PREVALENCE OF MOTHER-TO-CHILD TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS IN PREGNANT WOMEN ON ANTIRETROVIRAL PROPHYLAXIS AT KENYATTA NATIONAL HOSPITAL, NAIROBI COUNTY

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OCTOBER 2014
DECLARATION

I declare that this thesis is my original work and has not been presented for degree or any other awards in any other university

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DEDICATION

The first person I would love to dedicate this piece of work is my loving, caring and ever supportive husband, Harrison Kinyua. His perspective on life has taught me patience, resilience and the art of dreaming. To my siblings: Kevin Mwenda and Brian Muthomi for their devoted interest in my project. I hope that this work will be a source of inspiration and purpose for all of you and all of your offspring. And finally to all those who are giving their dreams their best and nothing seem to be happening. May this piece of work be a source of inspiration to you.
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Mother to child HIV transmission (MTCT) accounts for the majority of the paediatrics HIV-1 infections. Long and short term treatment of HIV-positive pregnant mother with ARV regimen has been reported to reduce MTCT rate by 70%. However, the current effect of ARVs on CD4 count and prevalence of MTCT of HIV needs to be established in an effort to completely eradicate MTCT of HIV. This study investigated the effects of triple ARV regimen on the CD4 count of HIV-positive pregnant mothers and the outcome of HIV-status of their infants at Kenyatta National Hospital, in Nairobi County. One hundred seventeen 117 HIV-1 infected pregnant mothers were enrolled in the study. A single-arm study design was used. Social demographic characteristics and knowledge of HIV, ARV and MTCT of HIV data was collected using structured questionnaires. Baseline CD4 count was determined at enrolment. HIV-1 infected pregnant mothers were treated with triple ARV regimen (3CT, d4T and NVP) from the range of 5-7 months gestation age to six weeks after delivery. CD4 count and viral load were determined at delivery (36 wks gestation). Infants were treated with a single dose of Nevirapine from birth to six weeks after delivery. Infant’s blood sample was collected at six week and PCR test done to determine their HIV-status. Results showed a highly significant statistical relationship between ARVs and CD4 cell count at delivery (t = 9.82; df=111; p < 0.0001) whereby increase in CD4 count from baseline to delivery were recorded in all age categories of the respondents, apart from those above 43 years old. Out 114 mothers who participated to the end of the study, only three mothers transmitted the HIV virus to their infants. Mean baseline CD4 count and mean CD4 count at delivery of mothers who infected their infants were, 80cells/ml of blood and 89cells/ml of blood respectively, thus very low, while the mean baseline CD4 count and mean CD4 count at delivery of mothers who did not transmit the HIV virus were 408 cells /ml of blood and 505 cells / ml of blood respectively. The mean viral load at delivery of mothers who transmitted the HIV virus to their infants was 407447 copies/ml of blood, while the mean viral load at delivery of mothers who did not transmit the HIV virus to their infants was 1578 copies/ml of blood. The estimated proportion of HIV-1 infected infants was 2.6% at 6 weeks after delivery. The results indicates that the level of knowledge among HIV positive pregnant women on HIV, ARVs and MTCT of HIV was good (> 80%) and there was a highly statistical relationship between knowledge and level of education of the respondents ($\chi^2$=39; df=3; p<0.0001). Anti-retroviral drugs should be made more accessible and affordable to HIV- positive pregnant women as they are highly effective in controlling MTCT of HIV-1.
CHAPTER ONE: INTRODUCTION

1.1 Background information

Human Immunodeficiency Virus (HIV) is a viral infection targeting T-lymphocytes (CD4) in humans. The CD4 cells’ DNA is manipulated to replicate and produce millions of HIV RNA virions (Malviya et al., 2009). The virions lyse CD4 cells and are released into the blood where they infect more CD4 cells. The CD4 cells infected by the HIV are also targeted by the cytotoxic-T-lymphocytes (CTLs) which kill them by cytolytic activity. This leads to a decline in CD4 cells, which are an important part of the immune system that defend the body against infections (John and Gregory, 2004). Normal CD4 cells count is usually >500 cells / ml of blood. Lower CD4 counts are associated with increased risks of complicating infections due to opportunistic infections, cancer and death (KAIS, 2009). HIV infected pregnant mothers are a highly vulnerable group due to constant exposure to re-infections as they fall in the population sub-group that is highly sexually active (Nduati et al., 2002). Other factors include domestic violence (Kiarie et al., 2006), and little or no involvement of the male partner in prevention of mother to child HIV transmission (David et al., 2009; Byamugisha et al., 2010), hence possible higher likelihood of MTCT.

Mother to child HIV transmission occurs in three main ways: through the placenta during pregnancy (5%-10%), labour or delivery (10%-15 %), and through breast feeding (5%-20%) (KAIS, 2009). Mother to child HIV transmission at delivery can be reduced by administering a single dose of antiretroviral drugs (200 mg Nevirapine) to the mother at the onset of the labour and 2 mg/kg single dose to the infant within 72 hours of birth (WHO, 2004; Palacios et al., 2009). Alternatively, a short course of Zidovudine (AZT) 300 mg can be given orally
twice a day at 34-36 weeks gestation to pregnant women before the onset of labour (Tindyebwa et al., 2006). Mother to child transmission of HIV can also be prevented through safe delivery procedures such as planned delivery which minimizes contact of the infant with maternal blood, vaginal cleansing with antiretroviral agents during delivery and use of home based Nevirapine taken at home as soon as labour starts (Cooper et al., 2002). After delivery, MTCT can be avoided by not breast feeding the infant and instead the infant is fed on formula feeds, exclusive breast feeding for 4-6 months and use of post exposure prophylaxis for both the mother and infant (Otieno et al., 2007; Michael et al., 2008; Kinuthia et al., 2010). A study carried out in the Republic of Kazakhstan demonstrated detectable immune abnormalities such as pathology of the nervous system, congenital pneumonia; prematurity and intra-uterine oligotrophy in HIV infected children at birth (Trumova, 2006). Further studies also associated intra-uterine retardation, small size for gestational age, low birth weight, intra-uterine and intra-partum fetal death with HIV infection (Brahmbhatt et al., 2008; Bukusuba et al., 2009).

Maternal antibodies to HIV and the virus itself are known to cross the placenta from the mother to the fetus during all the trimesters of the pregnancy. Factors important in this include immunological such as low CD4 cell counts and high viral load, nutritional factors i.e. deficiency of vitamin A, invasive procedures such as amniocentesis and episiotomy, co-infections with malaria, hepatitis B and C which increases the rate of MTCT (Molfenson et al., 2001; Brahmbhatt et al., 2008; Babirye et al., 2009; Bukusuba et al., 2009). Mother to child HIV transmission during pregnancy and delivery has no direct prevention methodology. Therefore, use of ARVs by pregnant mothers is a significant intervention for control of
MTCT. The current data on effectiveness of ARVs on PMTCT of HIV needs to be evaluated to monitor their effectiveness in control of MTCT of HIV.

1.2 Problem Statement

Kenya is among the 22 countries which collectively account for 90% of pregnant women living with HIV globally (KAIS, 2010). Each year about 1.6 million women get pregnant in Kenya. Among these women, an estimated 85,000 - 100,000 are HIV positive (KAIS, 2007). As a result of this nearly 13,000-16,000 new born acquires HIV from their mothers annually (KAIS, 2007). It has also been established that 15% of the child mortality and 20% of the maternal mortality in Kenya is attributed to HIV/AIDS (NACC, 2010). HIV/AIDS therefore impacts negatively in our efforts to achieve the goal of ‘Elimination of Mother to Child HIV Transmission (EMTCT)’ and ‘Keeping the Mother Alive (KMA)’ by the year 2015 (NASCOP, 2012). The goal of elimination of MTCT involves a multi-sectoral approach. Hence critical analysis of the status and effectiveness of PMTCT interventions in Kenya need to be emphasized to illustrate how accelerated efforts can lead to elimination of MTCT by 2015.

1.3 Justification

Use of anti retroviral therapy (ART), in prevention of mother to child transmission of HIV (PMTCT) in Kenya is one of the success stories in fighting against HIV pandemic, as use of ART has shown to reduce MTCT by over 50% (Molfenson et al., 2001). However, the question now is how low can we go in an effort to completely eradicate MTCT? Re-evaluation of success rate of methods of preventing mother to child HIV transmission already in use is vital if the response to HIV scourge is to be effective. Though a lot of research work
has been done on prevention of MTCT, current data on ART dependent CD4 cells count of HIV-1 positive pregnant mothers as an indicator of MTCT is needed to monitor effectiveness of ARVs and possibilities of development of resistance to ARVs.

1.4 Research Questions

i) What is the percentage level of knowledge of HIV, ARVs and PMTCT of HIV among HIV-positive pregnant mothers

ii) What is the current efficacy of ART in boosting CD4 cell counts of HIV-1 positive pregnant mothers

iii) What is the effect of maternal ART dependent CD4 cell counts on MTCT?

iv) What is the current prevalence of mother to child transmission of HIV in HIV+VE pregnant mothers

1.5 Hypothesis

Antiretroviral therapy dependent CD4 cell count of HIV-positive pregnant women does not influence MTCT of HIV.

1.6 Objectives

1.6.1 General Objective

To determine the prevalence of mother to child HIV transmission and CD4 cell counts in pregnant women on ARV prophylaxis in Kenyatta National Hospital, Nairobi County

1.6.2 Specific Objectives

i) To establish the level of knowledge on HIV, ARVs and MTCT among the HIV positive pregnant mothers at KNH
ii) To determine the effects of ARVs on CD4 cell counts in HIV-1 Pregnant women.

iii) To determine the role of CD4 counts as an indicator of MCTC on pregnant women on ARV prophylaxis on MTCT of HIV-1.

iv) To determine the prevalence of mother-to-child transmission of HIV in pregnant women on ARV prophylaxis

1.7 Significance of the Study

This study has established the current efficacy of Antiretroviral drugs (ARVs) used in prevention of MTCT of HIV, as resistance to ARVs has been reported in some populations. It has also established an optimal antiretroviral therapy dependent CD4 cell counts specific to HIV-positive pregnant mothers, a vital tool in prevention of mother to child HIV transmission, saving the lives of both the mother and the child and elimination of MTCT by the year 2015. In addition, data on CD4 cell count can be used to detect the level of Human Immunodeficiency syndrome HIV/AIDS in the body, analyse the vulnerability of the mothers to opportunistic infections and determine treatment options. Data on patient perception on ARV therapy collected using the questionnaire has been evaluated to provide a lead on how to improve mother to child HIV prevention service delivery in antenatal clinics countrywide.
CHAPTER TWO: LITERATURE REVIEW

2.1 History of HIV/AIDS

Human Immuno-deficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) was initially clustered with diseases such as Pneumonia, caused by Pneumocystis carinii and Kaposi sarcoma, a rare skin cancer (John and Gregory, 2004). It was first detected in 1981 among homosexuals, intravenous drugs users and haemophiliacs (Peter, 2001). The above diseases were only restricted to immunosuppressed individuals who also had low CD4 cells. Relevantly, the term acquired immunodeficiency syndrome (AIDS) was coined in 1982. The virus that causes AIDS was isolated from the lymph nodes of an infected individual (Bradley et al., 1998). Two strains were isolated, HIV-1 in 1983 (Bradley, 1997) and HIV-2 in 1986 (Haase, 1996). HIV-1 is more virulent and widely distributed than HIV-2 which primarily occurs in Western Africa (John and Gregory, 2004). Both HIV-1 and HIV-2 are harmless zooanthroponoses of primates but are harmful to man (Bradley, 1997). It is assumed that the virus initially infected man through the food chain (lower primates eaten by man) though there are many other theories that try to explain the origin of HIV in man (Malviya, 2009).

