv How your medication works.

Yes ☐ No ☐ Educator(s) _____

v Concept of drug resistance.

Yes ☐ No ☐ Educator(s) _____

vi Drug interactions and food restrictions.

Yes ☐ No ☐ Educator(s) _____

viii Common and/or serious potential side effects.

Yes ☐ No ☐ Educator(s) _____

ix Duration of drug Therapy.

Yes ☐ No ☐ Educator(s) _____

x Prevention of unintended pregnancy

Yes ☐ No ☐ Educator(s) _____

xi Safer sex practices to prevent unintended pregnancy

Yes ☐ No ☐ Educator(s) _____

60. Are you on co-trimoxazole (septrin)?

Yes ☐ No ☐

61. If no, did you care to ask your Doctor or Pharmacist why?

Yes ☐ No ☐

62. If yes to (60) above, what was his/her reason_____?

63. Do you have a child currently on ARV?

Yes ☐ No ☐

64. If yes, what drug is he/she taking and when was he/she initiated?

Your child drug_____

Date of initiation (weeks) _____

Dose of the drug_____

Child's age_____

His/her weight at birth (kg) _____

His/her present weight (kg) _____

His/her current height or length at birth_____

65. For how long has he/she being on the above drug(s)?

i 1 week ☐ ii 2 weeks ☐

iii 3 weeks ☐ iv 4 weeks ☐

v Others ☐ specify_____

66. Do you and your child always get your ARV drugs regularly in this clinic?

Yourself: Yes ☐ No ☐

Your Child: Yes ☐ No ☐

67. If no, to (66 above) what next?

i Referred to another health center by your clinic ☐

ii Wait until when it is available ☐

iii Buy it on your own in nearby pharmacy/chemist ☐

iv Others ☐ specify_____

Appendix iv: INFORMATION LEAFLET FOR THE PARTICIPANTS (PHARMACISTS).

TITLE OF PROJECT: Pharmacological interventions in the Prevention of Mother to Child Transmission of (PMTCT) HIV/AIDS.

INVESTIGATOR: Mrs Abubakar Aminat, M. Sc student, Department of Pharmacology and Therapuetics, ABU Zaria.

SUPERVISORS: Dr (Mrs) B B Maiha, Dr A U Zezi and Dr H M Muktar

BACKGROUND INFORMATION ABOUT THE RESEARCH

Mother-to-Child Transmission (MTCT) is when a Human Immunodeficiency Virus (HIV) infected woman passes the virus to her baby which can occur during pregnancy, labour and delivery, or breast feeding. Without treatment, about 15-30 percent of babies born to HIV positive women will become infected with HIV during pregnancy and delivery, and a further 5-20 percent will become infected through breast feeding (De Cock *et al.,* 2000). MTCT is an issue that directly affects women and at the same time, increases the spread of HIV.

Prevention of Mother to Child Transmission (PMTCT) is a clinical approach for preventing the transmission of HIV from an infected mother to her child. HIV presents an increasing risk to pregnant women, their infants and their families. At the end of 2009, globally, there were an estimated 2.5 million children (under the age of 15 years) living with HIV, most of whom became infected by their mothers, and without treatment, a large number of them will not live to adulthood (UNAIDS, 2011). Research has shown that PMTCT interventions can reduce the risk of HIV transmission from mother to child from about 40 percent to less than 2 percent (UNAIDS, 2011). The most effective way to prevent mother-to-child transmission of HIV involves a long course of antiretroviral drugs and avoidance of breastfeeding, which reduces the risk to below 2% and is less likely to cause drug resistance (WHO, 2010). In the US and Europe, aggressive prenatal HIV testing, couple with combination antiretroviral therapy and caesarean section further reduced HIV transmission to less than 1% (Loannidis and Abrams, 2001).

We therefore want to assess the effect of PMTCT in this North-West zone.

NATURE OF THE PROPOSED RESEARCH

The research involves administration of questionnaires to voluntary respondents and the questions in it are not far from what you know about PMTCT in day to day conduct as a Pharmacist.

PURPOSE OF THE RESEARCH

To assess the impact of pharmacological PMTCT interventions in Nasara Treatment and Care Centre (NTCC), supported by Harvard/PEPFAR ABUTH Zaria.

