PREGNANCY OUTCOMES AMONG SEROPOSITIVE AND SERONEGATIVE MOTHERS AT PUMWANI MATERNITY HOSPITAL, NAIROBI COUNTY

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DECLARATION

I declare that this research report is my original work and has not been presented for a degree in any other University or for any other award.

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DEDICATION

This work is dedicated to my dear husband David our children Mary, Ian and Daniel who tirelessly and willingly provided me with support and encouragement to accomplish this project.

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I wish to thank The Almighty God for enabling me to do this study. I also wish to appreciate my supervisors Dr. Oyieke and Dr. Wakasiaka for their commitment, guidance and support. Their sound guidance facilitated completion of this work. I am also grateful to Ms. Inyama for her invaluable contribution and support whenever I consulted her.

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LIST OF ABBREVIATIONS

AIDS……Acquired Immunodeficiency Syndrome

ANC……Antenatal Clinic

ART……..Antiretroviral Therapy

CBD……Central business District

CCC……Comprehensive Care Clinic

CDC……Centre For Disease Control and Prevention

HAART……..Highly Active Antiretroviral Therapy

HIV……..Human Immunodeficiency Virus

IUGR……Intrauterine Growth Retardation

KAIS REPORT……..Kenya AIDS Indicator Survey Report

KHDS……Kenya Health Demographic survey

KNH……Kenyatta National Hospital

MDG……...Millennium Development Goals

MMR……...Maternal Mortality Rate

NASCOP……National AIDS and STI Control Programme

NBU……New Born Unit

PMH……Pumwani Maternity Hospital

PMTCT……Prevention of Mother to Child Transmission of HIV

WHO……World Health Organization

VCT…….Voluntary Counseling and Testing

OPERATIONAL DEFINITIONS

Abortion/Miscarriage: Intrauterine death of a fetus before 20 weeks of pregnancy.

Ante-partum Haemorrhage (APH) is defined as bleeding from or in to the genital tract, occurring from 24+0 weeks of pregnancy and prior to the birth of the baby.

APGAR Score: (**A**ppearance, **P**ulse, **G**rimace, **A**ctivity, **R**espiration). The Apgar scale is determined by evaluating the newborn baby on five simple criteria on a scale from zero to two, then summing up the five values thus obtained. The resulting Apgar score ranges from 0 to 10.

Disseminated Intravascular Coagulopathy is a condition in which small blood clots develop throughout the bloodstream, blocking small blood vessels. The increased clotting depletes the platelets and clotting factors needed to control bleeding, causing excessive bleeding.

Intra-Uterine Growth Restriction (IUGR) is a fetal weight that is below the 10th percentile for gestational age as determined through an ultrasound. This can also be called small-for gestational age (SGA) or fetal growth restriction.

Low Birth Weight: Birth weight of a live born infant of less than 2500g regardless of gestational age.

Maternal Death ; death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental

Maternal exhaustion is inadequate progress of labour due to poor uterine action in the first stage and poor maternal effort in bearing down during the second stage of labour.

Maternal Outcomes: State of health of the mother during and after delivery i.e. presence or absence of complications during and after delivery up to discharge from hospital. The complications include; antepartum haemorrhage, poor maternal effort, post partum-haemorrhage, disseminated intravascular coagulopathy, sepsis, eclampsia, and maternal mortality.

Maternal Sepsis is defined by WHO as "infection of the genital tract occurring at any time between the onset of rupture of membranes or labor and the 42nd day postpartum, in which fever and one or more of the following are present: pelvic pain, abnormal vaginal discharge, abnormal smell/foul odor of discharge and delay in the rate of reduction of the size of the uterus".

Neonatal Mortality: Death of an infant within the first 28 days of life.

Neonatal Outcomes: State of health of the infant during and after delivery i.e. presence or absence of complications during and after delivery. The complications include, low birth weight, neonatal sepsis, prematurity, birth asphyxia, intrauterine growth retardation, neonatal mortality,

Neonatal Sepsis: Bacterial infection in the blood of an infant less than 28 days of age.

Opportunistic Infections: Any infection caused by a microorganism that does not normally cause disease in humans. Occurs in people with abnormally functioning immunity e.g. in people living with HIV.

Post partum haemorhage (PPH) is generally defined as blood loss from the birth canal greater than or equal to 500 ml within 24 hours after birth of the baby**.**

Pre-eclampsia; is a pregnancy complication characterized by high blood pressure of above 140/90 mm/Hg and signs of damage to another organ system, often the kidneys.

Pregnancy Outcomes: State of health of the mother and infant during and after delivery.

Pre Term Delivery: Birth of an infant before 37weeks of pregnancy**.**

Stillbirth: Intrauterine death of a fetus after 20 weeks of pregnancy prior to complete expulsion or extraction.

ABSTRACT

Introduction

Globally HIV/AIDS affects more women than men (WHO, 2013). Kenya has experienced high maternal morbidity and mortality rates with mortality being estimated at 488/100,000. HIV/AIDS is listed among the causes of maternal morbidity and mortality, (WHO, 2013). As a result global and local efforts to increase access to HIV care have been intensified. Early initiation and longer duration of antiretroviral therapy among seropositive pregnant women has been shown to improve pregnancy outcomes. (Kendall et al., 2014).There is need to find out the progress made by assessing maternal and fetal outcomes among these mothers.

Main objective: The main objective was therefore to establish pregnancy among seropositive and seronegative mothers at Pumwani Maternity Hospital.

Methodology: A descriptive cross-sectional study design was employed. Data was stored in a password protected computer under safe custody of the principal investigator. Data analysis was done using SPSS version 20.Categorical variables were summarized using frequency tables and continuous variables were summarized using measures of central tendency and dispersions. Bivariate analysis was used to compare characteristics and outcomes between seropositive and seronegative mothers. Data findings were summarized using prose.

Findings: The study showed no statistically significant differences in terms of maternal and fetal outcomes among the seropositive and seronegative mothers. However seropositive mothers are most likely to visit a public health facility than the seronegative mothers. (P-value=0.038)

CHAPTER ONE

1.0 Background information

HIV/AIDS is a major problem in Kenya. According to UNAIDS report- 2013, 1.6 million out of 40 million Kenyans are living with the HIV virus. Out of these 820,000are women aged 15 years and above. There are about 58,000 AIDS related deaths annually in Kenya. According to a sentinel survey done in Kenya in 2010 the prevalence rate among antenatal mothers is 6.2%.

Pregnancy suppresses the immune function in both the HIV infected and HIV uninfected women. This further compounds the immune suppression caused by the HIV virus. This can hasten the disease progression in HIV infected pregnant women (Paal et al., 2007) HIV can also be transmitted to the fetus in the uterus, during delivery or during breastfeeding (Fauci et al., 2008). Transmission to the fetus is related to high viral loads thus need for antiretroviral therapy before or during pregnancy.

Adverse pregnancy outcomes among HIV infected mothers are associated with advanced maternal disease (kim et al., 2012). HIV infection is a predisposing factor to perinatal mortality (Kennedy et al.,2012).

1.1 Problem Statement

Pregnancy outcomes are a major indicator of the progress made towards achieving the millennium development goals (MDGs) 4 and 5 which aim at reducing child mortality by 2/3 and reducing maternal mortality by 3/4 respectively. According to the Kenya demographic health survey done in 2008/2009 maternal mortality in Kenya is about 488/100,000 births in Kenya. This is slightly higher than the international mortality rate of 360/100,000.

HIV/AIDS is one of the causes of indirect obstetric complications. It contributes to maternal and fetal morbidity and mortality with close to 87,000 seropositive mothers giving birth yearly (WHO, 2015). Pregnant seropositive mothers bear a double burden of exposure to both direct obstetric complications and HIV related complications. MDG 4 aims at reducing under five mortality by 2/3. Significant proportions (34%) of under five deaths occur in the neonatal period (WHO, 2012). Babies born to seropositive mothers have an increased likelihood of having low birth weight, low APGAR scores and prematurity. This further exposes them to neonatal morbidity and mortality. With Kenya committed to MDGs efforts are being made to improve both maternal and fetal outcomes through PMTCT programmes.

ART initiation before and during pregnancy promotes the quality of health of both the mother and the infant by reducing morbidity and mortality. With the advent of free maternity health care it is expected that most mothers will be captured early in pregnancy for effective prevention of mother to child transmission of HIV and improvement of maternal and fetal outcomes.

1.2 Research Questions.

1. What are the maternal outcomes among seropositive and seronegative mothers at Pumwani Maternity Hospital?
2. What are the foetal outcomes among seropositive and seronegative mothers at Pumwani Maternity Hospital?

1.3 Broad Objective:

To establish maternal and foetal outcomes among seropositive and seronegative mothers at Pumwani maternal Maternity Hospital.

1.4 Specific Objectives:

1. Describe the socio-demographic characteristics of the study participants.
2. To describe maternal outcomes among seropositive and seronegative mothers at Pumwani Maternity Hospital.
3. Describe foetal outcomes among seropositive and seronegative mothers at Pumwani Maternity Hospital.