2.2 Clinical Presentation of HIV/AIDS

Acquired immune deficiency syndrome (AIDS) in an adult is defined by the existence of at least two major signs, in the absence of known cases of immune-suppression such as cancer or severe malnutrition or other recognized etiologies (WHO, 2004). However, the presence of generalized Kaposi’s sarcoma or cryptococcal meningitis is sufficient by itself for the diagnosis of AIDS (Malviya, 2009). The major signs are: weight loss that is
equivalent to or greater than 10% of the body weight, chronic diarrhoea (for more than one month) and fever (for more than one month, intermittent or constant) whereas the minor signs are: persistent coughs (for more than one month), generalized pruritic dermatitis, recurrent herpes zoster, orophageal candidiasis, chronic progressive and disseminated herpes virus infections and generalized lymphadenopathy (Haase, 1996).

2.3 Diagnosis of HIV/AIDS Infection

The most specific diagnosis of HIV/AIDS is the direct identification of the virus in the host tissue by virus culture and isolation. This technique is however, laborious, expensive and not widely available (WHO, 2004). An important invention is the Polymerase Chain Reaction (PCR), which is used to detect HIV-DNA sequences through multiple cycles of amplification from uncultured lymphocytes of subjects infected with HIV. PCR uses a primer oligonucleotide based on any of the HIV genes, which will anneal to the specimen if the homologous HIV-DNA is present.

Multiplication with DNA polymerase and recombinant techniques yields an enormous amplification, and thus makes viral DNA detectable only when a few copies are present ensuring high sensitivity (Holland et al., 2008). For clinical and public health purposes, diagnosis is made by serology. Initially a sensitive screening test is used, most commonly an enzyme linked immuno- sorbent assay (ELISA). Serum samples that test positive are tested repeatedly to eliminate laboratory errors; and those that test repeatedly positive are then confirmed by western blot or immuno-fluorescent assay (UNAIDS, 2005). The commercially available ELISA tests have been well standardized, and specificity of these tests far exceeds what is common in medical tests. Of those that are currently marketed,
both sensitivity and specificity are over 99% (Hollard et al., 2008). Two or more ELISA tests in sequence may also be good economic alternative to western blot confirmation (WHO, 2005).

2.4 Helper T-Lymphocytes (CD4+ T Cells)

Helper T-lymphocytes are a major lineage of T- lymphocytes that express CD4 receptors as the marker molecule on their surface. Helper T-lymphocytes recognise antigen fragment in association with major histocompatibility complex-II (MHC II) antigens, which are expressed by mammalian cells such as macrophages, B- lymphocytes, dendritic and endothelial cells. These cells participate in protective immunity by providing cognitive help to B- cells to secrete antibodies or cytokines, which act directly on the parasites or activate phagocytic cells such as the macrophages.

The role of CD4+ T cells in cell mediated immunity against intracellular viruses, bacteria, fungi and protozoa is generally accepted to be via the production of lymphokines that activate macrophages to express powerful antimicrobial activity. This mechanism has been hypothesised for the elimination of intracellular microbes (Stevenson, 1993). Helper T-lymphocytes may also provide help to expand effector CD8+ T cells population via production of interleukin-2 (IL-2). Interleukin-2 produced by CD4+ T cells has been demonstrated not only to enhance the effectiveness of cytotoxic -T cells but also the production of interferon-γ (IFN-γ) by these cells (Farrar, 1981; Stevenson, 1993).
2.5 Human Immunodeficiency Virus (HIV) and CD4+ T Cells

Human immunodeficiency virus primarily infects, among other cells, vital cells of the immune system such as the helper T-lymphocyte cells (specifically CD4+ T cells), macrophages and dendritic cells (Haase, 1996). HIV entry into the macrophages and CD4+ T cells is mediated by the interaction of the virion envelope glycoprotein gp120 with the CD4 molecule and β-chemokine receptor CCR5 for macrophage tropic strains of HIV-1 and α-chemokine receptor CCR4 for CD4 T cells tropic strains of HIV-1 of the target cells (Chan et al., 1997; Coakley et al., 2005). HIV infection leads to low level of CD4+ T cells through three main mechanisms: direct viral killing of infected cells; increased rates of apoptosis of the infected cells; and killing of the infected cells by CD8 cytotoxic lymphocytes that recognises infected cells (Binley et al., 2002).

When CD4+ T cell numbers decline below a critical level, cell mediated immunity is impaired, and the body becomes progressively more susceptible to opportunistic infections (Desrosier, 1990; Langner et al., 1993). If ARVs are not used, eventually most HIV-infected individuals develop AIDS and die. However, one in ten remains healthy for many years, with no noticeable symptoms (Buchbinder et al., 1994). Treatment with anti-retrovirals, where available, increases the life expectancy of people infected with HIV (Palella et al., 1998; Wood et al., 2003). It is hoped that current and future treatment may allow HIV-infected individuals to achieve a life-expectancy approaching that of the general public (Chene et al., 2003). Infection with HIV-1 is associated with a progressive decrease of the CD4+ T cell count and an increase in viral load. The stage of infection
can be determined by measuring the patient’s CD4+ T cell count and the level of HIV in the blood (Wood et al., 2003).

2.6 Immune Responses to HIV

Human immunodeficiency virus intracellular pathogen stimulates strong CD8+ cytotoxic cells and delayed type hypersensitivity responses (John and Gregory, 2004). It also stimulates strong antibody production to GP120 and P-24, whose combined responses eliminates about 99% of the HIV in latent phase (Peter, 2001). But the immune responses are not able to clear HIV because it has a very high mutation rate, a high rate of replication and can hide as a provirus inside host cells where it is not immunologically detectable (Peter, 2001).

2.7 Global Picture of HIV/AIDS

About 34 million people are living with HIV/AIDS worldwide, of which 23.5 million of people living with HIV/AIDS (PLWHA) lived in sub-Saharan Africa and about 1.7 million in Kenya by 2011 (UNIADS, 2012 and KAIS, 2012). There was 700,000 fewer new HIV infections globally in 2011 than in 2001, accounting for about 50% reduction in HIV infection (KAIS, 2012). Africa has experienced a reduction in HIV/AIDS related deaths by one third in the past six years (UNAIDS, 2012). Globally, new infections among children have decreased from 550,000 to 390,000 in 2010, and about half of the pregnant women living with HIV worldwide are receiving antiretroviral medicine (ARVs) to prevent the transmission of the virus to their unborn children (NACC, 2010).
In Kenya, HIV prevalence is high with an estimated 7.1% (1.4 million) adults aged 15-64 years living with HIV/AIDS. Adults in the reproductive age bracket, (15-49 years) have even a higher prevalence of 7.4% (KAIS, 2007).

Worldwide, the majority of those infected with HIV/AIDS are aged between 20-45 years (UNAIDS, 2004; KAIS, 2010), a bracket in which we have the largest proportion of females conceiving. The most recent statistics for pregnant women attending antenatal clinics reveals seropositivity rates of 9%, that is 58,000 HIV infected women nationally (KAIS, 2010). Further, HIV/AIDS prevalence data indicate that the rate of infections in young women is higher (8.4%) than in males (5.4%) of the same age, and is attributed to factors such as domestic violence, rape, female genital anatomy, low level of education and economic empowerment (Kiarie et al., 2006; Jenell et al., 2007; KAIS, 2007).

2.8 HIV/AIDS and women

According to Ministry of Health (MOH), for every infected man, there are about two infected women (KAIS, 2007). Among the 15-19 year olds, the ratio of infected women to men was 3:1 and the peak prevalence (13%) is among the women aged 25 to 29 years (MOH, 2007). HIV prevalence among women aged 15-49 years was 9.2% compared to men in the same age group which was 5.8% (KAIS, 2007). Women often attend to the nutrition needs of their children and other family members neglecting their own needs. The situation becomes worse when they themselves get the HIV infections and progresses faster towards AIDS, hence are at a greater risk of death compared to HIV infected men (WFP, 2010).
Some HIV positive women experience excessive bleeding and this is thought to be due to fewer blood platelets. For those who are already on antiretroviral therapy regimen, especially those on Zidovudine (AZT), the risk of iron deficiency anaemia is a real threat (WFP, 2001). Women’s health status, education, social economic status, legal rights and welfare have a significant influence on child’s survival and overall human development (Jackson, 2002). Unfortunately, women in Africa especially young women are the worst hit by HIV/AIDS pandemic. It is estimated that about 55% of all new infections in the continent occur among the women (WHO, 2004). The prevalence of HIV/AIDS among women in Kenya is very high compared to men. Several factors including social, economic, political, legal and cultural practices as well as biological factors make them more vulnerable to HIV infection than men (Gupta, 2002). Women are the main caretakers for everyone who becomes ill with HIV/AIDS, hence investing in their health, especially those with HIV and AIDS is guaranteed to generate social and economic returns.

2.9 Economic Impact of HIV/AIDS

HIV/AIDS retards economic growth by destroying human capital. UNIADS predictions for Sub - Saharan Africa up to year 2025, range from a plateau and eventual decline in deaths beginning around 2012 to catastrophic continual growth in the death rate with potentially 90 million cases of infections (UNAIDS, 2005). Without proper nutrition, health care and medicine that is available in developed countries, large numbers of people in these countries are falling victims of AIDS. They will not only be unable to work, but will also require significant medical care. The forecast is that this will likely cause a
collapse of economies and societies in the region. In some regions, the epidemic has left behind many orphans cared for by elderly grandparents (Cohen, 1994).