DURATION OF PARTICIPATION

All things being equal, the questionnaire is expected to be filled within 2 hours, just for a day.

CONSENT FORM FOR THE PHARMACISTS

POTENTIAL RISK AND BENEFIT

The research will increase access to new knowledge and provide a scientific basis for improved service. Participation is voluntary and there are no physical risks in participating. Information will be guarded and disseminated in anonymous mode only in scientific conferences. An independent Research Assistant would be trained and compensated to eliminate conflict of interest. Confidentiality and right to dropout without administrative consequences are guaranteed.

PHARMACIST PARTICIPANT

I _____ (No_____) hereby agree to participate in this research. This I do voluntarily and without force with the assurance of confidentiality. I also understand that if I decline participation, this will NOT adversely affect my appointment in this centre nor will administrative measures be taken against me.

Signature _____

APPENDIX v: PHARMACOLOGICAL INTERVENTIONS IN PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV /AIDS

Pharmacist's Questionnaire

PART I: SOCIO-DEMOGRAPHIC DATA

1. What is your sex?

   i male ☐ ii female ☐

2. What is your nationality?

   i Nigerian ☐ ii Non –Nigerian ☐ (specify country)_____

3. What is your state of origin? _____

4. What is your Local government area (LGA)? _____

5. To which ethnic group do you belong?

   i Hausa ☐ iii Ibo ☐

   ii Yoruba ☐ iv Others ☐ (specify)_____

6. What is your religion?

   i Islam ☐

   ii Christianity ☐

   iii Traditional religion ☐

   iv Others ☐ (specify)_____

7. What is your marital status?

   i Single ☐ iv Divorced ☐

   ii Married ☐ v Widowed ☐

   iii Separated ☐

8. What is the highest educational level attained by you?

i Bachelor of pharmacy ☐

ii M.Sc ☐

iii Doctorate ☐

iv Professor ☐

v Others ☐ specify _____

9. Are you presently undergoing any research programme?

No ☐

Yes ☐ specify_____

10. What language is best understood by your Clients?

i Hausa ☐ iii English ☐

ii Yoruba ☐ iv Igbo ☐

v Others ☐ (specify) _____

11. What is your capacity/strength in the language above (question 10)

i Speaks the language fluently and understand it to your ability. ☐

ii Speaks the language satisfactorily but still in the process of learning. ☐

iii Speaks the language with difficulty but partially understood by your clients. ☐

iv Learn and understood only the dispensing aspect of the language. ☐

v Cannot speak the language at all, usually employ an interpreter to convey message to your Clients. ☐

vi Speaks the language but sometime encounter difficulty communicating some words so employ an Interpreter. ☐