1.5 Study Justification

Due to increased efforts by the Kenyan government to scale up antiretroviral therapy, more pregnant mothers are able to access HAART for their health and the health of the baby. Several studies have confirmed increased incidences of adverse pregnancy outcomes among seropositive mothers who are not on ART (Lucas et al., 2010). Pregnancy outcomes have a significant bearing on child survival and maternal well-being. This study aims to find out if these efforts have been successful in lowering the incidences of adverse pregnancy outcomes among the seropositive mothers.

1.6 Study Benefits

The study findings will provide useful information for policy makers and health care providers in planning for the needs of women living with HIV/AIDS. For health care providers the findings will help in counseling of women living with HIV/AIDS to make informed choices about ART uptake.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

There are 35 million people living with HIV/AIDS around the world. Sub-Saharan Africa accounts for 24.7 million people living with HIV/AIDS and 70% of new infections globally. (WHO, 2013). In 2002 there were approximately 2.3 million new infections (WHO, 2012).

The general prevalence of HIV in Kenya is 5.6%. HIV accounts for 106,000 new infections in the general population yearly. Women are disproportionately affected by HIV at (6.9%) than men (4.4%). The HIV prevalence in pregnancy is about 6.5%. However, 46.5% Kenyans are unaware of mother to child transmission of HIV. (KAIS Report, 2012).Women have the highest HIV prevalence at 52%. (WHO, 2013) .Access to treatment by pregnant women living with HIV is about 62%. HIV prevalence among pregnant women aged 15-49 years in Kenya is about 6.5. Sub Saharan maternal mortality rate (MMR) is estimated at 640/100,000. This is slightly higher than the Kenyan MMR which is estimated at 488/100,000. This is way higher than the world MMR which is estimated at 360/100, 000 (KHDS, 2008/2009).

HIV/AIDS in pregnancy is also associated with adverse fetal outcomes which include, prematurity, low birth weight, intrauterine growth retardation, neonatal sepsis, still births, and neonatal mortality. (Kak.L et al., 2005)

Antenatal attendance among pregnant women in Kenya is over 94.8%. However most of the women (90.1%) make their first visit in the third trimester (Kenya AIDS Indicator Survey, 2012). This means that majority of those who are newly diagnosed in pregnancy delay initiation of ART. Seropositive mothers living with HIV/AIDS have a high likelihood of developing both

intra-partum and postpartum complications (Kak et al., 2013). For those mothers who opt for ART initiation, several barriers have been cited as hindering compliance and adherence. They include social stigma, unfavourable work schedules and lack of disclosure. (Colvin et al., 2014)

Studies done to establish the relationship between pregnancy and HIV/AIDS progression in pregnancy have yielded conflicting results. According to Calvert,c and Ronsmans.c, (2014), pregnancy has no effect on HIV/AIDS progression in pregnancy. Another study done in Italy showed that pregnancy does not influence progression of the disease. (Baroncelli et al., 2012).

However a study done by Paal et al, (2007) revealed that HIV positive mothers who become pregnant have a faster disease progression after delivery than during the antenatal period. It is thus safer to become pregnant during the early clinical stage of the disease. This is because the rapid decline in CD4 cell counts after delivery can lead to AIDS and death. HAART is associated with good response when initiation is done during pregnancy as compared to initiation after pregnancy. (Melekhin et al., 2009).Women who are infected with HIV perinatally have poor immunologic indicators durg pregnancy and are at risk of disease progression and death. This is not related to treatment failure but self discontinuation. (Munjal et al., 2013).

2.1 Socio-demographic Characteristics and PMTCT Profiling among Seropositive Pregnant Mothers.

Mother to child transmission of HIV can occur at any stage during pregnancy, labour, delivery, or breastfeeding. Without any intervention vertical transmission of HIV can range from 15-45%. With effective ART, transmission rates can be lowered to below 5 %.(WHO, 2013).The goal of antiretroviral therapy initiation is to promote the quality of health of both the mother and the infant and to reduce morbidity and mortality in these two groups. (WHO, 2013).The benefits of ART in pregnancy have widely been acknowledged in literature and practice. However there are

conflicting reports on whether ART contributes to adverse fetal outcomes. Some studies have demonstrated a relationship between protease inhibitors and preterm deliveries. (Alemu et al., 2015).

Early initiation and longer duration of ART among pregnant women living with HIV has been shown to lower maternal deaths (Kendall et al., 2014). Initiation of HAART early in pregnancy reduces the probability of adverse fetal outcomes which include, prematurity, intrauterine growth restriction (IUGR), and poor apgar score of less than 7.(Onakewhor et al., 2011). However Use of HAART before conception is associated with preterm deliveries and low birth weight babies (Machado et al, 2009). Women who get pregnant after initiation of antiretroviral therapy have a higher risk of virologic failure i.e. failure to suppress the HIV virus to less than 400 copies per ml or virologic rebound. (Weistreich et al., 2012).

Pregnant women should be started on lifelong ART at CD4 $\leq$ 350cells/mm^3 irrespective of the WHO staging and gestational age. (Sturt et al., 2010). HIV/AIDS is associated with weight loss which may impact on the fetal outcomes i.e. small for gestation babies and preterm deliveries. When started on treatment, this group may have improved nutritional status which may contribute to better fetal outcomes. (Young et al., 2012). Male involvement in antenatal care contributes to initiation and retention of ART. (Kendall et al., 2014). Pregnant women residing in rural areas have low rates of ART uptake as compared to their urban counterparts (Hogson et al., 2014).

Adolescent pregnant mothers living with HIV who receive antiretroviral therapy are fewer than those who attend antenatal clinic. There is also low utilization of skilled birth attendants and postnatal/post -abortion care for the pregnancies that end up in miscarriages abortions or

stillbirths. This further exposes them to morbidity and mortality. (Birungiet al., 2011). Young women are less likely to start or adhere to ART, while older ones are most likely to start and adhere to treatment. Women with higher education levels and good knowledge on PMTCT were shown to have higher rates of ART uptake and adherence. (Hogson et al., 2014).Several factors have been cited as hindering uptake of ART among seropositive mothers in the reproductive age bracket. Lack of HIV disclosure leads to poor uptake of HAART and adherence to PMTCT practices. Religion also influences PMTCT practices in that some women opt for prayers while others opt for alternative medicine leading to suboptimal adherence, interruption and lack of uptake of ART. Barriers that hinder seropositive mothers from initiating HAART for PMTCT and for their own health include: ignorance about the benefits of ART, psychological factors (such as shock, denial, fear of treatment side effects), lack of symptoms, lack of financial resources and stigma, especially lack of disclosure, and absence of partner and family support (Ferguson, Grant et al. 2012, Turan et al., 2008).

Certain personal factors have been cited as barriers to initiation of ART. They include fear of stigma and unfavorable work schedules. (Hogson et al., 2014). Lack of integration of maternal child health services together with HIV/AIDS management lowers the uptake of ART. (Gorman, 2013). Stigma and gender discrimination create barriers to utilization of HIV services and indirectly contributes to poor pregnancy outcomes. Disrespect and abuse among health care workers have been cited as barriers to utilization of health services including initiation and retention of ART by pregnant women living with HIV. Partner violence also reduces chances of ART uptake. (Kendall et al., 2014

2.2 Maternal Outcomes among Seropositive Pregnant Mothers.

There is a high maternal mortality rate among pregnant women living with HIV/AIDS as compared to women who are seronegative.(Van lettow et al.,2012).Use of ART in pregnancy and extended use during the postnatal period has been proven to be of benefit in terms of maternal survival (Marazzi,et al 2012). HAART initiated during pregnancy for PMTCT purposes has a significant impact on prevention of maternal mortality (Liotta, G. et al., 2013).Opportunistic infections are the major cause of maternal mortality in these mothers. A study done by Desai et al., 2013 in western Kenya found out that among indirect obstetric deaths, 45% were ascribed to HIV/AIDS, 13% to malaria, and 10% to TB.

Seropositive pregnant mothers are also predisposed to anemia, which is another cause of maternal mortality (Onakewhor et al., 2011).Advanced maternal HIV disease predisposes seropositive pregnant mothers to morbidity, maternal mortality and mother to child transmission of HIV. (Uzoma et al., 2015)“ The most common underlying causes of death in HIV-positive women are tuberculosis, pneumonia, PCP and meningitis, and the iMMR for each of these conditions is higher than those for HIV-negative women. These figures suggest that measures against such co-morbid disease conditions must be strengthened so that they are detected early and treated timeously."(chweneyagae et al, 2012). An interpregnancy interval of 18-59 months is associated with a low probability of adverse fetal and maternal outcomes (Onubogu.C and Ugochukwu .E., 2013). HIVrelated anaemia and tuberculosis may be aggravated by pregnancy (Munjal et al., 2013). HIV/AIDS increases the prevalence and incidence of anaemia in pregnancy. (waweru et al., 2009).