The increased mortality in this region will result in a smaller skilled population and labour force (Papadopoulos et al., 2004). This smaller labour force with predominantly young people with reduced knowledge and less work experience leads to reduced productivity. An increase in workers’ time-off to look after sick family members or on sick leaves will also lower productivity. Increased mortality will also weaken the mechanisms that generate human capital and investment in people, through loss of income and death of the parents. By killing off mainly young adults, AIDS seriously weaken the taxable population, reducing the resources available for public expenditure such as education and health services resulting in increased pressure for the state’s finances and slower growth of the economy. This is especially true if the sharp increase in adult mortality shifts the blame and responsibility from the family to the government in caring for these orphans (UNAIDS, 2005).

On the level of household, AIDS results in both the loss of income and increased spending on healthcare. The income effects of this lead to spending reduction as well as the substitution effects away from education and towards healthcare and funeral spending. A study in Cote d’Ivoire showed that a household with an HIV/AIDS patient spends twice as much on medical expenses as other households (Cohen, 1994).
2.10 Government Policy on HIV/AIDS

Human immunodeficiency virus, a major health and developmental problem in Kenya was declared a national disaster on 25th of November 1999 by former head of state (GOK, 2001). Since then, extensive research has taken place to address the epidemic. Several studies propose antiretroviral therapy to HIV sero-positive patients with less than 350 CD4 cells/ml of blood (NACC, 2005; UNAIDS, 2006; Michael et al., 2008 and NASCOP, 2012), or a total lymphocytes count below 1200 cells/µl of blood (http://www.who.int/3by5/publications/en). Further, different recommendations have been given in different regions on when to start ARV drugs (McKenna and Hu, 2007).

In Kenya, the Ministry of Medical Services recommends that adults and adolescents with advanced HIV/AIDS disease - defined as patients with WHO stage III or IV disease or where CD4 is available, any stage with CD4 count < 350 cells/ml should be put on ARV therapy. In infants and children, clinical stage III or IV at any age or where CD4 count is available with CD4 < 25% in infants under twelve months, CD4 < 20% for infants between 12 – 59 months and CD4 < 350 cells /ml of blood in children five years and above should be put on ARV therapy. In addition, co-trimoxazole prophylaxis should be given to all HIV exposed infants and children until HIV – infection is excluded and to all HIV-infected infants and children (WHO, 2005; NACC, 2010 and UNAIDS, 2012). World Health Organization (WHO) clinical staging of HIV-related diseases for adults and children is designed to be used once HIV infection has been confirmed with an antibody or virologic test. It is a universal four stage system i.e. Clinical stage 1; Asymptomatic and persistent generalized lymphadenopathy: Clinical stage 2; weight loss
less than 10% body weight, minor mucocutaneous manifestations, Herpes zoster within the last five years and recurrent upper respiratory tract for example bacterial sinusitis: Clinical stage 3; weight loss more than 10% body weight, unexplained chronic diarrhoea or prolonged fever, oral candidiasis or hairy leukoplakia and pulmonary tuberculosis within the past year or severe infection such as pneumonias pyromyositis: Clinical stage 4; HIV wasting syndrome, severe opportunistic infections and opportunistic malignancies (MOH/GOK, 2009). Each stage is a simplified, standardized descriptors of clinical staging events related to survival, prognosis and progression of the clinical disease without ART. It is useful in clinical management of HIV especially where there is limited laboratory services (WHO, 2005; GOK/MOH, 2007; NASCOP, 2012).

The decision to start therapy is done after considering the patient acceptance or readiness and the probability of the adherence (GOK, 2004). The decision is further dependent on the prognosis as determined by the clinical state, CD4 cells counts and viral load (Cooper, 2002; Palacios et al., 2009). Effective chemotherapy consist of the combination of a non-nucleoside analogue reverse transcriptase inhibitor like Nevirapine, a nucleoside analogue reverse transcriptase inhibitor like the zidovudine and a protease inhibitor like Lopinavir (Bradley and Mccluskey, 1997; Janell et al., 2007; Michael et al., 2008). However, there are considerable toxicities to the bone marrow and the gut (Peter, 2001) coupled with complicated procedure for taking the drugs thus limiting ARV use (Anderson et al., 2004; Palacios et al., 2009). The government of Kenya is committed to increasing access to ARV drugs as part of its wider declaration of total war on HIV/AIDS in its National
HIV/AIDS Strategic Plan, 2005/6-2009/10 and 2010/11-2012/13 (NACC, 2005 and NACC, 2010). In addition, it is now mandatory for all pregnant women attending antenatal clinic to undergo counselling and HIV testing in all government hospitals and health centres, a measure that has remarkably increased the number of HIV positive mothers that access ARV therapy (KAIS, 2007; KAIS, 2010).

2.11 Prevention of Mother to Child HIV Transmission (PMTCT)

Human immune deficiency virus (HIV) infections and AIDS threaten to reduce gains made in child survival through wide-spread use of childhood vaccines, improved management of diarrhoea and acute respiratory infections. For women who have not received prior antenatal care, an enzyme-linked immunosorbent assay test should be done as early as possible in labour to determine their HIV status with informed consent. Although chemoprophylaxis given solely in labour has been found to reduce the risk of transmission, these interventions are not as effective as regimen given earlier in pregnancy (Conner et al., 2001; Palacios et al., 2009; Lippincott and Wilkins, 2010).

Selective caesarean section can reduce the risks of transmission by half but it’s not yet a realistic option for poor countries. Alternative options for reducing transmission such as vitamin A supplementation and chlorohexidine cleansing of the birth canal have not shown much success (Ekouevi et al., 2009). For poor countries, the two most cost-effective interventions are ARV prophylaxis and modification of infant feeding (Conner et al., 2001; Ekouevi et al., 2009; Lippincott and Wilkins, 2010). Prevention of MTCT has a threefold strategy which includes preventing women and girls of child-bearing age from becoming infected with HIV, avoidance of unwanted pregnancies among HIV
positive women and preventing the infants from infections by providing ARV drugs, safe delivery procedures, breast milk substitutes and adherence to infant feeding guidelines (UNAIDS, 2003; Bukusuba et al., 2009; Babirye et al., 2009). Infants feeding counseling is associated with improved adherence to feeding guidelines, hence should be scaled up in all postnatal clinics in an effort to reduce MTCT (Babirye et al., 2009).

Avoidance of breast feeding is efficacious in preventing MTCT of HIV, but this intervention has significant associated morbidity; for example due to diarrhoea if formula feed is prepared without clean water (Michael et al., 2008). Offering voluntary counselling and testing (VCT) services to male at antenatal clinic (ANC) with options for couple or individual counselling is an important opportunity and an acceptable strategy for increasing male involvement in PMTCT and promoting male HIV testing (David et al., 2009). Peer counselling in urban ANC increases the number of HIV-infected women who delivers and attend postnatal clinic (PNC), thus feasible to implement PMTCT using peer counsellors (Shetty et al., 2008).

Antiretroviral drugs administered orally or intravenously are effective in controlling the progression of HIV/AIDS and prevents perinatal transmission of HIV/AIDS to infants. Antiretroviral therapy increases T-helper lymphocytes numbers and improves the survival rate of people living with HIV/AIDS. In PMTCT, antiretroviral therapy can reduce viral load in the pregnant mother and/or through post-exposure prophylaxis in newborns, and consequently reduces chances of perinatal transmission (Yerlys et al., 2002; Palacios et al., 2009 and Kinuthia et al., 2010). Pregnant mothers should be offered
a standard combination antiretroviral therapy, usually two nucleoside reverse transcriptase inhibitors and a protein inhibitor, or two nucleoside reverse transcriptase and a non nucleoside reverse transcriptase inhibitors (Molfenson, 2001).

The most commonly prescribed ARVs in pregnancy are zidovudine, stavudine, lamuvidine, Nevirapine and nelfinadir. Zidovudine reduces MTCT by 65% (infection status by 15 months); while Nevirapine reduces MTCT by 47% (infection status at 6 weeks of age). However, HAART results in lower breast milk HIV-1 RNA than zidovudine or even Nevirapine, and suppresses plasma HIV-1 RNA during the antenatal and postnatal period (Michael et al., 2008; Lippincott and Wilkins, 2010). Further, giving breastfeeding mothers a triple-ARV regimen from late pregnancy to six months is a safe, effective and feasible way of reducing MTCT of HIV in resource limited settings (Molfenson et al., 2001 and Debora et al., 2010). Generally, monotherapy and combination anti-retroviral therapeutic agents will increase CD4 cells count, but greater clinical benefits of such an increase in prevention of MTCT can be realized if a benchmark of ART dependent CD4 cell count is established.

### 2.12 Methods of Determining CD4 Counts

The stage of HIV disease is determined by the number of CD4 – positive-T cells in an individual’s blood (Alexander et al., 1994). This value is obtained by determining the percentage of the lymphocytes which co express CD3 and CD4 by flow cytometry and multiply the value by the absolute lymphocytes counts, as determined by a hematologic analyzer which is a duo-platform method (Nicholson et al., 1996). More efficient single-platform flow cytometry systems which directly determines absolute CD4 counts have
been introduced. These systems includes the Ortho TRIO Panel, Coulter XL, True counts and the BD FACS Counts systems (Nicholson et al., 1997).

2.13 Methods of Determining Viral Load

The HIV viral load test is used to monitor the HIV infection over time. It’s a quantitative measurement of HIV ribonucleic acid (RNA) which reports how many copies of virus are present in the blood (Shi et al., 2001). Viral load is measured using one of the three different types of tests; Reverse- transcriptase polymerase reaction (RT-PCR), Branched DNA test (bDNA) and Nucleic acid sequence-base amplification (NASBA) test (martin et al., 2000). These tests measures the amount of RNA of HIV in the blood but each reports the results differently, hence its vital to use the same test over time (Shi et al., 2001).

Branched DNA test (bDNA) is a signal amplification technology built as a series of hybridization reactions that are highly amenable to full automation. This lessens the burden of the amount of labour required to perform this type of analysis (Martin et al., 2000). Nucleic acid sequence-based amplification (NASBA) test is an amplification technology which involves use of three enzymes; reverse transcriptase, TY RNA polymerase and RNase H (Shi et al., 2001). The final amplification product is a single stranded RNA with a polarity opposite that of the target. The amplified RNA product is detected through use of target- specific capture probe bound to magnetic particles in conjunction with nitherium-labelled detector probe and a Nuclisens Reader; bioMetrieux instrument capable of detecting electromi- illuminescence (Martin et al., 2000).
Reverse transcriptase polymerase reaction (PCR) test is relatively simple and inexpensive method that is used to focus on a primers of DNA and copies it a billions times over. It uses fluorescent dyes or fluorophore DNA probe to measure the amount of amplification product in real time (Shi et al., 2001).
CHAPTER THREE: MATERIALS AND METHODS

3.1 Study Area

The study was carried out at Kenyatta National Hospital in Nairobi County, Kenya. The hospital was selected because it is the referral hospitals with attendees drawn from all over the country. This is supported by the fact that Nairobi has seen a large influx of people from all over the country particularly looking for employment, thereby presenting a fairly representative cosmopolitan sample of Kenya’s AIDS scenario of its most sexually active bracket of people. The hospital is located just a few kilometres from Nairobi’s capital Central Business District hence easily accessible by people of all social and economic backgrounds.