vii Others ☐ (specify) _____

12. What extra-effort are you making to improve on the language (question 11)?

i Employ an educator to teach you the language outside the clinic hours ☐

ii Bought a book that teaches the language. ☐

iii Ignore, as your clients can pick the little you understand. ☐

iv Feels your interpreter is capable enough. ☐

v Not necessary, your ability is excellent. ☐

vi Others ☐ specify _____

PART II: PERSONNAL DATA

13. What is the status of your appointment in this clinic?

i Permanent appointment ☐

ii Casual appointment ☐

iii On contract ☐

vi Others ☐ specify _____

14. Are you satisfied with your appointment in question (13) above?

Yes ☐

No ☐

15. If no to question (14) above, why?

i Salary ☐

ii Stigmatization ☐

iii Job security ☐ (specify)_____

iv Equipment and stationary ☐

v Others ☐ (specify)_____

16. For how long have you being with this clinic? _____

PART III: JOB PERFORMANCE

17. How do you monitor Client adherence to medication?

i Self reporting by Clients ☐

ii Pills count ☐

iii Biological markers ☐

iv Use of pharmacy refill data ☐

v Clients readiness to continue medication ☐

vi Others ☐ (specify) _____

18. What effort have you made or are you making to promote Clients adherence to medication?

i Prepare a daily medication administration schedule for each Client. ☐

ii Provide memory aids for medication. ☐

iii Engaging the adherence coach. ☐

iv Educating and motivating Clients and care givers. ☐

v Making phone calls. ☐

vi Others ☐ (specify)_____

19. How generous are you in giving your phone number to your Clients to call you when the need arise?

i Give to all ☐

ii Give to few ☐

iii Give to many ☐

iv Others ☐ (specify)_____

v None of the above (i.e. did not give any) ☐

20. How informed are you on PMTCT?

i Excellent ☐ ii Satisfactory ☐

iii Good ☐ iv Fair ☐

v Others ☐ specify_____

21. How do you counsel your Clients on PMTCT?

i Make them know that PMTCT will prevent their child/children from HIV infection as well as improve their own health. ☐

ii Educate them on the general aim and objectives of PMTCT. ☐

iii Educate them on the stages of PMTCT and persuade them to cooperate. ☐

iv Referring them to the adherence counselors. ☐

v Others ☐ (specify)_____

22. Have you attended a training workshop on PMTCT matters?

Yes ☐ No ☐

23. If yes, how often does your institute send you for a workshop to raise your awareness on PMTCT?

i Once a month ☐

ii Every two months ☐

iii Every three months ☐

iv Once a year ☐

v Twice in a year ☐

vi Others ☐ (specify)_____

24. Have you attended a workshop on the following topics before now? (Tick more than one if applicable)

i HIV /AIDS counseling and testing ☐

ii PMTCT ☐

iii Infant feeding counseling in the context of HIV/ AIDS ☐

iv Early infant diagnosis ☐

v Monitoring and evaluating PMTCT intervention ☐

vi Others ☐ (specify)_____

25. How do you view your relationship with your Clients?

(Please specify in percentage (%) in the bracket provided, estimate of the total Clients).

i Interactive ( ) iv Instructive ( )

ii Participative ( ) v Informal ( )

iii Interrogative ( ) vi Others if any specify_____

26. What is your mission as a Pharmacist in this clinic? (You may tick more than one option)

i To dispense drugs to Clients as well as educate them on their medications. ☐

ii To improve Client's quality of life using your professional judgment. ☐

iii Interact with Clients and the Physicians to significantly achieve the PMTCT goal. ☐

iv Others ☐ (specify)_____

27. Do you partake in Clients counseling on the following?

(Please where not applicable to your institute or department, indicate on the line provided)

i Evaluation and control of therapy-associated side effects which may adversely impact materno-fetal outcomes (e.g. aneamia, hepatic toxicity, hyperglycemia).

Yes ☐ ; No ☐ (specify whose responsibility) _____

ii Determining the appropriate prophylaxis for opportunistic infections and immunizations.

Yes ☐ ; No ☐ (specify whose responsibility)_____

iii Initiation or modification of ART avoiding agents with potential teratogenicity for the developing foetus and choosing agents effective in reducing MTCT.

Yes ☐ ; No ☐ (specify whose responsibility) _____

iv Selection of effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy.

Yes ☐ ; No ☐ (specify whose responsibility) _____

v Benefits of PMTCT intervention.

Yes ☐ ; No ☐ (specify whose responsibility) _____

vi Disclosure, partner notification and testing

Yes ☐ ; No ☐ (specify whose responsibility) _____

vi Adherence to medication

Yes ☐ ; No ☐ (specify whose responsibility) _____

vii Nutritional care for the mother and child (exclusive breast feeding, exclusive formula feed or mixed feed where appropriate).

Yes ☐ ; No ☐ (specify whose responsibility) _____

viii Screening and detection of inappropriate prescription

Yes ☐ ; No ☐ (specify whose responsibility) _____

ix lifestyle and behavioral changes.