Pregnant women living with HIV/AIDS are susceptible to puerperal sepsis and post surgical complications due to alteration in the patient’s immune system. Opportunistic infections in

HIV/AIDS e.g. pneumocysticjiroveci, tuberculosis etc can also complicate the pregnancy and cause death. (Lucas et al., 2010). HIV/AIDS is associated with anaemia and PPH and increases the client's susceptibility to infections which can result in death. (Ezechi et al., 2012).The patients who are not tested during pregnancy have a higher risk of maternal morbidity and mortality. (Deon et al., 2014).There are no significant differences in prevalence of preeclampsia in both seropositive and seronegative pregnant mothers. However seropositive pregnant mothers tend to have an increased risk to elevated liver enzymes and thrombocytopaenia. (Boyajian et al., 2012)

A Meta-analysis done by Gorman, 2013 noted a relationship between HIV infection and maternal mortality.25% of maternal deaths in the sub Saharan region are as a result of HIV related complications. Pregnant women living with HIV mostly die of non-pregnancy related conditions e.g. pneumonia, sepsis etc. Onubogu and Ugochukwu (2013) found out that short inter-pregnancy intervals were associated with adverse pregnancy outcomes among seropositive pregnant mothers. They findings necessitate the need for good contraception practices among these mothers.

2.3 Fetal Outcomes among Seropositive Pregnant Mothers.

HAART during pregnancy is associated with undisputable health benefits for the infant i.e. drastically lowering the risk of HIV transmission during pregnancy, labor and delivery, and breastfeeding from about 45% to 5 %.(Volmink et al., 2007) . HAART improves pregnancy outcomes including reduction in prematurity, irrespective of the CD4 levels and is also associated with successful PMTCT and protection against adverse pregnancy outcomes. (Marazzi M.C et al.,2009)

Use of HAART is associated with adverse pregnancy outcomes i.e. preterm deliveries, small for gestation deliveries, still births andlow birth weight babies. This could be linked to HAART or HIV itself (Boyajian et al., 2012, Chen et al, 2012,). High rates of perinatal mortality and neonatal encephalopathy have been reported in seropositive mothers as compared to the seronegative mothers. The common causes of mortality include; infection, intrauterine growth retardation and antepartum hemorrhage (APH). Naniche et al.,(2009) noted no difference in adverse fetal outcomes among both seropositive and seronegative mothers.

Viral infections are associated with preterm labour and congenital malformations of the central nervous system and cardiovascular system. (Mor and Cardenas, 2010)There is increased risk of mother to child transmission of HIV with non-use of antiretroviral therapy. Use of ART lowers mother to child transmission of HIV by 68%.However elective caesarian section is associated with prematurity and low birth weight. (Barralet al., 2004).Several factors have been associated with adverse fetal and infant outcomes.CD4 cell counts of less than 350/$mm^3$are predisposing factors to miscarriage, low birth weight and early neonatal mortality. Still births are highly associated with viral loads of more than 50,000/ml and symptomatic disease.

Neonatal mortality is associated with prematurity, low birth weights, poor APGAR scores and caesarian sections. Advanced maternal HIV disease is a predisposing factor to pregnancy loss and perinatal mortality, HIV transmission, low birth weight and prematurity. (Kim et al.,2012).A study done by Zack et al,(2014), showed that HIV stage $\geq$ 2 disease, low weight gain during pregnancy, maternal age $\leq$ 20years and illiteracy were associated with premature births. Nutritional status of pregnant women living with HIV has a bearing on the fetal outcomes. Gaining less than 0.1kg/week is associated with adverse fetal outcomes which include intrauterine growth restriction, low birth weight and preterm deliveries

2.4 Key Variables:

Independent Variables;

- Demographic factors; age, residence, level of education, marital status, occupation.
- Social factors; family support
- Service provider factors; counselling

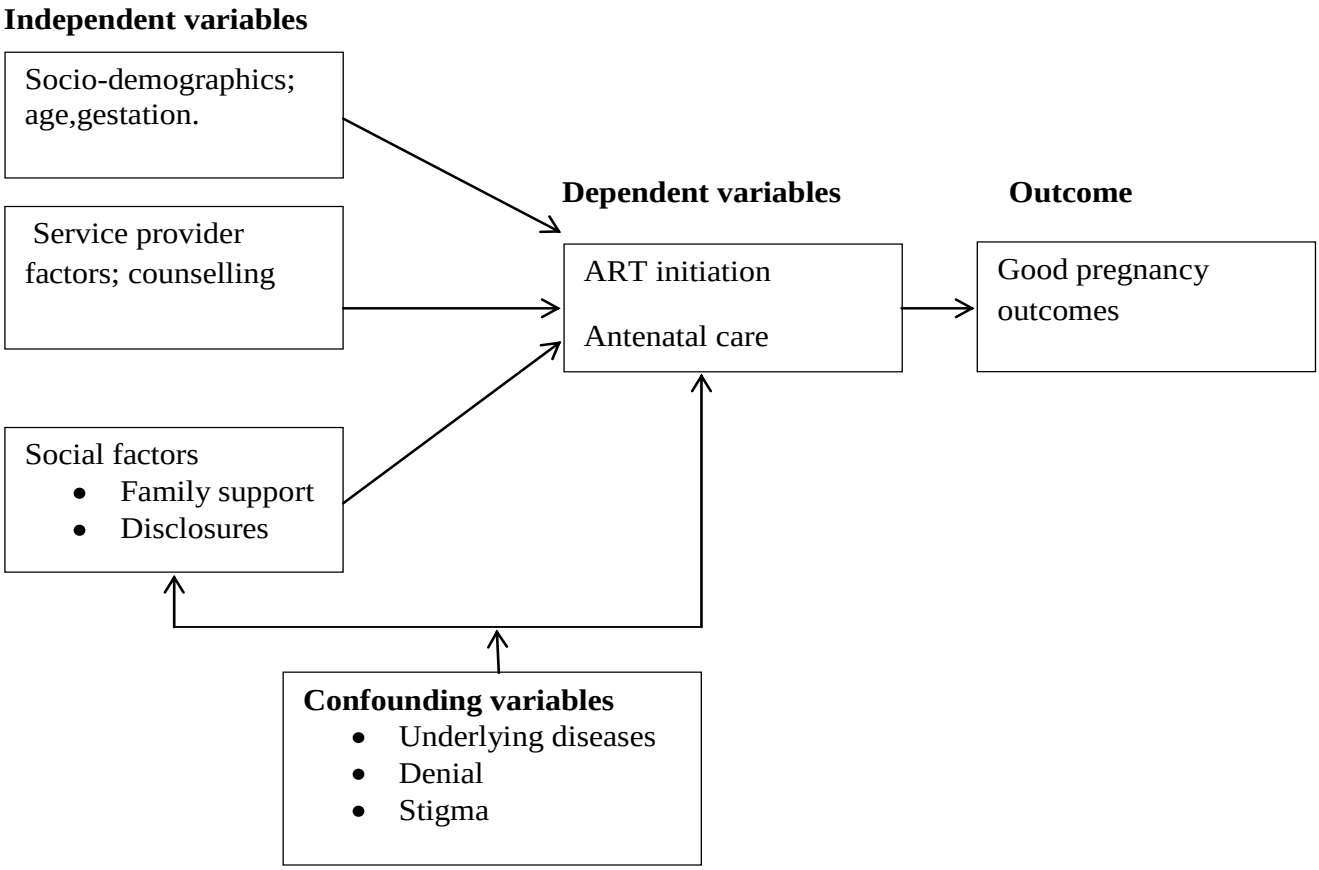
Dependent variables;

- Antenatal care
- ART initiation

Outcomes

- Good maternal and fetal outcomes.
- Adverse fetal outcomes include; small for gestation deliveries, preterm babies, poor APGAR scores, fetal distress, asphyxia, neonatal sepsis, still births, neonatal death.
- Adverse maternal outcomes include; antepartum haemorrhage, postpartum haemorrhage, maternal sepsis, eclampsia, poor maternal effort, maternal death.

2.5 Conceptual framework



CHAPTER THREE

METHODOLOGY

3.0 Study Design:

A descriptive cross-sectional study design was used to describe maternal and foetal outcomes among pregnant mothers at Pumwani Maternity Hospital from July 2015 to September 2015.

3.1 Study Area:

The study area was the maternity unit at Pumwani Maternity Hospital. It is located within Nairobi County in kamukunji constituency, approximately 5 kilometers from the Central Business District (CBD) of the capital city of Nairobi. It is the largest referral maternity hospital in Kenya. It has capacity of 350 beds. The facility handles between 80-100 deliveries per day. Out of these around 8 are seropositive.

It has an antenatal clinic where close to 60 mothers are seen on a daily basis. It has a labour ward with a capacity of 60 beds. It has 3 postsurgical post natal wards with a capacity of 80 beds. There is one mixed ward where antenatal mothers and postnatal mothers who deliver via SVD and their babies are in NBU are admitted. It has 2 Maternity theaters, and a new born unit with a bed capacity of 144 cots.