3.2 Study Population

The study subjects were HIV-positive pregnant women attending antenatal clinic at Kenyatta National Hospital, Nairobi County in Kenya, and their infants after birth.

3.3 Inclusion and Exclusion Criteria

The study considered only HIV-1 positive pregnant women, eighteen (18) years old and above attending ANC at KNH. These were also between 20 to 28 weeks of gestation (to enable collection of at least two blood samples of the mothers by delivery) following their consent to participate in the study. This was also authenticated by appending their signatures in the participation consent form (Appendix VI). HIV-negative pregnant mothers were not considered for this study. HIV positive mothers below 18 years of age, not within the range of 20-28 weeks of gestation and those who did not consent to participate were excluded from the study.
3.4 Sample Size Determination

The number of the HIV-positive pregnant women attending antenatal clinic at Kenyatta National Hospital included in the study was determined using the formula for clinical trials developed by Kirby et al. (2002).

\[ N = \frac{2(Z_{a} \times 1 - \beta^2)}{\Delta^2} \]

Where:

- \( N \) = minimum sample size required
- \( Z_{a} \) = Standard error = 95% = 1.96
- \( \Delta^2 \) = proportion of MTCT during pregnancy and labour among antenatal attendee = 5% - 10%, (KAIS, 2009) Average = 7.5% = 0.075
- \( \beta^2 \) = Confidence limit (level of statistical significance) = 0.05, the inverse of 95%. Hence

\[ N = \frac{(1.96)^2 (0.075) (1-0.075)}{(0.05)^2} = 107 \]

Then add 10% of the sample size to cater for attrition and dropout = 10. Thus, total sample size = 117

3.5 Study Design

A single Arm-trial study design was used. In this design there is no sample population for a control experiment. This is in accordance to government policy on PMTCT of HIV+ that all HIV+ pregnant mothers must be treated with a combination ARVs. The mothers were sampled by selecting the subjects as they reported at the hospital’s antenatal clinic.
(ANC). HIV+ pregnant mothers within the range of 5-6 months gestation were given consent forms to read with assistance of the researcher. Those who consented signed the assent form to confirm their willingness to participate. The mothers were followed up to delivery and six months after delivery.

### 3.6 Data Collection Instruments

A questionnaire was used to collect data on social demographic characteristics of the participants and knowledge of HIV, ARVs and PMTCT of HIV. Kenyatta National Hospital records on HIV status, CD4 count and viral load of HIV+ pregnant women at the ANC were also used.

### 3.7 Data Collection Procedure

Five (5) ml of blood for determining HIV status were collected from the pregnant mothers using EDTA Vacutainers by a qualified laboratory technician. Five (5) ml of blood for baseline CD4 count were collected from HIV+ pregnant mothers at enrolment using EDTA Vacutainers by a qualified laboratory technician. Combinational ARVs regimen (Zidovudine, Lamuvidine and Neviravine) was given to HIV positive pregnant women in the range of 20 - 28 weeks of gestation enrolment. At each monthly visit, a supply of ARV drugs was provided and adherence counselling performed. Five (5) ml of blood for determination of CD4 count at delivery and viral load were collected from the pregnant mothers using EDTA Vacutainers at 36 week gestation age by a qualified laboratory technician. Five hundred (500) µl of blood obtained from a foot prick of infants at six weeks of age and collected using a filter paper for PCR was collected by a qualified technician.
3.8 Laboratory Methods

3.8.1 Unigold HIV 1/2 Test

Maternal HIV testing was done by subjecting blood samples to Unigold HIV-1 test cards (CDC, 1988) and Tie-breaker reagent (Matemo et al., 2009). Briefly, the procedure was as follows: To each labelled test card, droplets of whole blood produced by a finger prick from each individual were applied to the sample pad. Four drops of the chase buffer were then applied. Results were read after 10 - 15 minutes. The test is positive when two red bars appears, one on the control window and the other on the patient’s window of the strip in the test card. The result is negative when one red bar appears in the control window of the strip and no red bar appears in the patient’s window of the strip. HIV positive samples were confirmed using Bioline HIV test kit (Matemo et al., 2009).

3.8.2 Separation of Peripheral Blood Mononuclear Cells (PBMC) from whole blood for determination of CD4 count in pregnant women

Peripheral blood mononuclear cells were extracted from whole blood by the method described by Alois et al. (1998). Briefly, 5ml of whole blood was added to a falcon tube containing 10 ml of 0.8% ammonium chloride, vortexed to mix completely, and then incubated at 37 °C for 10 minutes. The mixture was then spun at 1500 x g in a centrifuge for 10 minutes at room temperatures and the supernatant discarded. Another 10 ml of the 0.84 ammonium chloride was added to the pellet and the procedure repeated three times until PBMC pellet appeared white in colour. The supernatant was then discarded and one ml of the 0.84% ammonium chloride was added to the falcon tube with the pellet and mixed with a pipette. The pellet was then drawn into 1.5 ml eppendorf tube and span at
12000 x g in a microcentrifuge at room temperature. The supernatant was then pipetted off to recover the PBMC, which appeared as white pellet.

3.9.3 Polymerase Chain Reaction (PCR) for Determination of Infants HIV Status

Qualitative HIV-1 DNA PCR testing (Amplicor HIV-1 DNA PCR Test, version 1.5; Roche Branchburg) was performed on dried blood spot (DBS) collected on specimen filter paper from a foot prick of the infant at six week after deliver. Briefly, a master mix was constituted as per the number of samples for the PCR reaction. Extracted provirus DNA served as the starting template. Double stranded DNA is denatured; a pair of HIV-DNA specific primer is annealed to the separated DNA strands and these primers are extended by heat resistant DNA-dependent RNA polymerase (Taq polymerase) and dinucleotide triphosphate (dNTPs). The PCR conditions for denaturing, annealing and extension were 94 °C for 2 min, followed by 35 cycles of 94 °C for 30 s, 58 °C for 30 s, 72 °C for 30 s respectively with a final extension for 7 minutes at 72°C. Each PCR was conducted in a final volume of 25 μl containing 0.2 - 0.5 μg template DNA, PCR buffer, 200 μm of each dNTPs, 1Mm MgCl2, 1.25 U Tag polymerase (perkin-Elmer Corporation, Norwalk, CT-USA), and 50 nM each primer. This procedure was continued for 45 cycles. The PCR products were then demonstrated on polyacrylamide gel electrophoresis.
3.8.4 Viral Load Determination

Viral load was determined using ABBOT Real time HIV-1 assay (Crump et al., 2009) according to the protocol provided by the manufacturer. Briefly, the kit procedure was divided into two main parts; the plasma was first treated to inactivate cellular enzymes by adding 100 µl of plasma treatment additive. One millilitre of the sample was pipetted into each of the 32 plasma processing tubes placed in a sample box and incubated for one hour in darkness at room temperatures. One and half µl of separation gel was then added to each plasma processing tube, the sample box placed on a moving table and incubated at room temperature for 90 minutes. After incubation, the gel was sucked dry in all the tubes using a vacuum pump, the gel was then washed four times using 250 ml of gel wash buffer. The gel was sucked dry again and washed again using 250 ml of the gel reconditioning buffer. Five hundred µl of lysis buffer was added to each tube and the lysates transferred to lysates collection tube.

To obtain the reverse transcriptase (RT), the virion was lysed and the lysate collected for further analysis. During the RT-assay, the lysate was analysed in an Elisa set up. A reaction mixture containing primer and an RT substrate was added to the plate together with the lysates. If the lysate contained any RT enzymes, the enzymes synthesized a DNA-strand. This product was detected with an alkaline phosphate conjugate anti bromodeoxyribouridine antibody (α-BradU). The product was quantified by addition of a colorimetric alkaline phosphate (AP) substrate, p-nitrophenyl phosphate (pNPP). For comparison of results, in house HIV positive controls and in house HIV negative controls were prepared. For in house HIV-positive, about 10 ml of plasma prepared from a pool
of EDTA blood from HIV-positive patients were prepared by mixing samples with high and low HIV RT activity levels. When no plasma with determined RT amount was available, a pool was prepared that corresponded to 25,000 copies/ml. The material was aliquoted into 1.5 ml portion and 1 ml of one portion was used as a positive control. For in house HIV-negative control, about 10 ml of pool of plasma from a healthy blood donor were prepared; the material was aliquoted into 1.2 ml portions and 1 ml of one portion used as a negative control. When alkaline phosphate substrate p-nitrophenyl phosphate was added to the product, the plate was incubated in darkness at room temperatures. The plate was read at an optical density of 405 (A405) ten minutes after the addition of the substrate. The plate was read a second time after 2-3 hours and a third time after 5-6 hours or the following day (16-24 hours) after addition of the substrate. Calculations of the viral load values of the plasma samples were performed using ABBOT real time analyzer. Viral load determination was carried out in all patients at 36 weeks gestation.

3.8.5 Determination of CD4 Count

The CD4+ cell count was measured using standard procedure; TruCount on FACScalibular, Becton-Dickson (Stevenson et al., 1993). Briefly, the method is as follows; five ml of whole blood were added to each tube of BD FACS count reagent kit (Absolute CD4+, CD8+ and CD3+) vortexed, and the samples ran in BD FACS count machine. The system employs the principle that when whole blood is added to the reagent fluorochrome-laballed antibodies, the antibodies bind specifically to lymphocytes surface antigens. When the fluorochromes labelled cells come into contact with laser light in the instrument, they fluoresce. The fluorescent light provides the information
necessary for the instrument to count the cells. Result are analysed automatically and reported on a sample print out sheet. The CD4, CD8 and CD3 absolute counts are displayed and printed automatically as number of cells per ul.

3.9 Ethical Approval

Clearance to carry out research was obtained from Kenyatta National Hospital Ethics and Research Secretariat (Appendix VIII). The purpose of the study was explained to all potential participants so as to get an informed verbal consent from the patients. All information obtained was treated with confidentiality to protect the source. The participants were at liberty to terminate their participation any time.

3.10 Data Analysis

Data on change in CD4 cell counts from baseline to delivery after initiation of antiretroviral therapy was analyzed using paired t - test. Mother to child HIV transmission (MTCT) rates were worked out as a percentage of the sampled mothers. Chi-square test was used to establish relations between knowledge of HIV, ARVs and PMTC with age, level of education, occupation and marital status for the data collected using the questionnaire.