Yes ☐ ; No ☐ (specify whose responsibility) _____

28. In what way does your health facility provide nutritional support and prevention of opportunistic infection to your Clients? (Tick more than one where applicable)

i Provide infant formularies to their children when available. ☐

ii Provide infant formularies to their children regularly. ☐

iii Educate the mother on healthy diet. ☐

iv Provide insecticide treated net to reduce incidence of malaria. ☐

v Supply aids of purifying their water (e.g. filtered buckets, water disinfectant etc). ☐

vi Provide micronutrient supplements (e.g. iodine, zinc, calcium, iron, folic, solarium and vitamin A, C B6, B2 an D) ☐

vii Supply prophylactics for common infections (e.g. cotrimoxazole, suphadoxine-pyrimethamine, iron and folate etc. ☐

29. How do you monitor Client's adherence to medication?

i Pill counts. ☐

ii Biological markers. ☐

iii Use of pharmacy refill data. ☐

v Self reporting by Clients. ☐

vi Treatment response data base. ☐

vii Client's readiness to continue medication. ☐

vii Others ☐ (specify)_____

30. How do you access Clients' response to prescribed medications?

i Consulting clients clinic notes. ☐

ii treatment response data base. ☐

ii Studying the clinical and laboratory results. ☐

iii Enquiring from Clients on how they feel. ☐

iv Objective assessment on how they feel. ☐

31. If your Client is not responding well to medication despite good adherence, what do you do?

i Alert the Physician to review the Client. ☐

ii Suggest alternative therapy to the Physician. ☐

iii Dispense the prescribed drug assuming that the Physician is aware. ☐

iv Dispense the prescribed drug assuming is a Client's factor. ☐

v Others ☐ (specify)_____

32. Which of these Clients database do you access regularly? (Tick more than one if applicable)

i Diagnosis. ☐

ii Past medical history. ☐

iii Present medications and medication history. ☐

iv Medical allergies/intolerances. ☐

v Smoking /alcoholic/caffeine/drug use history. ☐

vi Abnormal laboratory and physical exam results. ☐

vii Renal and liver functions data. ☐

viii Recent referral to other service areas or specialties. ☐

ix All of the above ☐

33. Of what importance is/are they to you? _____

34. Do you have access to your Client's laboratory test results and history of hospitalizations?

Yes ☐ No ☐ (please specify reason)

35. Are you involved in decision making or have regular interaction with the Physician about Client's medications and medication related problems?

Yes ☐ No ☐ (please specify reason) _____

36. Which of these drug related problems do you frequently observe in your Client's prescriptions?

(Tick more than one if applicable)

i Untreated indications ☐

ii Improper drug selection ☐

iii Sub-therapeutic dosage ☐

iv Treatment failure ☐

v Over dosage ☐

vi Adverse drug events ☐ (specify)_____

vii drug-drug interactions ☐ (specify)_____

viii drug-food interaction ☐ (specify)_____

37. If applicable, do you know whether these drug- related problems have been treated?

Yes ☐ No ☐

38. If no what efforts have you made or are you making to improve your Client's quality of life?

i Communicate it to the Physician. ☐

ii Recommend drugs for untreated indications. ☐

iii Suggest the appropriate drugs to the Physician. ☐

iv Modify the prescription using your professional knowledge. ☐

v All of the above ☐

vi Others ☐ (specify)_____

39. Do you discuss with your Clients on their medications and improvement on previous medications?

Yes ☐ No ☐

40. Do you care to enquire from your Clients about their non-prescription medication history and their reasons for taking it?

Yes ☐ No ☐

41. Do you have a record of drug-related problems?

Yes ☐ No ☐

42. Do you monitor/screen your Client's prescription in accordance with their gestational age?

Yes ☐ No ☐

43. How do you determine the appropriateness of dosing of drugs to both the mother and child?

Based on:

i Client's weight ☐

ii Client's age ☐

iii liver and renal function ☐

iv Concomitant medications ☐

v Others ☐(specify)_____

44. How do you update your knowledge on Client's disease condition and drug treatment?

(Tick more than one if applicable)

i Consult relevant textbooks. ☐

ii Consult appropriate guidelines (e.g. by WHO or federal ministry of health). ☐

iii In-house presentation with colleagues and other health workers. ☐

iv Consult available official books (e.g. BNF,BPC, Matinde, EMDEX etc.☐

v Consult the internet. ☐

vi Others ☐ (specify)_____

vii All of the above ☐

45. Do you have access to internet in your office?

i Yes, provided by the facility ☐

ii Yes, owned by you ☐

iii No ☐

iv Others ☐ (specify)_____