Other services offered within the facility include antiretroviral therapy, HIV counselling and testing and family planning services, child welfare services and adolescent health care. There is a school of Nursing and midwifery. The hospital runs a PMTCT project in conjunction with the University Of Nairobi and University Of Maryland. The University of Manitoba runs the comprehensive care centre (CCC) which serves clients from within and without the capital city of Nairobi. HIV counseling and testing is done to all women seeking services at the hospital. On average mothers whose deliveries are uneventful stay in the hospital for 24 hours.

The hospital has a total of 187 nurses. All seropositive pregnant mothers who test positive for HIV are usually recruited in option B+ where they are commenced on lifelong HAART irrespective of the CD4 counts and clinical staging. Viral loads are usually done between 34-36 weeks gestation for all the seropositive mothers.CD4 profiling is usually done after every 6 months. Babies born of seropositive mothers are usually commenced on nevirapine for six weeks coupled with exclusive breastfeeding. Mixed feeding is discouraged. PCR testing is usually done for the children at 6 weeks, 6 months, 9 months, and 18 months respectively. After delivery, the mothers are usually followed up at the clinic of their preference.

3.2 Study Population:

All Pregnant women admitted for delivery at Pumwani Maternity Hospital.

3.3.1 Inclusion Criteria:

- Seropositive and seronegative pregnant women admitted for delivery at Pumwani Maternity Hospital.
- Pregnant mothers aged 15-49years.
- Willing and consenting mothers.

3.3.2 Exclusion Criteria:

- Pregnant mothers admitted for other management other than delivery.
- Women in coma or with severe complications.
- Pregnant mothers aged below 15 years and above 49 years.
- Non-consenting pregnant mothers.

3.4 Sample Size Determination

The Cochrane (1986) formula for comparing proportions was used for calculation of sample size. A study done by Musana et al (2009) revealed that on average the proportion of seropositive women who were hospitalized for more than a week at Kenyatta National Hospital was 44% as compared to seronegative group at 27%. This estimation was used to calculate the sample size since Kenyatta National Hospital is comparable to Pumwani maternity Hospital since as they are all referral facilities located within Nairobi county.

$$n = \frac{Z_{\frac{\alpha}{2}} + Z_{\beta}\ ^{2} P_1\ 1 - P_1\ P_2\ 1 - P_2}{P_1 - P_2\ ^{2}}$$

Where

$Z_{\frac{\alpha}{2}}$ = 1.96 which is the critical value for 95% confidence interval.

Z_{β}=0.84 which is the critical value for 80% power.

P_1=estimated proportion of seropositive mothers delayed for more than 3 days.

P_2=estimated proportion of seronegative women delayed for more than 3 days

$$n = \frac{1.96 + 0.86\ ^{2} 0.44\ 1 - 0.44\ 0.27\ 1 - 0.27}{0.44 - 0.27\ ^{2}}$$

=120 mothers per group

Total clients for the two groups will be 240 clients.

120 seropositive and 120 seronegative pregnant women.

3.5 Sampling technique/method

Purposive sampling method was used to select mothers from labour ward at Pumwani Maternity Hospital where every mother who met the selection criteria was included in the study after consenting.

3.6 Recruitment and Consenting Procedures;

Clients were recruited at the Pumwani maternity Hospital labour ward as they came in for delivery. Upon referral to labour ward they were introduced to the study. Study information was explained to the clients. Clients were allowed to ask questions for clarification. The consent was obtained from the respondents by the researcher or research assistant. Participation in the study was voluntary.

3.7Data Collection Tool

Data was collected using a standardized questionnaire. The information was cross checked with the antenatal card and the patient file for validation.

Questionnaires were checked for accuracy and completeness.

3.8 Research Assistants

Two research assistant were selected from among Pumwani Maternity hospital nurses. The research assistants were trained on how to collect information using questionnaires, importance of maintaining integrity and adherence to ethical principles.

3.9 Pre-Testing of Study Instruments

Pretesting of study tools was done at Kenyatta National Hospital. 24 questionnaires were administered to seropositive mothers in labour ward. Some questions were clarified after the pretest. The findings of the pretest were not included in the study.

3.10 Data Collection Procedures

Upon receiving clearance from Pumwani maternity hospital the researcher introduced self to the labour ward in-charge and postnatal ward in-charges and provided a copy of authentification from KNH-ERC and from Pumwani Research Committee. Mothers were identified as they came in for admission in the admission room. Once a seropositive mother was identified, a seronegative mother matched for age ±5 years and gestation by dates ±4 weeks was identified and interviewed in the admission room. Then the questionnaire was administered to the research participants. Initial information on socio-demographic data for all the study participants was obtained. PMTCT profiling was done for the seropositive women. Study participants were followed up post-natally for three days from admission until discharge whichever came early, to establish maternal and foetal outcomes.

3.11 Data Management;

Data obtained through questionnaires was checked for accuracy and completeness before data entry was done. Data was entered into a password protected Microsoft access data base and the forms stored in a lockable cabinet. The consent forms were not stored together with the questionnaires to maintain anonymity. The questionnaires will be stored for at least ten years before they are destroyed.

3.12 Data Analysis and Presentation

Once entry was complete, entered data was compared with the hard copy forms to ensure accuracy and completeness. SPSS software version 20 was used for data analysis. Once errors and inconsistencies had been resolved exploratory data analysis was conducted where categorical variables were summarized using frequency tables and continuous variables were summarized using measures of central tendency and dispersions e.g. mean median and standard deviation.

Maternal outcomes, neonatal outcomes and duration of hospital stay were described in this manner. Bivariate analysis was used to compare characteristics and outcomes between seropositive and seronegative mothers. Data was summarized using prose text, tables, charts and graphs.

3.13 Ethical Considerations

Ethical approval was obtained from Kenyatta National Hospital/university of Nairobi Ethics and Review Board. The interviews were done in a private room within the unit. The purpose and objectives of the study were explained to the clients. Participation was voluntary without coercion or enticement. Participants gave informed consent to participation. No client was denied service if they chose not to participate in the study. Anonymity of the clients was ensured through coding of questionnaires. Responses had no personal identifiers. Data base systems were password protected. The study findings will be made public for utilization across board.

3.14 Dissemination Plan

The results will be disseminated to the University of Nairobi and Pumwani Maternity Hospital and Kenyatta National Hospital. Further dissemination shall be done through seminar presentations, workshops and conferences. Findings will be published in scientific journals.

3.15 Study Limitations

The findings may not be generalized to the mothers who don't utilize health care facilities since the study was confined to a hospital set up. One site findings may not be replicated in other counties.

CHAPTER FOUR

RESULTS

4.0: Introduction

This chapter reports the findings on progress and outcome of labor among 240 women including 120 HIV infected and 120 HIV negative women delivering in Pumwani Maternity Hospital (PMH) and enrolled in the current study.

4.1.1: Socio-demographic characteristics of the study participants at Pumwani Maternity Hospital

Table 1 summarizes the characteristics of the mothers delivering at PMH. The mean age of the seropositive mothers was 27.7 years (SD 5.8) compared to a mean age of 26.5 years (SD 5.1) among seronegative mothers. Approximately one-third of both seropositive (n = 42, 35%) and seronegative (n = 41, 34.2%) mothers were aged between 25 and 29 years. Most (n = 67, 55.8%) seronegative mothers had secondary level education and 54 (45%) seropositive mothers also reported that they had attained secondary level education. Most mothers reported that they were married (seropositive n = 97 (80.8%) and seronegative n = 100 (80.3%)). Christians accounted for at least 95% of participants in seropositive (n = 117, 97.5%) and seronegative (n = 114, 95%) groups.

Table 1: Socio-demographic characteristics of the study participants at Pumwani Maternity Hospital

	Seropositive n=120	**Seronegative n=120**	**OR (95% CI)**	**P value**
Age (mean ± SD)	**27.7 ± 5.8**	26.5 ± **5.1**	NA	NA
15-19 years	4(3.3)	10(8.3)	1.00	
20-24 years	36(30.0)	32(26.7)	2.81(0.80-9.85)	0.106
25-29 years	42(35.0)	41(34.2)	2.56(0.74-8.82)	0.136
30 years and above	38(31.7)	37(30.8)	2.57(0.74-8.91)	0.138
Level of education				
None	2(1.7)	3(2.5)	1.00	
Primary	45(37.5)	27(22.5)	2.50(0.39-15.93)	0.332
Secondary	54(45.0)	67(55.8)	1.21(0.19-7.50)	0.838
College	19(15.8)	23(19.2)	1.24(0.19-8.20)	0.824
Marital status				
Single	17(14.2)	15(12.5)	1.00	
Married	97(80.8)	100(83.3)	0.86(0.40-1.81)	0.684
Divorced	4(3.3)	1(0.8)	3.53(0.35-35.16)	0.282
Separated	2(1.7)	4(3.3)	0.44(0.07-2.76)	0.382
Occupation				
House wife	52(43.3)	56(46.7)	1.00	
Self employed	46(38.3)	40(33.3)	1.24(0.70-2.18)	0.46
Employed	22(18.3)	24(20.0)	0.99(0.49-1.97)	0.971
Religion				
Christian	117(97.5)	114(95.0)	1.00	
Muslim	2(1.7)	5(4.2)	0.39(0.07-2.05)	0.266
Atheist	1(0.8)	1(0.8)	0.97(0.06-15.77)	0.985

4.1.2: Obstetric and gynecologic history of the study participants at Pumwani Maternity hospital

The attendance of ANC in seropositive mothers was 100% compared to 99.2% in seronegative mothers (Table 2). Most mothers in both seropositive (n = 110, 91.7%) and seronegative (n = 99, 82.5%) group attended ANC clinics in government health facilities. There was a significant association between HIV status and type of facility visited by seropositive women. HIV positive women were 57% less likely to visit private ANC facilities compared to seronegative women (OR = 0.43, 95% CI 0.19-0.95).Among the women attending ANC care 59 (49.2%) in the seropositive group and 61 (50.8%) in the seronegative group made four ANC visits. The mean gestational age (SD) at first ANC visit was 37.6 weeks ± 2.2 in seropositive women compared to 37.3 weeks ± 2.4 in seronegative women. Thirty eight (31.7%) seropositive mothers and 36 (30%) seronegative women had any disease during pregnancy.