3.11 Validity and reliability

Validity is concerned with the extent to which an instrument measures what it is intended to measure. Reliability is concerned with the ability of an instrument to measure consistently. It should be noted that the reliability of an instrument is closely associated with its validity. An instrument cannot be valid unless it is reliable. However, the reliability of an instrument does not depend on its validity. It is possible to objectively
measure the reliability of an instrument and in this paper, the researcher used Cronbach’s alpha, the most widely used objective measure of reliability. Alpha is a measure of the internal consistency of a test or scale; it is expressed as a number between zero and one (0-1). Internal consistency describes the extent to which all the items in a test measure the same concept or construct and hence it is connected to the inter-relatedness of the items within the test. Internal consistency should be determined before a test can be employed for research or examination purposes to ensure validity. In addition, reliability estimates show the amount of measurement error in a test. Put simply, this interpretation of reliability is the correlation of test with itself. Squaring this correlation and subtracting from 1.00 produces the index of measurement error. If the alpha will be more than 0.5 the validity will be acceptable otherwise it will not be reliable.

3.12 Scope and Limitations

In the course of research, the researcher encountered several limitations. The reagents and laboratory procedures used were limited to the standards operations procedures (SOP) of KNH antenatal clinic. HIV+ pregnant women < 18 years of age were not enrolled for study as they are mentally, psychologically and emotionally immature hence required to be accompanied by a guardian. The class 0f 15-19 used by KAIS could not be used as patients < 18 years were excluded from the study. Some mothers also withdrew from the study citing ARVs use side effects. Others were uncooperative hence declined to participate.
CHAPTER FOUR: RESULTS

4.1 Demographic Characteristics of the Study Population

A total of 117 HIV-positive pregnant mothers were enrolled at Kenyatta national Hospital ANC in Nairobi, but only 114 participated to the end of the study. Two of the respondents withdrew citing side-effects of ARVs, while one respondent suffered a miscarriage.

4.1.1 Respondents Age Distribution

This section captures the age categories of the participants. The respondent’s age ranged from 18 to 44 years, with a peak of 28 to 32 years. Of all the respondents, majority were in the age group of 28-32 years (39.3%), followed by 33-37 years (22.2%), 23-27 years (18.8%), 18-22 years (10.2%) and only two respondents were aged above 43 years, accounting for 1.8% of the total respondents (Table 4.1).

Table 4.1: Percentage age Distribution of the Respondents

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Mean age</th>
<th>Number of participants</th>
<th>% proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 22</td>
<td>21</td>
<td>12</td>
<td>10.2</td>
</tr>
<tr>
<td>23 – 27</td>
<td>25</td>
<td>22</td>
<td>18.8</td>
</tr>
<tr>
<td>28 – 32</td>
<td>30</td>
<td>46</td>
<td>39.3</td>
</tr>
<tr>
<td>33 – 37</td>
<td>35</td>
<td>26</td>
<td>22.2</td>
</tr>
<tr>
<td>38 – 42</td>
<td>39</td>
<td>9</td>
<td>7.7</td>
</tr>
<tr>
<td>Above 42</td>
<td>44</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Total</td>
<td>194</td>
<td>117</td>
<td>100</td>
</tr>
</tbody>
</table>
4.1.2 Marital Status of the Respondents

This section determines the marital status of the respondents. Out of the 117 HIV-positive pregnant women enrolled, a significantly large number (68.4%) were married, 29.8% were single, 1.11% were separated and (0.69%) were windowed (Figure 4.1).

Figure 4.1: Marital status of the respondents
4.1.3 Occupation of the Respondents

This establishes the various occupations of the respondents. Among the respondent, 49.6% were in informal employment, 24.8% were permanently employed (the formal sector) while 25.6% were unemployed. (Table 4.2).

Table 4.2: Distribution of the Respondents According to Occupation

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Frequency</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casual/Informal employment</td>
<td>58</td>
<td>49.6</td>
</tr>
<tr>
<td>Permanent/Formal employment</td>
<td>29</td>
<td>24.8</td>
</tr>
<tr>
<td>Unemployed/Housewives</td>
<td>30</td>
<td>25.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>114</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

4.1.4 Education Level of the Participants

It captures the various level of education of the participants. Most respondents had attained primary or secondary school education, 24.8% and 43.6% respectively. Among the women, 24.8% had attained college and 3.4 % had university education. Majority (43.6%) of the respondent had secondary education (Figure 4.2).
4.2 Respondents Knowledge of HIV, ARVs and MCTC of HIV

4.2.1 Knowledge of HIV, ARVs and Mother to Child HIV Transmission (MTCT)

This was carried out to establish the proportion of the HIV-positive mothers who had previous knowledge on MTCT of HIV. All the respondents, 100% knew about HIV/AIDS. Majority of the mothers, 78.6% knew that ARVs can prevent MTCT of HIV, while 94.9% of the women had heard of ARVs. Only 17.9% of the respondents knew one or more ARV by name, while 35.0% of the HIV-positive mothers knew where to obtain the ARVs when they needed them. There was even higher knowledge (94.9%),
that ARVs can be used to reduce the rate of progression of HIV to AIDS, while 94.9% had heard of ARVs before. Of all the respondents, 35% said that ARVs reduces pain (Table 4.3).

Table 4.3: Percentage Distribution of Knowledge of HIV, PMTCT and ARVs Among the Respondents

<table>
<thead>
<tr>
<th>Knowledge category</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heard of HIV/AIDS before</td>
<td>100.0 %</td>
<td>0.0</td>
</tr>
<tr>
<td>Heard of ARVs before</td>
<td>94.9 %</td>
<td>5.1 %</td>
</tr>
<tr>
<td>ARVs prevents MTCT</td>
<td>78.6 %</td>
<td>21.4 %</td>
</tr>
<tr>
<td>ARVs reduces pain</td>
<td>35 %</td>
<td>65.0 %</td>
</tr>
<tr>
<td>ARVS reduces pregression of HIV</td>
<td>94.9 %</td>
<td>5.1 %</td>
</tr>
<tr>
<td>Where to obtain ARVs</td>
<td>35 %</td>
<td>65.0 %</td>
</tr>
<tr>
<td>Knew any ARV used</td>
<td>17.9 %</td>
<td>82.1 %</td>
</tr>
</tbody>
</table>

4.2.2 Relationship Between Knowledge of HIV, PMTCT and ARVs and Level of Education

This determines the effect of level of education on knowledge of HIV ARVs and PMTCT of HIV of the mothers. In almost all categories of knowledge, percentage participants increased with increase in level of education. Participants with university education recorded the highest percentage, and in decreasing order, followed by secondary, then
college, with primary education scoring the lowest percentage apart from effects of ARVs on pain. (Figure 4.3). Chi-square test between education level and knowledge of HIV, ARVs and PMTCT revealed a significant statistical relationship ($X^2 = 39; df = 3; P < 0.001$) whereby, the majority of the respondents who had good knowledge of HIV, ARVs and PMTCT had secondary education level and above (Appendix II).

![Figure 4.3 Relationship Between Knowledge of HIV, PMTCT and ARVs and the Level of Education](image-url)

**Figure 4.3** Relationship Between Knowledge of HIV, PMTCT and ARVs and the Level of Education
4.3 Respondents CD4 Cell Count

4.3.1 Respondents Mean CD4 Count with Age Category

It establishes the effect of age of mothers on CD4 counts increment. The results show that there was an increase in mean CD4 cell count from the time of initiation of ARVs (baseline), to the time of delivery in the majority of the age distribution, apart from the respondents who were 43 years and above. The highest increment was recorded in age category of 23 – 27 with an increment of 30.9%, followed by 38 – 42 with 29.6%, 28 -32 with 25.4%, 12 -22 with 20.7% and lastly 33 – 37 with 17.5 % CD4 cell count increment. Respondents above 43 years recoded a decline of 0.7 % (Figure 4.4). A paired t-test revealed a highly significant statistical relationship between use of ARVs and CD4 cell counts of the respondents, (t = 9.825; df =111; P < 0.0001) whereby increase in CD4 count from baseline to delivery was recorded in all age categories (Appendix I).
Figure 4.4: Distribution of Respondents mean Baseline CD4 Count and Mean CD4 Count at Delivery with age Category.

4.3.2 Relationship between Mean Percentage CD4 Increment and Gestation Age at which ARVs were Started

It compares mean CD4 count increment of the mothers with the gestation age at which ARVs were initiated. There was significant increase in mean CD4 cell count \((t=111; P<0.0001)\) from baseline to delivery in all categories of gestation. The highest percentage CD4 count increment was recorded among the respondents who were initiated ARVs at five months of gestation (32%), followed by those initiated at six
months (24%) while the least increment (22%), was recorded among the respondent who were initiated ARVs at seven months gestation (Table 4.4).

Table 4.4: Relationship Between Mean Percentage CD4 Increment and Gestation Age at which ARVs were Initiated

<table>
<thead>
<tr>
<th>Gestation age(months) at which ARVs were started</th>
<th>Mean baseline CD4 count</th>
<th>Mean CD4 count after delivery</th>
<th>% CD4 increment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>547</td>
<td>723</td>
<td>32.0</td>
</tr>
<tr>
<td>6</td>
<td>369</td>
<td>453</td>
<td>24.0</td>
</tr>
<tr>
<td>7</td>
<td>412</td>
<td>505</td>
<td>22.0</td>
</tr>
</tbody>
</table>

4.3.3 Relationship Between Mean percentage CD4 Count Category and Gestation Age at which ARVs were Started

This is to determine the effect of gestation age at which ARVs were initiated on CD4 count categories of the mothers. All the HIV-positive pregnant mothers who were started on ARVs at five months gestation had baseline CD4 count above 350 cells/ml of blood. Results on HIV-positive pregnant mothers who were started on ARVs at six months gestation indicated that 23.0% had baseline CD4 count below 250 cell/ml of blood, 20.0% had a baseline CD4 count of 250-350 cell /ml of blood while 57.0% had a baseline CD4 count >350 cell/ml of blood. For respondents who were put on ARVs at seven months gestation, 21.0% had a baseline CD4 count < 250 cells/ml of blood, 15.0% had a baseline CD4 count of 250-350 cells /ml of blood while 64% had a baseline CD4 count >350 cells /ml of blood. At delivery, all the HIV-positive mothers who started on ARVs
at five months of gestation had a CD4 count > 350 cells /ml of blood, 78.0% of those started at six months gestation had a CD4 count > 350 cell/ml of blood, while 80.0% of respondent started ARVs at seven months gestation, had a CD4 count > 350 cell/ml of blood (Table 4.5).

**Table 4.5: Relationship Between CD4 Cell Count Categories and Gestation Age at which ARVs were Started**

<table>
<thead>
<tr>
<th>CD4 count category</th>
<th>% participants starting ARVs at 5 months of gestation</th>
<th>% participants starting ARVs at 6 months of gestation</th>
<th>% participants starting ARVs at 7 months of gestation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>At delivery</td>
<td>Baseline</td>
</tr>
<tr>
<td>&lt;250</td>
<td>0</td>
<td>0</td>
<td>23</td>
</tr>
<tr>
<td>250-350</td>
<td>0</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>&gt;350</td>
<td>100</td>
<td>100</td>
<td>57</td>
</tr>
</tbody>
</table>

**4.3.4 Relationship Between Infants HIV Status and Mothers’ CD4 Count Categories**

This compares mothers CD4 count categories with the infants HIV status. HIV- positive mothers with CD4 count of <150 cells/ml of blood during pregnancy and delivery and who had started ARVs at seven months transmitted the HIV virus to their infants (reactive) despite use of ARV. HIV positive mothers with a CD4 count > 150 cells /ml of blood during pregnancy and at delivery and had started ARVs at either 5th or 6th of gestation did not transmit the HIV virus to their infants (non-reactive) (Table 4.6).
Table 4.6: Distribution of Infants HIV Status with Mothers’ CD4 Cell Count Categories at Delivery

<table>
<thead>
<tr>
<th>CD4 cell count Category (cells/ml of Blood)</th>
<th>Mean CD4 count (cells/ml of blood)</th>
<th>Infants HIV status</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100</td>
<td>63</td>
<td>Reactive</td>
</tr>
<tr>
<td>101 - 150</td>
<td>109</td>
<td>Reactive</td>
</tr>
<tr>
<td>151 – 200</td>
<td>178</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>201 – 250</td>
<td>217</td>
<td>Non - reactive</td>
</tr>
<tr>
<td>251 – 300</td>
<td>279</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>301 – 350</td>
<td>330</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>351 – 400</td>
<td>357</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>451 _ 500</td>
<td>478</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>501 – 550</td>
<td>523</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>551- 600</td>
<td>517</td>
<td>Non - reactive</td>
</tr>
<tr>
<td>601 – 650</td>
<td>624</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>651 – 700</td>
<td>672</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>701 – 750</td>
<td>731</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>751 – 800</td>
<td>776</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>801 - 850</td>
<td>837</td>
<td>Non - reactive</td>
</tr>
<tr>
<td>851 – 900</td>
<td>896</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>Above 900</td>
<td>1206</td>
<td>Non - reactive</td>
</tr>
</tbody>
</table>
4.3.5 Relationship Between Mothers Mean Baseline CD4 Count and Mean CD4 Counts at Delivery with HIV Status of the Infants

This compares the mothers CD4 count with the infants HIV status at six weeks after delivery. There was increase in mean CD4 cell count from baseline to the time of delivery in mothers who transmitted and those who did not transmit the HIV virus to their infants. The mean baseline CD4 cell count and mean CD4 cell count at delivery in mothers who transmitted the HIV virus to their infant was very low (80 cells/ml of blood and 89 cells/ml respectively). Mothers who did not transmit the HIV virus had very high mean baseline CD4 cell count and mean CD4 cell count at delivery (408 cell/ml and 505 cell/ml of blood respectively) (Table 4.7).

Table 4.7: Relationship Between Mothers Mean Baseline CD4 count and mean CD4 count at delivery with HIV status of the infant

<table>
<thead>
<tr>
<th>Infant HIV status</th>
<th>Mothers mean baseline CD4 counts (cells/ml of blood)</th>
<th>Mothers mean CD4 count at delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>80</td>
<td>89</td>
</tr>
<tr>
<td>Non – reactive</td>
<td>408</td>
<td>505</td>
</tr>
</tbody>
</table>

4.3.6 Distribution of infants HIV status by mothers’ viral load categories

This compares the various categories of mothers viral load at delivery with the infants' HIV status at six weeks after delivery. HIV-positive mothers with undetectable viral load and viral load below 80,000 copies /ml of blood did not transmit the HIV virus to their infants (non-reactive), while mothers with a viral load above 80,000 copies /ml of blood transmitted the HIV virus to their infants (Table 5.8).

Table 4.8: Distribution of the infants HIV status with mother’s viral load categories

<table>
<thead>
<tr>
<th>Mothers viral load Categories (copies/ml)</th>
<th>Grouped mean viral load (copies/ml)</th>
<th>Frequency</th>
<th>Infants HIV status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable</td>
<td>0</td>
<td>47</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>1 -10, 000</td>
<td>794</td>
<td>37</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>10,001 – 20,000</td>
<td>13, 459</td>
<td>12</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>20,001 – 30,000</td>
<td>22, 959</td>
<td>3</td>
<td>Non – reactive</td>
</tr>
<tr>
<td>30,001 – 40,000</td>
<td>35, 313</td>
<td>5</td>
<td>Non - reactive</td>
</tr>
<tr>
<td>40,001 – 50,000</td>
<td>45, 832</td>
<td>5</td>
<td>Non- reactive</td>
</tr>
<tr>
<td>50,001 – 60,000</td>
<td>56, 816</td>
<td>2</td>
<td>Non - reactive</td>
</tr>
<tr>
<td>60,001- 70,000</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>70,001 – 80,000</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Above 80,000</td>
<td>407, 447</td>
<td>3</td>
<td>Reactive</td>
</tr>
</tbody>
</table>
4.3.7 Percentage Respondents with Infants HIV Status

This is to establish the percentage proportion of mothers who transmitted the HIV to their newborn. Only three HIV-positive pregnant mothers transmitted the HIV-1 virus to their infants, which accounted for 2.6%, while a majority of the mothers (97.4%) did not transmit the HIV-1 virus to their infants. The mean viral load for mothers who transmitted the HIV virus to their infants was very high (407, 447 copies/ml of blood), compared to 25,140 copies/ml of blood for mothers who did not transmit the HIV virus to their infants (Table 4.9).

**Table 4.9: Percentage Respondents and Infants HIV-Status**

<table>
<thead>
<tr>
<th>No. of the respondents</th>
<th>% respondents</th>
<th>Mean viral load</th>
<th>Infants HIV status</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>2.6</td>
<td>407, 447</td>
<td>Reactive</td>
</tr>
<tr>
<td>111</td>
<td>97.4</td>
<td>25,140</td>
<td>Non-reactive</td>
</tr>
</tbody>
</table>
CHAPTER FIVE: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion
This section describes the results obtained in respect to other related studies.

5.1.1 Social and Demographic Characteristics of the Respondent
This captured data on age, marital status, occupation, level of education and knowledge of HIV, ARVs and PMTCT of HIV.

5.1.1.1 Age Distribution of the Respondents
Out of the total of 117 HIV-positive pregnant mothers enrolled for this study at Kenyatta National Hospital ANC in Nairobi, only 114 mothers participated to the end of the study. The results of the age distribution of the respondents reflect the expected distribution, whereby all the respondents were within the reproductive and the most sexually active age group of 15-49 years. NASCOP (2003) indicates that women aged between 25 to 30 years have the highest HIV/AIDS prevalence, while KAIS (2007) reported a HIV prevalence peak in pregnant women aged between 30 to 34 years.

According to KAIS (2007), young women aged between 15 - 49 years are the majority of HIV-infected and disproportionately infected compared to young men. Findings from this study indicate a peak between 28-32 years. This difference could be attributed to fact that women below the age of 18 years were not recruited for this study. This could also be due to increase in awareness in girl-child education in the society, thus more women are taking more number of years scaling the academic height hence taking a little longer to settle in marriage. From above 38 years, HIV prevalence estimates declined among
pregnant women. This could be due to the fact that fertility rate and sex libido reduces as women approaches 40 years and above (KAIS, 2007). Consequently, fewer women are predisposed to HIV/AIDS infection in this age bracket. In general, these results mitigate for the need of the government and other stakeholder to upscale HIV/AIDS and PMTCT education campaigns targeting young people in the society.

5.1.1.2 Marital status of the respondents

A large number of women (68.4 %) who participated in this study were married, while a few were single, separated or windowed. These results reflect a typical African family set-up where divorce cases are not a common practice. According to KAIS (2007) marriage was still varied at 68%, despite the high prevalence of HIV/AIDS in marriage. Separation has been a rare phenomenon among Kenyan communities where divorce cases accounted for 5.9% (KDHS, 2003). In this study, there is a slight difference in the proportion of divorce cases among the participants, where there is a decrease to less than one percent. This could be attributed to increase in awareness campaigns on prevention of HIV transmission among discordant couples, thus no need for separation/divorce. In the recent past there has been a significant improvement in couple counselling and testing of HIV/ANDS and use of ARVs (NASCOP, 2012).

5.1.1.3 Occupation of the Respondents

The results indicate that 49.6 % of the HIV- pregnant women were self employed, suggesting that most of the women were in business and menial work. Mainly, individuals in this occupation do not have any professional skills, and this could explain why this was the most common occupation. According to KDHS (2003) report, 70% of the women in Nairobi are unemployed and out of which, the highest proportion, 49% and
26.6% are engaged in business and menial work respectively. Of most significance is the 26.3% of the women who were not involved in any economic activity as they were housewives. This study shows that women are poorly economically empowered and consequently low income earners. Income reflects the purchasing power, diet and medical care in a family set-up (KDHS, 2003). The findings of this study shows that a majority of the family inflicted by HIV/AIDS in Kenya are less economically empowered, which in turn worsen their HIV/AIDS conditions as they can hardly afford a neither balanced diet nor proper medical care which are core in management of HIV/AIDS. Economic empowerment of women is crucial for general human development in any nation, as they are the family managers. The government and the private sectors should therefore increase funding in economic sectors that are women friendly, to boost women involvement in economic development and consequently an increase in family income earnings.

5.1.1.4 Respondents Level of Education

All the respondents who participated in this study had formal education with the 42% proportion having attained secondary education. The study shows the level of literacy among women in urban centres may be higher than in rural set-up as all the HIV–positive women recruited in this study had at least primary education, in comparison to a study carried out in a rural set – up of Suba district in western Kenya, where 14% of the women were illiterate (Jane, 2008).

The study differs with KDHS (2003) report, which indicated the highest respondents (27.2%), as those who had completed primary education, whereas in the present study,
majority (41.2%) had attained secondary education level. This disparity could be attributed to the fact that there has been heightened awareness on girl child education particularly in urban centres. These results suggest that if the respondents were given basic education on HIV, PMTCT and ARVs, they would be in a position to understand and make the right choices in matters pertaining reproductive health, thus further reducing cases of MTCT of HIV (Jane, 2008).

5.1.1.5 Respondents Knowledge on HIV, ARVs and PMTCT of HIV

Knowledge on HIV/AIDS, PMTCT and benefits of ARVs are a key element in comprehensive response to the HIV epidemic in general and PMTCT in particular. The good knowledge on HIV, ARVs and PMTCT of HIV in the majority of the mothers could have been attributed to the intensive PMTCT awareness campaigns on the importance of HIV testing during pregnancy in Kenya. Knowledge of HIV infection is vital because it has the potential benefits of reducing the risks of HIV transmission to the infants, as necessary precautions can be taken during pregnancy, delivery and breastfeeding (UNAIDS, 2006).