Table 2: Obstetric and gynecologic history of the study participants at PMH

	seropositive n=120	**seronegative n=120**	**OR(95% CI)**	**P value**
ANC attendance				
Yes	120(100.0)	119(99.2)	NA	NA
No	0(0.0)	1(0.8)		
Any disease during pregnancy				
Yes	38(31.7)	36(30.0)	1.00	
No	82(68.3)	84(70.0)	0.92(0.53-1.60)	0.78
Type of ANC facility attended				
Government hospital/clinic	110(91.7)	99(82.5)	1.00	
Private clinic/hospital	10(8.3)	21(17.5)	0.43(0.19-0.95)	0.038
Frequency of ANC attendance				
Once	3(2.5)	1(0.8)	1.00	
Twice	13(10.8)	9(7.5)	0.48(0.04-5.40)	0.553
Thrice	21(17.5)	23(19.2)	0.30(0.03-3.16)	0.319
Four times	59(49.2)	61(50.8)	0.32(0.03-3.19)	0.333
Five	15(12.5)	19(15.8)	0.26(0.02-2.79)	0.268
Six times	8(6.7)	7(5.8)	0.38(0.03-4.55)	0.446
Over six times	1(0.8)	0(0.0)	NA	
Gestation at first ANC visit (mean ± SD)	**37.6 ± 2.2**	**37.3 ± 2.4**	**NA**	**NA**
0-12 weeks	58(48.3)	50(41.7)	1.00	
13-28 weeks	50(41.7)	59(49.2)	0.73(0.43-1.25)	0.249
29-40 weeks	12(10.0)	11(9.2)	0.94(0.38-2.32)	0.894

4.1.3: Previous pregnancy losses among study participants

Previous pregnancy losses were not significantly associated with maternal HIV status (OR = 0.73, 95% CI 0.36-1.47; p = 0.373) There were 21 (17.5%) previous pregnancy losses in seropositive mothers compared to 16 (13.3%) pregnancy losses in seronegative mothers (Table 3).

Table 3: pregnancy losses among seropositive and seronegative mothers at PMH

	HIV positive n=120	**HIV negative n=120**	**OR(95% CI)**	**P value**
Previous pregnancy loss				
Yes	21(17.5)	16(13.3)	1.00	
No	99(82.5)	104(86.7)	0.73(0.36-1.47)	0.373

4.1.4: PMTCT profiling of the seropositive mothers

Table 4 shows that maternal testing for HIV was most commonly done before conception of the index pregnancy (n = 45, 37.8%) or within 12 weeks of conception (n = 35, 29.4%). In 67 (55.8%) of the HIV positive women CD4 counts were not done and in 26 (21.7%) mothers the CD4 count was between 350 and 500 cells/mm^3. Most women reported that their initial reaction to a positive HIV diagnosis was shock (n = 44, 36.7%) or acceptance (n = 43, 35.8%).

Table 4: PMTCT profiling of the seropositive mothers at PMH

	Frequency	Percent
First time tested for HIV		
Before pregnancy	45	37.8
0-12 weeks	35	29.4
13-24 weeks	23	19.3
25-36 weeks	3	2.5
Over 36 weeks	13	10.9
CD4 levels at time of testing		
Below 200 cells/mm^3	3	2.5
350-500 cells/mm^3	26	21.7
Above 500 cells/mm^3	24	20
Not done	67	55.8
Reaction to HIV results		
Shock	44	36.7
Anger	6	5
Denial	27	22.5
Acceptance	43	35.8

4.1.5 HIV status disclosure among seropositive women at PMH

The rates of HIV status disclosure in seropositive women attending ANC care in PMH was 69.2% with 89 out of the 120 HIV positive women reporting that they had disclosed their HIV status. (Figure 1)

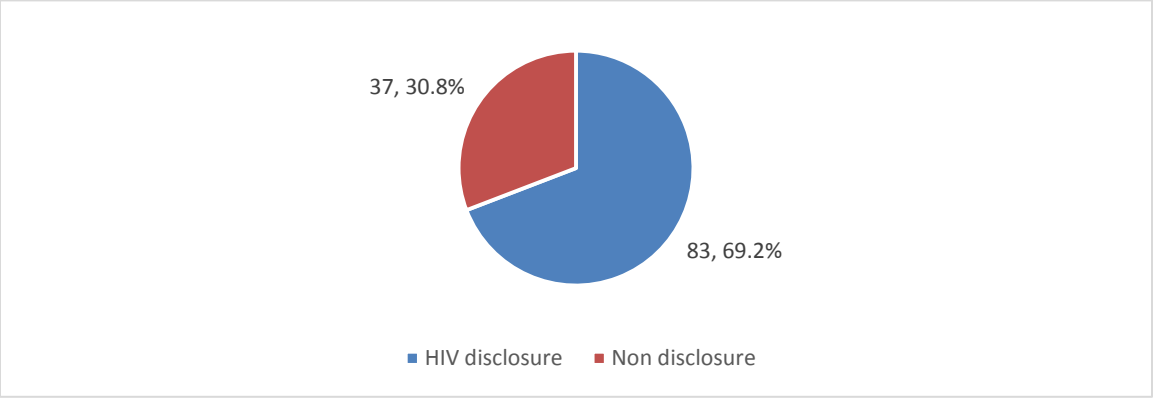


Figure 1: HIV status disclosure among seropositive women at PMH

4.1.6: Timing of ART initiation during pregnancy

ARV therapy had been initiated in 115 (95.8%) of the seropositive women attending ANC in PMH. Figure 2 shows that most women had ART initiated prior to the index pregnancy (n = 37, 32.2%) or during 13-24 weeks after conception of the index pregnancy (n = 36, 31.3%).

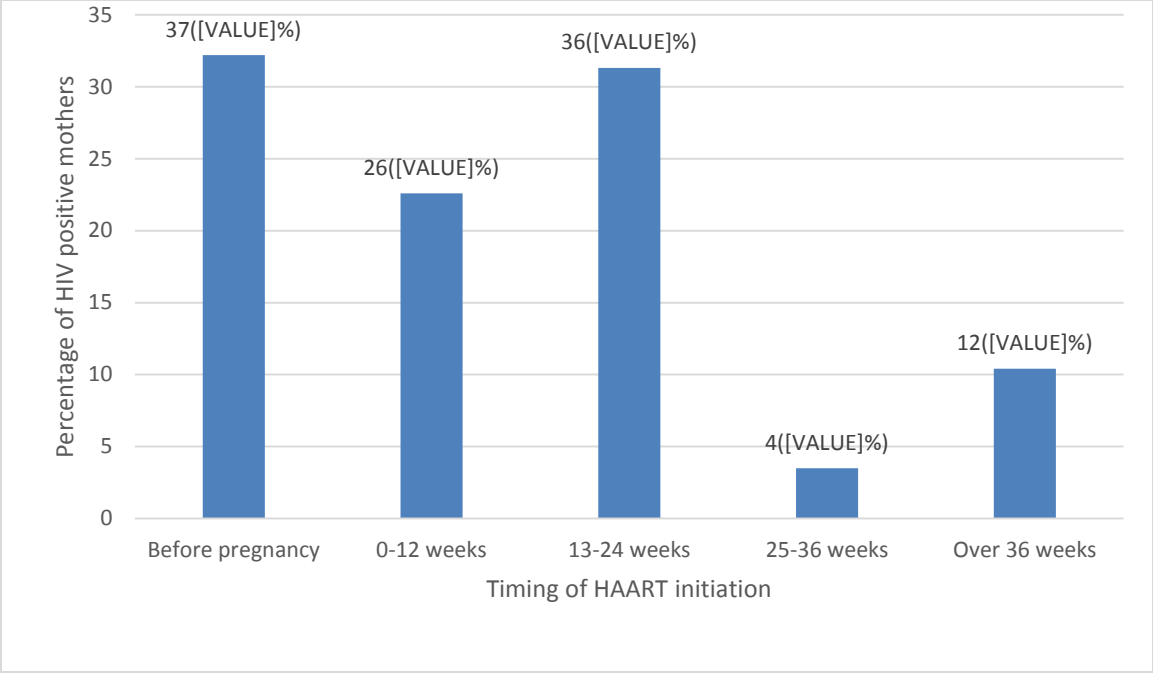


Figure 2: Gestational age at initiation of ART in HIV positive women at PMH

4.2 Maternal outcomes in seropositive women at Pumwani Maternity Hospital

The rates of caesarean section in HIV positive women was not significantly different from that in HIV negative women (OR = 1.04 95% CI 0.59-1.84, p = 0.885). As shown in Table 5. 33(27.5%) HIV positive women had caesarean sections performed compared to 32 (26.7%) seronegative women

Table 5: Mode of delivery in seropositive and seronegative women in PMH

	seropositive n=120	**seronegative n=120**	**OR(95% CI)**	**P value**
Mode of delivery				
Normal SVD	87(72.5)	88(73.3)	1.00	
Caesarean section	33(27.5)	32(26.7)	1.04(0.59-1.84)	0.885

4.2.2 Indication for caesarean section in seropositive and seronegative mothers in PMH.

The indications for caesarean section deliveries are presented in Figure 3. Fetal distress (n = 16) and obstructed labor (n = 15) were the predominant indications of caesarean delivery in HIV positive mothers while fetal distress (n = 19) was the leading cause of caesarean delivery in HIV negative women.

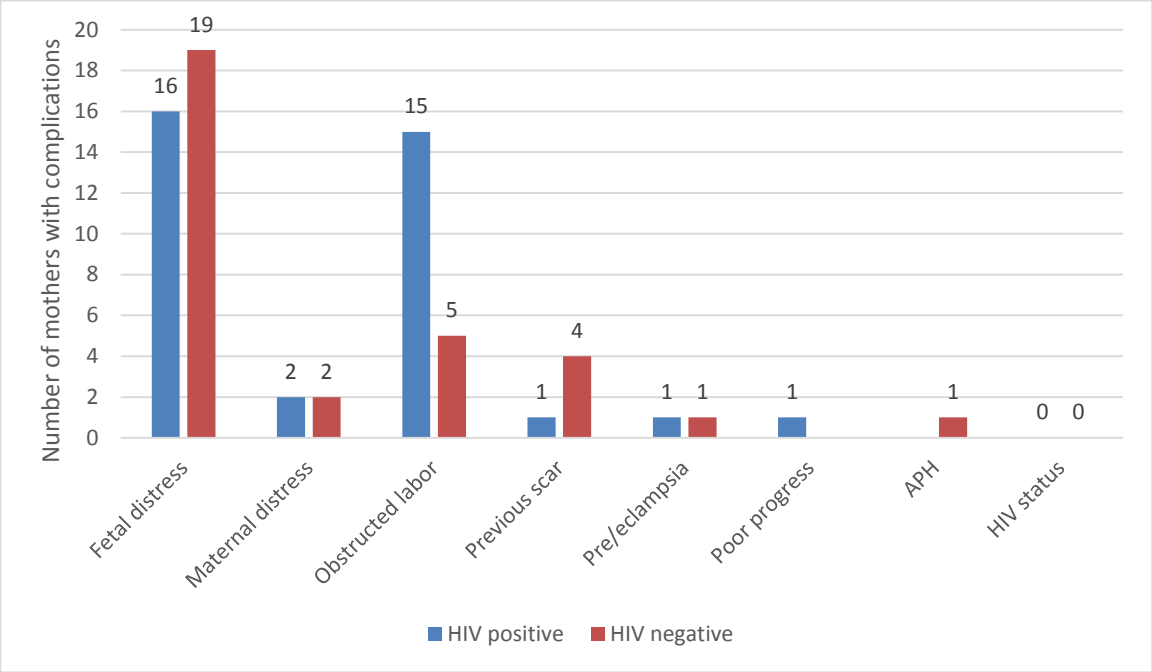


Figure 3: Indication for caesarean section in seropositive and seronegative women in PMH.

4.2.3 Maternal complications among seropositive and seronegative women at PMH

Seventeen (14.2%) seropositive women and 13 (10.8%) seronegative women had complications during delivery (Table 6). PPH was the prominent cause of complicated delivery affecting 17 (14.2%) and 12 (10%) seropositive and seronegative women, respectively

Table 6: Maternal complications among seropositive and seronegative women at PMH

	seropositive n=120	**seronegative n=120**	**OR(95% CI)**	**P value**
Maternal complications				
Yes	17(14.2)	13(10.8)	1.00	
No	103(85.8)	107(89.2)	0.74(0.34-1.59)	0.436
Type of complications				
No complication	102(85.0)	108(90.0)	1.00	
Eclampsia	1(0.8)	0	NA	NA
PPH	17(14.2)	12(10.0)	1.50(0.68-3.30)	0.313

4.3: Fetal outcomes among seropositive and seronegative women at Pumwani Maternity Hospital

The mean weight (SD) of babies delivered by seropositive women was 2.94± 0.5 compared to a similar mean weight (SD) of 2.94 ± 0.6 among babies born to seronegative women (Table 7). Most women in both groups delivered babies weighing at least 3 kgs (n = 59, 49.2% in seropositive and n = 59, 49.2% in seronegative group). Of the babies born to seropositive women 113 (94.2%) babies were born alive compared to 116 (96.7%) of births to seronegative women (OR = 0.59, 95% CI 0.14-2.53; p = 0.477). Ten (8.3%) babies born to seropositive women had low APGAR scores compared to 5 (4.2%) of babies delivered by seronegative women (p = 0.191).

Table 7: Fetal outcomes among seropositive and seronegative women at PMH

	Seropositive	Seronegative	OR (95% CI)	P value
Baby's sex	**n=120**	**n=120**		
Male	65(54.2)	58(48.3)	1.00	
Female	55(45.8)	61(50.8)	0.80(0.48-1.34)	0.401
Congenital malformation	**n=120**	**n=120**		
Yes	5(4.2)	3(2.5)	1.00	
No	115(95.8)	117(97.5)	0.59(0.14-2.53)	0.477
Outcome	**n=120**	**n=120**		
Live	113(94.2)	116(96.7)	1.00	
Fresh still birth	2(1.7)	2(1.7)	1.03(0.14-7.41)	0.979
Macerated still birth	2(1.7)	0(0.0)	1.00	
Neonatal death	2(1.7)	1(0.8)	2.05(0.18-22.96)	0.559
APGAR score	**n=120**	**n=120**		
6 and below	10(8.3)	5(4.2)	1.00	
7 to 10	110(91.7)	115(95.8)	0.48(0.16-1.44)	0.191
Birth weight (mean ± SD)	**2.94 ± 0.5**	**2.94 ± 0.6**	**NA**	**NA**
1-1.5 kgs	0(0.0)	2(1.7)	1.00	
1.5-2 kgs	1(0.8)	3(2.5)	0.33(0.03-3.30)	0.347
2.0-2.5 kgs	14(11.7)	10(8.3)	1.40(0.58-3.40)	0.458
2.5-3.0 kgs	46(38.3)	46(38.3)	1.00(0.58-1.72)	1
Over 3 kgs	59(49.2)	59(49.2)	1.00	

4.4: Length of hospital stay

The mean length of hospital stay of seropositive and seronegative women following delivery did not differ significantly (t = 1.03, p = 0.302). seropositive women stayed in hospital on average for 2.18 days (SD = 1.21) compared to an average length of stay of 2.03 days (SD 1.18) among the seronegative women, resulting in a mean difference in length of stay of 0.16 days (95% CI -0.14 to 0.46)