The national PMTCT guidelines indicate that provision of information is an essential component of HIV counselling in ANC (NASCOP, 2002; NACC, 2012). In case of HIV–positive mothers, the information given includes the available MTCT interventions such as ARVs, safer obstetrical practices and safer sexual practices among other factors. Comprehensive knowledge of HIV and AIDS has improved since 2003, and knowledge was highest among persons with more years of education and among urban residents (KAIS, 2007). This was found to be consistent with the MOH (Kenya) requirement that
mothers visiting ANC whether HIV-positive or not, be given information on HIV transmission and ways of prevention (NASCOP, 2003). Knowledge about HIV, PMTCT and ARVs are considered critical for reducing the risk of HIV acquisition and transmission. In the current study, knowledge on types of ARVs and where to obtain ARVs is below average, at 21.0% and 36.0% respectively. This can be traced in the fact that a majority of the people in the society still associates HIV/AIDS with sex which is a taboo in most Kenyan communities (KAIS, 2012). This in turn hinders open and free discussions on use and accessibility of ARVs (Jane, 2008). Intensive national-wide campaigns on PMTCT with emphasis on different types of ARVs available and where to obtain ARVs should be strengthened if MTCT of HIV is to be eradicated.

Respondent’s knowledge on HIV, ARVs and PMTCT was to a greater extent dependent on the respondent’s level of education. Respondents who had good knowledge had at least secondary education, thus literacy is still a vital tool in response to HIV/AIDS scourge in general and mother to child HIV transmission in particular. The increase in knowledge of HIV, ARVs and PMTCT with level of education can be attributed to the Ministry of Education policy of integration of HIV/AIDS and sex education in primary and secondary curriculum (GOK, 2004).

5.1.2 Respondents CD4 count and MTCT of HIV

The most significant immunological factor in diagnosis and management of HIV/AIDS patients’ is CD4 cell count. A HIV/AIDS patient’s CD4 cell count serves as an indicator
of the progression of the disease in the body, a pointer as to when to start ARV therapy in addition to indicating the level of susceptibility to infection by opportunistic diseases (Rashid et al., 2010). The results show that there was significant increase in mean CD4 cell count from the time of initiation of ARVs (baseline), to the time of delivery in the majority of the age distribution, apart from the respondents who were 43 years and above. A CD4+ T cell absolute number of an HIV-infected patient is an immunological factor most closely associated with HIV-disease progression and is recommended for patients’ prognosis. The observed higher mean values of CD4+ T cells in the HIV-infected ARV treated pregnant mothers may be associated with the suppression of viral replication and may also be a marker of improved immunity. This reflects not only inhibition of HIV-dependent CD4+ T cell killing but also a lack of HIV-related antigenic stimuli that drives CD8 and CD28 + T cells in the blood and thus determining the decrease in CD4+ T cells number (Eric et al., 2004).

Anti-retroviral drugs (ARVs) increases helper T-lymphocytes numbers and improves the survival rates and quality of life of people living with HIV by suppressing viral replication thus lowering the rate of viral replication. In PMTCT, reduction of viral load in the mother lowers the chance of perinatal transmission of HIV (Hames, 2001). The benefits of ARVs therapy include a reduction of MTCT of HIV, reduction of the cost of caring for HIV-positive infants by the health care systems and family structure and reduction of the viral load in the mother that prolongs the onset of AIDS. This, in a Kenyan family set-up, will translate into increased availability of finances for other
sectors such as education, food, better housing and other social amenities, thus general improvement in the living standards of the families infected or affected by HIV.

Combination anti-retroviral therapy (standard triple combination anti-retroviral therapy, usually consisting of two nucleoside reverse transcriptase inhibitors and non-nucleoside reverse transcriptase inhibitor or a protease inhibitor) has been shown to have superior effectiveness in controlling viral replication thus increasing CD4 cell count and in limiting the emergence of resistant viruses (Yerly et al., 2002). The present study reveals a highly significant statistical relationship between ARVs use and CD4 cell count. Therefore, although there are special considerations in using anti retroviral drugs during pregnancy, the basic principal should be that all HIV-positive pregnant mothers should be started on ARVs therapies of known benefits to the mother and her baby, as early as possible unless there are any known adverse effects on the mother, fetus or the infant that outweighs the potential benefits of ARVs irrespective of CD4 cell count of the mother.

Besides, a recent study on PMTCT has shown that use of CD4 cell count criterion is superior to clinical staging in identifying pregnant and postpartum HIV-positive mothers eligible for ART (Rashid et al., 2010). This means that improving access to CD4 cell count testing is essential in identifying HIV-positive women during pregnancy who are eligible for initiation of ART for their own health, to reduce maternal morbidity and mortality while preventing mother to child HIV transmission and improving child survival. More importantly, most pregnant women identified as HIV-positive in PMTCT programme are generally less likely to have advanced HIV-disease, and clinical staging
without CD4 cell count testing may not be sufficiently sensitive to be used solely to determine ART eligibility (Rashid et al., 2010).

Up-scaling access to CD4 cell count testing and ARVs in all public and private ANC clinics where PMTCT programs are integrated is an essential component in successful prevention of mother to child transmission of HIV. This study has also revealed that ARVs started early in pregnancy have greater immunological benefits than when started later in pregnancy. A similar study carried out in S. Africa indicated that maternal CD4 cell count and gestational age were significant predictors of intrapartum transmission probability, while maternal CD4 count and haemoglobin were significant predictors of postpartum transmission probability (Justin et al., 2008). This present study is in consistent with similar studies carried elsewhere, thus all HIV-positive pregnant mothers should be started on ARVs as early as possible to increase the effectiveness of ARVs in PMTCT.

Mothers who transmitted the HIV virus to their infants had high viral loads and low CD4 counts as compared to mothers who did not transmit the virus to their infants. Low CD4 cell count is an indicator of a compromised body immune system, including the immunological barrier in the uterus thus increasing the chances of perinatal MTCT of HIV. The high viral load, despite use of ARVs may be attributed to development of resistant HIV viral strains in some or all of the mothers who transmitted the HIV virus to their infants. This may have led to rapid replication of the resistant strain and further increasing the chances of perinatal MTCT of HIV.
A similar study carried out in Zambia showed that low CD4 cell count and a high viral load at enrolment were associated with MTCT of HIV (Kilewo et al., 2008). Thus, the results of the present study are consistent with similar studies carried out elsewhere and thus highly recommend close monitoring of CD4 count of HIV - positive pregnant mothers through repeated CD4 cell count testing in all ANC clinics in the country. The estimated proportion of HIV-1 infected infants was 2.8% at 6 weeks after delivery. In a similar study carried out to investigate the possibility of reducing MTCT of HIV, the cumulative proportion of HIV-1 infected infants was 3.8% at week six after delivery (Kilewo et al, 2008). The difference in rates of transmission could be due to studies carried out at different times. It could also due to intensified educational campaigns on PMTC in the recent past by the government and other stakeholders coupled with intensive follow – up employed through KNH antenatal clinic in the current study. This has led to strict adherence and consequently the low transmission rates recorded.

The rate of MTCT of HIV-1 in this study at 6 weeks after delivery is among the lowest reported in Kenya. Although the results are limited by the single arm study design, they support that giving HIV positive mothers triple ARVs regimen from early pregnancy to six weeks after delivery with exclusive breastfeeding is safe and a feasible way to reduce PMTCT in resource – limited settings. Thus, efficacious ARV regimens should be implemented in all resource-limited settings and are highly effective in controlling MTCT of HIV.

5.2 Conclusion

(i) Majority of the HIV positive pregnant mothers were married.
(ii) Literacy greatly influences the level of knowledge of HIV/AIDS, ARVs and PMTCT of HIV.

(iii) Accessibility and availability of ARVs is still a greater barrier in the fight against HIV/AIDS scourge in general and PMTCT in particular.

(iv) Treating HIV – positive pregnant mothers with ARVs greatly boosts their CD4 cell count and consequently reduces the chance of MTCT of HIV.

(v) Treatment of HIV – positive pregnant mothers with ARVs as early as five months gestation results to greater immunological benefits than later intervention.

(vi) The higher the CD4 cell count of HIV positive pregnant mother, the more the immunological benefits of use of ARVs.

(vii) Introduction of ARVs to HIV- positive pregnant mothers with very low CD4 cell count (< 150 cells/ ml of blood), and high viral load (> 80,000 copies/ml of blood) does not decrease the chances of MTCT of HIV.

5.3 Recommendations

5.3.1 Recommendations from this work

(i) All HIV-positive pregnant mothers should be started on triple-ARV regimen as early as five months gestation to avert chances of MTCT of HIV.

(ii) The ministries of medical services and public health should ensure that all public and private health facilities offering ANC services must have FACS COUNT Machine for CD4 count testing of all pregnant HIV-positive mothers, as CD4 cell count is a more feasible and affordable way of monitoring and predicting the chances of perinatal MTCT of HIV than viral load.
(iii) Free or government subsidized monthly CD4 count testing for all HIV-positive pregnant mothers should be implemented in all ANC and PNC, to monitor their CD4 cell count and mitigate timely and appropriate precaution for PMTCT.

(iv) The government and other stakeholders should step-up the availability of free ARVs in all medical facilities, HIV/AIDS awareness campaigns and PMTCT programs to further reduce HIV/AIDS stigma and increase use of ARVs by people living with HIV/AIDS.

(v) More studies should be carried out on a larger sample size, and/or in a rural set-up to for comparison.

5.3.2 Recommendations for Further Work

(i) Studies to unearth the immunological mystery behind mothers with very low CD4 cell count but undetectable viral load should be carried out.