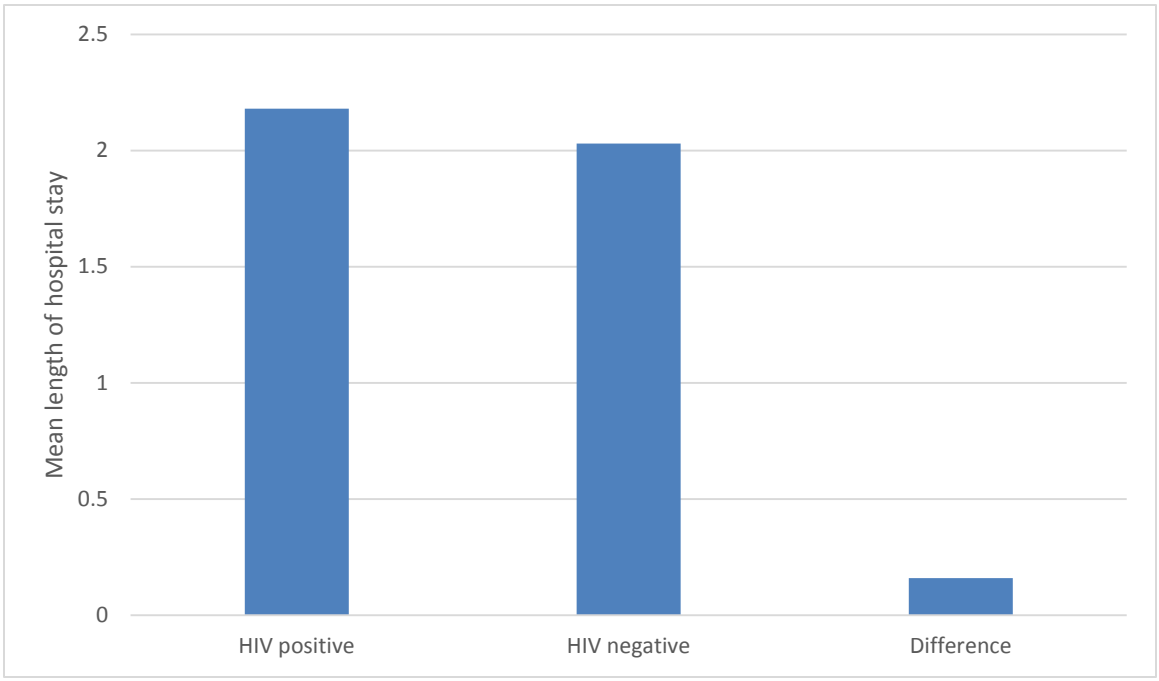


Figure 4: Length of hospital stay

CHAPTER FIVE

DISCUSSION

5.0 Introduction

This was a descriptive cross sectional study which aimed at comparing pregnancy outcomes between HIV positive and HIV negative mothers admitted for delivery at Pumwani Maternity Hospital. Characteristics of the mothers in the two groups were compared.

5.1.1: Socio-demographic characteristics of the study participants at PMH.

The mean age of the seropositive mothers was 27.7 years (SD 5.8) compared to a mean age of 26.5 years (SD 5.1) among seronegative mothers. Approximately one-third of both seropositive (n = 42, 35%) and seronegative (n = 41, 34.2%) mothers were aged between 25 and 29 years. Most mothers reported that they were married (seropositive n = 97 (80.8%) and seronegative n = 100 (80.3%) with an OR (95% CI) of 0.86(0.40-1.81) and a P-value of 0.684. Most of the mothers were Christians i.e. seropositive (n = 117, 97.5%) and seronegative (n = 114, 95%) groups.

Overall there were no major statistical differences in terms of socio demographic characteristics between the two groups.

5.1.2: Obstetric and gynecologic history of the study participants at Pumwani Maternity hospital

The attendance of ANC in seropositive mothers was 100% compared to 99.2% in HIV negative mothers. There was a significant association between HIV status and type of facility visited by seropositive women. Seropositive women were 57% less likely to visit private ANC facilities compared to seronegative mothers (OR = 0.43, 95% CI 0.19-0.95) P-value of 0.038. This could most likely be attributed to the comprehensive PMTCT management programmes put in place by

the government in order to improve maternal child health. The mean gestational age (SD) at first ANC visit was 37.6 weeks ± 2.2 in HIV positive mothers compared to 37.3 weeks ± 2.4 in seronegative women. Antenatal attendance among pregnant women in Kenya is over 94.8%. A study done by the Kenya AIDS Indicator Survey in 2012 revealed similar findings where most of the pregnant mothers (90.1%) make their first visit in the third trimester. Among the mothers attending ANC care 83 (69.2%) in the seropositive group and 87 (72.4%) in the seronegative group made at least four ANC visits as recommended by WHO.

5.1.3: Timing of ART initiation and PMTCT profiling.

Maternal testing for HIV was most commonly done before conception of the index pregnancy (n = 45, 37.8%) or within 12 weeks of conception (n = 35, 29.4%). In 67 (55.8%) of the seropositive mothers and all the mothers tested before pregnancy were already on antiretroviral therapy. CD4 profiling was not done in 26 (21.7%) mothers the CD4 count was between 350 and 500 cells/mm^3. However this did not influence the initiation of ART therapy as recommended by WHO in option B+ where all mothers diagnosed with HIV in pregnancy are supposed to be started on ART irrespective of CD4 profiling. ART was initiated in 115 (95.8%) of the seropositive mothers attending ANC in Pumwani Maternity Hospital. This high percentage could be attributed to the fact that the facility is located in an urban setting where mothers are more informed. Other studies have shown that pregnant women residing in rural areas have low rates of ART uptake as compared to their urban counterparts (Hogson et al., 2014).

According to Hogson et al., 2014 young women are less likely to start or adhere to ART, while older ones are most likely to start and adhere to treatment however in this study age did not influence antiretroviral therapy initiation. The same study revealed a relationship between education levels ART uptake and adherence but this study demonstrated that education level

does not influence uptake of ART. The rates of HIV status disclosure in seropositive mothers attending ANC care in PMH was 69.2% with 89 out of the 120 HIV positive mothers reporting that they had disclosed their HIV status. Similar findings were reported in a study done in Lilongwe Malawi where the percentage of women who disclosed their status during pregnancy was 65 %.(Bobrow., 2008). Lack of HIV disclosure leads to poor uptake of HAART and adherence to PMTCT practices (Turan et al., 2008).

5.2: Maternal outcomes in seropositive mothers at Pumwani Maternity Hospital

The rates of caesarean section in HIV positive women was not significantly different from that in HIV negative women (OR = 1.04 95% CI 0.59-1.84, p = 0.885). 33(27.5%) HIV positive women had caesarean sections performed compared to 32 (26.7%)seronegative women. No caeserian section was done for PMTCT reasons. The indications for caesarean section deliveries included fetal distress, obstructed labor, previous scar, Eclampsia and APH. Caeserian deliveries have been shown to lower mother to child transmission of HIV. More studies need to be done to evaluate whether there is a statistical difference in terms of seroconversion rates in children born to seropositive mothers through C/S and SVD. Seventeen (14.2%) seropositive mothers and 13 (10.8%) seronegative mothers had complications during delivery. PPH was the prominent cause of complication affecting 17 (14.2%) and 12 (10%) seropositive and seronegative mothers, respectively with an OR (95%C.I) of 1.50(0.68-3.30) and a P-value of 0.313. These findings correspond with a study carried out by (Ezechi et al., 2012), who found an association between HIV/AIDS and PPH. There was only one case of eclampsia in the seropositive cohort. A study done by Boyajian et al., 2013 also showed no significant differences in prevalence of eclampsia in both seropositive and seronegative mothers.

5.3: Fetal outcomes in seropositive mothers at Pumwani Maternity Hospital

There were no major differences in terms of fetal outcomes in both seropositive and seronegative mothers. A similar study done by Marazzi et al., 2009 also noted no difference in adverse fetal outcomes among both seropositive and seronegative mothers. This could be attributed to the use of HAART during pregnancy since some studies have shown that use of HAART in pregnancy reduces incidences of adverse pregnancy outcomes. A study done by Onakewhor et al ., 2011 noted high rates of intrauterine growth restriction, prematurity and caeserian delivery among the seropositive mothers with untreated maternal HIV infection as compared to the seropositive mothers who received HAART antenatally. These findings confirm the importance of HAART in preventing adverse pregnancy outcomes. However ten (8.3%) babies born to HIV positive mothers had birth asphyxia compared to 5 (4.2%) of babies delivered by HIV negative mothers ($p = 0.191$). this difference is however not statistically significant. Musana et al 2009 noted that advanced HIV disease is associated with increased risk of adverse fetal and maternal outcomes.

5.4: Duration of hospital stay

The mean length of hospital stay of HIV positive and HIV negative mothers following delivery did not differ significantly ($t = 1.03$, $p = 0.302$). A study done by Musana et al 2009 at Kenyatta national hospital on mothers with advanced maternal infection found out that the proportion of mothers who were hospitalized for more than a week were 44% as compared to the seronegative group at 27%. This difference could be attributed to the fact that the study looked at mothers with advanced HIV disease who are already predisposed to complications of HIV and pregnancy.

5.5: Conclusions

1. Seropositive women are less likely to visit private ANC facilities compared to seronegative mothers.
2. Caeserian sections are not performed for PMTCT reasons in Pumwani Maternity Hospital.
3. Seropositive mothers are more likely to suffer PPH after delivery than the seronegative mothers.

5.6: Recommendations

1. Seropositive mothers should be monitored closely after delivery and active management of third stage done to prevent incidences of PPH.
2. Replication of this study should be done in different sites so that findings can be generalizable.

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Appendix 1; Gantt Chart

FROM 0CTOBER 2014													
ACTIVITY	Oct 2014	Nov 2014	Jan 2015	Feb2 015	Mar 2015	April 2015	May 2015	June 2015	July 15	Aug '15	Sep '15	Oct '15	Nov' 15
TOPIC IDENTIFICATION													
PROPOSAL WRITING													
ETHICS RESEACH COMMITTEE REVIEW													
DATA COLLECTION													
DATA ANALYSIS													
THESIS WRITING													
THESIS EXAMINATION													
DEFENCE OF THESIS AT SONS													
REFINE THESIS													

Appendix 2: Verbal Informed Consent Script

Title: Pregnancy outcomes among pregnant mothers living with HIV/AIDS at Pumwani Maternity Hospital.

Principal Investigator: Everlyne Makokha

I am a master's student at the School of Nursing sciences, University of Nairobi. I am conducting a research about pregnancy outcomes among women living with HIV/AIDS. You are being requested to participate in this study. No one has a right to force you to participate and you will only participate if you wish to do so. Also note that whether you decide to participate or not will not affect the usual care that you are entitled to receive at this health facility. This is a consent form that gives you information about the purpose, procedure, risks, benefits, confidentiality/privacy and the process that will be expected during the study.

Purpose: You are invited to participate in a research study, carried out at Pumwani Maternity Hospital. The purpose of this research study is to assess pregnancy outcomes among pregnant mothers at Pumwani Maternity Hospital. The purpose of this study is to help ascertain the effect of HIV on pregnancy outcomes at Pumwani Maternity Hospital. The information collected will be used to help develop programmes for improving health care and services in the community, particularly for pregnant women

Procedures: If you agree to participate, you will be asked some general questions about your background, such as your age, marital status, education level attained, and occupation.. The interview will last about 20 to 30 minutes.

Risks: There are minimal risks involved; the discomfort is due to the questions asked in the questionnaire. However effort will be made to minimize the risks. Information given will be held with utmost confidentiality and is meant purely for the research purposes. The finding of this study will be published but your identity will not be revealed.

Benefits: Regarding benefits, there may not be any direct benefits for you as an individual participant, but the information collected will help us to better understand the effect of ART in ppregnancy with the aim of improving maternal and fetal outcomes among mothers living with HIV/AIDS.

Voluntary Participation and Withdrawal: Remember, your participation is entirely voluntary. Should you change your mind, you have the right to drop out at any time.

Confidentiality: After data collection the questionnaires will be kept under lock and key. There will be no way to identify individual participants. Your name will not be recorded on the questionnaire neither reported in any project document and all your answers will be strictly confidential

Contact Persons: You will be given a card to take with you containing contact information for the researcher. This research has been approved and reviewed by the KNH/UoN ethical committee. This committee has reviewed this study in order to help protect participants. If you have any questions about your right as research participant you may contact the researcher on 0721888980

Confirmation of Consent

Respondents' statement and signature

I fully understand the purpose and benefits of this study as explained to me by the researcher and I agree to participate in this study. I have been given a copy of this form and having read it. I fully have willingly agreed to participate.

Signature of Participant……..Date……Time……..

Signature of research assistant……Date……Time…….

Investigator's signature …….Date: ……..Time…….

Appendix 3: Questionnaire

Maternal and Fetal Outcomes in a Cohort of Seropositive Pregnant Mothers at Pumwani Maternity Hospital, Nairobi County

Code: **Date:**

Instructions

Do not write your name on the questionnaire.

Tick the correct answer in the brackets provided.

Write the correct response in the spaces provided.

1.0 Socio-demographic characteristics

1. How old are you in years?

   Specify ……..

2. What is your marital status?

   Single [ ] Married [ ] Divorced [ ] Separated [ ]

3. What is your highest level of education?

   Specify ……..

4. What is your religion?

   Christian [ ] Muslim [ ] Atheist [ ]

5. What is your occupation?

   House wife [ ] Self employed [ ] Employed [ ]

6. Where do you live?.....

Section 2.0 obstetric history

7. When was your last menstrual period?

   …….

8. How old is the pregnancy in weeks?

   State ……

9. How many pregnancies have you ever had?

   Specify: ……

10. Have you lost any pregnancies in the past?

    Yes [ ] No [ ]

11. If yes how many? ……

12. What were the causes? ……..

13. Have you lost any children in the past?

    Yes [ ] No [ ]

14. If yes, what were the causes?

    Illness [ ] Trauma [ ] Unknown [ ]

15. At what ages did you lose them?

    Specify:……

16. Did you attend antenatal clinic during this pregnancy?

    Yes [ ] No [ ]

17. If yes where?

    Government facility [ ] Private facility [ ]

18. What was the gestation at the first antenatal visit?

    0-12 weeks [ ] 13-28 weeks [ ] 29-40 weeks [ ]

19. How many times did you attend the clinic?

Once [ ] Twice [ ] Three times [ ] Four times [ ] Five times [ ] Six times [ ] Over six times [ ]

20. Did you suffer from any of diseases during pregnancy?

Yes [ ] No [ ]

21. If yes, which diseases?

Diabetes [ ] High Blood Pressure [ ] Urinary tract infections [ ] Candidiasis [ ] Malaria [ ]

Others, specify:……..……

3.0 PMTCT profiling

22. When were you first tested for HIV?

Before pregnancy [ ] 0-12 weeks [ ] 13-24 weeks [ ] 25-36 weeks [ ] Over 36 weeks [ ]

23. Did you receive any counseling before being tested?

Yes [ ] No [ ]

24. Did you receive post test counseling?

Yes [ ] No [ ]

25. To what extent were you satisfied with the counseling?

Not satisfied [ ] partially satisfied [ ] fully satisfied [ ]

26. What was your reaction?

Shock [ ] Angry [ ] Denial [ ] Accepted [ ]

27. Have you disclosed to anyone?

Yes [ ] No [ ]

28. If yes, who?

Husband [ ] parent [ ] friend [ ] sibling [ ]

29. Are they supportive?

Yes [ ] No [ ]

30. What were the CD4 levels after testing?

Below 200 cells/ mm^3 [ ] 350 – 500 cells/ mm^3 [ ]

Above 500cells/ mm^3 [ ] Not done [ ]

31. Have you been started on antiretroviral therapy?

Yes [ ] No [ ]

32. If yes when was it initiated?

Before pregnancy [ ] 0-12 weeks [ ] 13-24 weeks [ ]

25-36 weeks [ ] Over 36 weeks [ ]

33. If no, why? .....

34. Do you have any challenges in taking the antiretroviral drugs?

Yes [ ] No [ ]

35. If yes which ones?

Lack of disclosure thus need to hide the medication [ ]

Forgetting to take the medication [ ] Nausea or vomiting [ ]

Any other reason, specify…… ,

Section 4.0 fetal outcomes

36. What was the mode of delivery?

Normal SVD [ ] Caesarian section [ ] Vacuum delivery [ ]

37. If c/s what was the indication?

HIV status [ ] Fetal distress [ ] Maternal distress [ ] Obstructed labour [ ]

Any other reason……

38. What is sex of the baby?

Male [ ] Female [ ] Ambiguous [ ]

39. What was the newborn outcome?

Live [ ] Fresh still birth [ ] Macerated still birth [ ] neonatal death [ ]

40. What was the Apgar score of the baby at 10 minutes if live?

Specify …….

41. What is the weight of the baby? .....

42. Are there any congenital malformations?

Yes [ ] No [ ]

43. If yes which ones? Specify:

……

44. Was the baby admitted to nursery? Yes [ ] No [ ]

45. If yes, what was the reason for admission?

……

Section 4.0 Maternal outcomes

46. Were there any maternal complications?

Yes [ ] No [ ]

47. If yes which ones?

APH [ ] PPH [ ] Pre/Eclampsia [ ] Cervical dystocia [ ] Maternal distress [ ] Sepsis [ ] Puerperal psychosis [ ] DIC [ ]

Others, specify……..

48. What was the duration of hospital stay in days? Specify……..

Appendix 4: Letter of Approval KNH/UON- ERC

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

20 JUL 2015

Ref: KNH-ERC/A/317

20th July 2015

Everlyne Shitoyi Makokha
H56/67594/2013
School of Nursing Sciences
University of Nairobi

Dear Everlyne

RESEARCH PROPOSAL – PREGNANCY OUTCOMES IN A COHORT OF SEROPOSITIVE MOTHERS AT PUMWANI MATERNITY HOSPITAL, NAIROBI COUNTY (P139/03/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 20th July 2015 – 19th July 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF. A.N. GUANTAI
CHAIRPERSON, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Director, School of Nursing Sciences, UoN
Supervisors: Dr. Jennifer Oyieke, Dr. Sabina Wakasiaka

Appendix 5: Letter of Approval from Pumwani Maternity Hospital

NAIROBI CITY COUNTY

Telephone: 020 344194
Web.www.nairobi.go.ke

City Hall
P. O. Box 30075 - 00100
Nairobi
Kenya

COUNTY HEALTH SERVICES:
PUMWANI MATERNITY HOSPITAL

PMH/DMOH/75/0470/2015

22nd July 2015

TO:
Everlyne Shitoyi Makokha
H56/67594/2013
School of Nursing Sciences
University of Nairobi.

RE: APPROVAL OF RESEARCH PROPOSAL

This is to inform you that the research entitled "**Pregnancy Outcomes in Cohort of Seropositive Mothers at Pumwani Maternity Hospital, Nairobi Kenya**" has been approved.

You are hereby allowed to collect data. We look forward to receiving a summary of the research findings upon completion of the study.

Yours sincerely,

DR. L.O. KUMBA
MEDICAL SUPERINTENDENT

Appendix 6:Map for Pumwani Maternity Hospital