(ii) A long-term follow-up of children born to HIV-positive mothers introduced to pre-and postnatal combinational anti-retroviral therapy is highly recommended to establish drug safety to the infants
REFERENCES


APPENDICES

APPENDIX I: Paired t-test tables to test the effect of ARVs treatment on CD4 count

t-Test

(a) Paired Samples Statistics

<table>
<thead>
<tr>
<th>Pair</th>
<th>CD4 count at delivery</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>baseline CD4 count</td>
<td>493.98</td>
<td>112</td>
<td>216.415</td>
<td>20.449</td>
</tr>
<tr>
<td></td>
<td></td>
<td>401.40</td>
<td>112</td>
<td>188.110</td>
<td>17.775</td>
</tr>
</tbody>
</table>

(a) Paired Samples Correlations

<table>
<thead>
<tr>
<th>Pair</th>
<th>CD4 count at delivery &amp; baseline CD4 count</th>
<th>N</th>
<th>Correlation</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>112</td>
<td>0.888</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Highly significant effect of Baseline CD4 count on CD4 count at delivery (P= 0.0001)
(c) Paired Samples Test

<table>
<thead>
<tr>
<th>Pair</th>
<th>Paired Differences</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>95% Confidence Interval of the Difference</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CD4 count at delivery - baseline CD4 count</td>
<td>92.58</td>
<td>99.725</td>
<td>9.423</td>
<td>73.908 - 111.253</td>
<td>9.825</td>
<td>111</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

The ARV treatment significantly increases CD4 cell count ($t_{0.05} = 9.825; \ df = 111; \ P<0.0001$)
APPENDIX II: Chi-Squire test tables for effects of level of education on knowledge of HIV, ARVs and PMTCT of HIV

Chi-Square Test

Frequencies

(a) Level of education

<table>
<thead>
<tr>
<th>Level of education</th>
<th>Observed N</th>
<th>Expected N</th>
<th>Residual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>11</td>
<td>22.2</td>
<td>-11.2</td>
</tr>
<tr>
<td>Secondary</td>
<td>41</td>
<td>22.2</td>
<td>18.8</td>
</tr>
<tr>
<td>College</td>
<td>32</td>
<td>22.2</td>
<td>9.8</td>
</tr>
<tr>
<td>University</td>
<td>5</td>
<td>22.2</td>
<td>-17.2</td>
</tr>
<tr>
<td>Total</td>
<td>89</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b) Test Statistics

<table>
<thead>
<tr>
<th>level of education</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chi-Square</td>
<td>39.135</td>
</tr>
<tr>
<td>Df</td>
<td>3</td>
</tr>
<tr>
<td>Asymp. Sig. (P)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Level of education had significant effect on knowledge on PMTCT ($\chi^2_{0.05} = 39.135; \text{df} = 3; P < 0.001$)
**APPENDIX III: Respondents percentage Knowledge of ARVs with Locality**

<table>
<thead>
<tr>
<th>Village/estate</th>
<th>Number of participants</th>
<th>Knowledge on where to get ARV</th>
<th>% Knowledge rating among participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Athi river</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dandora</td>
<td>3</td>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>Eastleigh</td>
<td>5</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Embakasi</td>
<td>1</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Githurai</td>
<td>7</td>
<td>2</td>
<td>29</td>
</tr>
<tr>
<td>Huruma</td>
<td>1</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Industrial area</td>
<td>1</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Jericho</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Juja</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kahawa</td>
<td>2</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Kahawa west</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kangemi</td>
<td>5</td>
<td>3</td>
<td>60</td>
</tr>
<tr>
<td>Kariobangi</td>
<td>1</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Kasarani</td>
<td>8</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>Kawangware</td>
<td>6</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>Kayole</td>
<td>7</td>
<td>4</td>
<td>57</td>
</tr>
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<td>1</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Kenyatta</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kibera</td>
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<tr>
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<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Komarock</td>
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</tr>
<tr>
<td>Makadara</td>
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</tr>
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</tr>
<tr>
<td>Ruai</td>
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<td>100</td>
</tr>
<tr>
<td>Village/estate</td>
<td>Number of participants</td>
<td>Knowledge on where to get ARV</td>
<td>% Knowledge rating among participants</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------</td>
</tr>
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<td>Athi river</td>
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</tr>
<tr>
<td>Industrial area</td>
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<td>100</td>
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<tr>
<td>Huruma</td>
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<td>Estate/ Village</td>
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<td>Knowledge on where to get AVR</td>
<td>% knowledge rating among participants</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------</td>
<td>--------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
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<tr>
<td>Tassia Embakasi</td>
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<td>1</td>
<td>100</td>
</tr>
</tbody>
</table>

Note: Could be biased due to low participation rates from some villages/estates, Needs further study (Knowledge gap)
APPENDIX IV: QUESTIONNAIRE

Kindly respond to the questions below if you have agreed to participate in this study.

Instructions:

i. Do not write your name on this questionnaire.

ii. All information you give will be treated with utmost confidence.

iii. Where there are brackets ( ), put a tick ( √ ) where appropriate.

iv. Give a short answer or a tick where necessary.

1. Name of your village / estate ________________________________ .

2. Division ________________________________ .

3. Age in years ________________________________ .

4. Level of education: Primary ( ), Secondary ( ), College ( ), University ( ), Non ( )

5. Marital status: Single ( ), Married ( ), Window ( ), Separated ( ).

6. Occupation: Casual ( ), Permanent ( ), Not employed ( ).

7. Gestation age in months.__________________________ .

8. Is this your first time to attend antenatal clinic (ANC) for this pregnancy? Yes ( ), No ( ).


10. Are you willing to undergo a HIV test? Yes ( ), No ( ).

11. Are you ready for whatever outcome of the results? Yes ( ), No ( ).

12. Do you know that a HIV positive pregnant mother can transmit HIV to her child during pregnancy, during birth and through breast feeding after birth? Yes ( ) No ( )
13. It is advisable to start ART if the results are HIV+, after diagnostic testing. Would you accept this? Yes ( ), No ( ).

14. Have you heard of anti retroviral (ARV) drugs? Yes ( ), No ( ).

15. Do you know of any ARV drugs that are in use? Yes ( ), No ( ).

16 Do you know where to get ARV if you need to use them? Yes ( ), No ( ).

17. What are the benefits of ARVs? Tick against one /more of the options.

   a) Curing HIV/AIDS
   b) Reducing pain.
   c) Reducing progression of HIV
   d) Prevention of mother to child HIV transmission.
   e) I do not know.

For official use only

Patient no ________________.

Interviewed by ________________.
APPENDIX V: CONSENT FORM

Title: Determination of CD4 Cell Counts of Pregnant Women in relation to Mother to Child HIV Transmission in Nairobi.

Participation: Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefit to which you are otherwise entitled to. You may discontinue in any time unconditionally though you are highly encouraged not to for purposes of precision and relevance of the data collected. The principal investigator may decide to withdraw you from the study if we are unable to obtain the required minimum number (2) of blood samples from you.

Purpose: The study will seek to establish how maternal CD4 cell count of HIV+ pregnant women is influenced by antiretroviral medication and if this determines if the mother will transmit HIV (through the placenta) to the unborn child. Your blood will be tested for HIV/AIDS while the CD4 cell count will be monitored in 3 phases between the 6th month of pregnancy and at child birth. This information is important in the illustration of maternal CD4 cell count trends as an indicator of placental HIV MTCT. It will also reveal a case proportion of the pregnant women population who are infected with HIV/AIDS.

Sample collection: If you agree to participate, we will ask you questions on where you come from, your age, marital status, your occupation and readiness to take the HIV test. Replicates of 5ml blood samples will be drawn employing standard sterile techniques from a suitable arm location and taken to KEMRI laboratories for investigations stated above.
Benefits: You will know your HIV status (if you do not already know it) besides receiving counseling and education on HIV/AIDS management. You will also be advised accordingly concerning ART whereas the results of your CD4 cell count will be at your disposal if you wish to have them. The CD4 cell count parameter is important in assessing your health status and in this study, the progression of HIV to AIDS. This should lead to a facilitated health care approach since it will influence health care policy for the infected pregnant women population.

Risks: The risk from participation in this study is minimal. There is possibility of mild discomfort, bruising and very rarely infection at the site where blood is drawn. The nurses employ utmost care to minimize any pain or trauma during the exercise. If the area becomes infected, you will be in the right hands of medics to be treated by them as you attend your ANC. Further we guarantee you that your blood samples will not be used for any other purpose other than for this study.

Compensation: There is no compensation to volunteers since this exercise will not violate your welfare in any way.

Duration of participation: Once you have completed the questionnaire at the introductory stage of this study, blood samples will be obtained from you between your 6th and 9th months of gestation as well as from your infant at birth.

Confidentiality: Records relating to your participation in the study will remain confidential. Your name will not be used in any report resulting from this study. All computerized records and results will have no names of the source individuals but will be given codes for identification not your name. All the results of the tests performed will be
recorded using the study number only. You will receive a signed copy of this consent form. In

case of any queries contact-

1. JANE KAREGI – 0714704901/0733578119

2. Dr. J. Ong’ech
   Kenyatta National Hospital
   Head of Department
   Obstetric and Gynaecology
   Tel-2726009
   2725272
APPENDIX VI: ASSENT FORM

I ____________________________ (Name), of age _____ do hereby assent to participate in this research study that will lead to a better understanding and appropriate management of placental HIV/AIDS MTCT. The study above has been explained to me and that I am free to direct any questions concerning the study now or in future to the concerned officers. I understand that I am being asked to volunteer to participate and that I agree to be interviewed, also I understand that sample collection is a harmless process to be conducted by qualified personnel. I may withdraw or stop my participation in the study without victimization of any sort.

Subject name: ____________________________

Subject signature: ________________.

Date: __________

Study number: __________

In-charge/guardian/witness name: ____________________________

Witness signature: ____________________________

Date: __________

APPENDIX VII: ETHICAL CLEARANCE LETTER
APPENDIX VIII: DATA COLLECTION AUTHORIZATION FORM

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd.
P.O. Box 20723, Nairobi.
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP*, Nairobi.
Email: KNHplan@KenHealthnet.org
25th November 2010

Ref: KNH-ERC/ A/641

Jane Karegi Kinyua
ADM No.156/12271/09
School of Pure and Applied Sciences
Kenyatta University

Dear Jane

Research proposal: “Prevalence, Association of Antiretroviral Therapy Dependent CD4 Cell counts of HIV-positive mothers and Mother-To-Child HIV Transmission in Kenyatta National Hospital” (P228/07/2010)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and approved your above revised research proposal for the period 25th November 2010 - 24th November 2011.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On behalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH/UON-ERC

C.c. The Deputy Director CS, KNH
The HOD, Records, KNH
Supervisors:  Dr. Micheal M. Gichuru, Dept.of Zoological Sciences, Kenyatta University
Dr. Alex Wamachi, KEMRI
Dr. Dalton C. Wamalwa, Dept.of Paediatrics & Child Health, UON
RE: KNH/OBS/GYN/RESEARCH/16

To

Jane Karegi Kinyua
Kenyatta University
School of Pure & Applied Science

Date: 27th January, 2011

RE: APPLICATION FOR PERMISSION TO OPERATEIZE DATA COLLECTION AT KNH

This is in reference to your application dated 11th January, 2011 on the above subject matter. The permission has been granted.

Kindly liaise with ACN Obs/Gyn to facilitate your work. You are also instructed that you must ensure all results are returned to the patients file in a timely manner.

The department expects copies of the progress report on your study. You will also be expected to disseminate the final results of your study to the department.

Dr. J. Ong‘eich
HEAD OF DEPARTMENT
OBSTETRIC & GYNAECOLOGY

CC: ACN – Obs/Gyn