MATERNAL PREDICTORS OF PERINATAL TRANSMISSION OF HIV AT THIKA LEVEL 5 HOSPITAL.

DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNECOLOGY, AT THE UNIVERSITY OF NAIROBI.

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DEDICATION

This book is dedicated to my caring husband Mbondo, son Muuo and daughter Ndanu whose endurance, love and patience has made my work enjoyable.

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As I conclude my studies in Obstetrics and Gynaecology, I thank the Almighty God for this far He has brought me.

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To you all as well as many others not mentioned, Asante Sana and may God bless you all.

DECLARATION

I declare that this research work for the dissertation in part fulfilment of the Masters of Medicine degree in Obstetrics and Gynaecology is my original work and has been read by my supervisors.

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This is to certify that Dr Mary Ingabo researched upon this dissertation under my guidance and supervision and this book is submitted under my approval.

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CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr.Mary Ingabo, MMed student registration number H58/63531/2010 in Obstetrics and Gynaecology department, University of Nairobi (2010-2014).The research was carried out in the department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences. It has not been presented in any other university for award of a degree.

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ABBREVIATIONS

AFASS Available Feasible Acceptable Safe Sustainable

AIDS Acquired Immunodeficiency Syndrome

ANC Antenatal Clinic

ART Antiretroviral Therapy

ARVs Antiretroviral drugs

AZT Azidothymidine (Zidovudine)

CCC Comprehensive Care Clinic

CD4 All cells bearing the CD4 receptor including Langerhan cells and dendritic cells. (CD4+ T lymphocytes)

C/S Caesarean section

EFV Effavirenz

ELISA Enzyme Linked Immunosorbent Assay

HAART Highly Active Antiretroviral Therapy

HIV Human Immunodeficiency Virus

KAIS Kenya Aids Indicator Survey

KDHS Kenya Demographic Health Survey

MCH Maternal and Child Health

MTCT Mother to Child Transmission

NACC National AIDS Control Council

NASCOP National AIDS and STD Control Programme

NVP Nevirapine

PCR Polymerase Chain Reaction

PEPFAR President`s Emergency Plan for HIV/AIDS Relief

PMTCT	Prevention of Mother to Child Transmission
PROM	Premature Rupture of membranes
STIs	Sexually Transmitted Infections
SPSS	Statistical Package for Social Sciences
3TC	Lamivudine
TDF	Tenofovir
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children`s Education Fund
WHO	World Health Organization

DEFINITION OF TERMS

HIV infected children: children who have acquired the HIV virus. In this study transmission is vertically from their HIV infected mothers either transplacentally, during delivery or through breastfeeding.

HIV exposed children: those who were exposed to the virus through their HIV positive mothers during pregnancy but did not contract the virus.

Safe infant feeding: this includes breastfeeding the child and also complementary feeding as long as the child is on infant prophylaxis. Replacement feeding can also be done as long as it is affordable, feasible, acceptable safe and sustainable.

ABSTRACT

BACKGROUND: Perinatal transmission of Human Immunodeficiency Virus has been shown to be the main route of transmission to children accounting for 90% of new paediatric HIV infection in Kenya. Prevention of perinatal transmission is a major goal in care of HIV positive pregnant women. The country has made commitment to eliminating vertical transmission. By determining the factors that are associated with perinatal transmission, further strategies can be drawn to address these shortcomings.

OBJECTIVE: To determine the difference in maternal factors that determine perinatal HIV transmission between HIV infected women with 2 year old children who are confirmed HIV positive and negative between March and August 2013.

STUDY DESIGN: This was a cross-sectional study in which 114 HIV positive mother-child pairs were recruited. Those mothers with HIV positive babies (33) were compared with those with HIV negative babies in a subgroup analysis.

SETTING: Thika Level 5 Hospital was the site for the study.

DATA COLLECTION AND ANALYSIS: Mothers'biodata, antenatal care including CD4 cell count, ARV regimen used, mode of delivery, mode of infant feeding and prophylaxis and ELISA test at 18 months results were entered in the questionnaire (Appendix I) and analyzed using SPSS package.

RESULTS: A total of 114 HIV mother child pairs were recruited into the study. The number of mothers 30 years and below and above 30 years was same. Majority of the mothers were married, had attained primary school level and had some form of employment at 75.5%, 57%and 60% respectively. About a third (28.9%) of the 2 year old children in the sample size (33) was HIV positive. There were significant associations between delayed and few attendance of antenatal care, delayed mother ARV initiation and infant prophylaxis and mixed feeding with perinatal HIV acquisition. Multiple logistic regression analysis revealed predictors of perinatal transmission as delayed initiation of ARVs (p value 0.013) and few counselling packages (p value 0.003).

CONCLUSION: There was significantly less transmission of HIV to children whose mothers were initiated ARV'S before or during early pregnancy and received counselling on infant prophylaxis and nutrition, couple testing and use of condoms in pregnancy to prevent co infection.

RECOMMENDATION: More emphasis should be placed towards empowering all health facilities on programmes initiating ARV treatment or prophylaxis early in the pregnancy, along with couple and infant counselling and postnatal follow up in order to achieve zero infections in the next generation.

INTRODUCTION/LITERATURE REVIEW

The overall growth of the global AIDS epidemic appears to have stabilized. The annual number of new HIV infections has been steadily declining since the late 1990s mirrored by fewer AIDS related deaths due to significant scale up of antiretroviral therapy(ART) over the past few years. Although the number of new infections has been falling, levels of new infections overall is still high and with significant reductions in mortality, the number of people infected with HIV has increased (UNAIDS 2009).

In Kenya, the HIV prevalence dropped from 7.4% in 2007 to 6.3% in 2009(Kenya Demographic Health Survey 2009).A higher proportion of women aged 15-64 years(6.9%)than men(4.4%) were infected with HIV(Kenya AIDS Indicator Survey 2012).In Kenya, an estimated 37 000 to 42 000 children are infected annually due to mother to child transmission(National AIDS/STI Control Program 2012).As a result of increased access to Prevention of Mother to Child Transmission of HIV (PMTCT) services, the total number of children being born with HIV has decreased. An estimated 370 000 children were newly infected in 2009 which marked a drop of 24% from the previous 5 years (KDHS 2009,).However, the long term care of these infants is not only a major burden to the healthcare system but also the affected families. Prevention of new infections is therefore one of the key strategies in the National HIV/AIDS Strategic Plan (2009/10-12/13).

The risk of mother to child transmission (MTCT)of the HIV virus during antenatal period is 5-10%,intrapartum10-20% whereas it is 10-15% during the breastfeeding period without interventions to reduce MTCT.The estimated risk of transmission ranges from 15-25% in non breastfeeding populations and 20-25% in breastfeeding populations.(De Cock KM et al 2000) Risk factors for perinatal transmission include high maternal HIV RNA load, low levels of CD4 count,vaginal delivery with high viral load, prolonged rupture of membranes episiotomy, prematurity and low birth weight .

Studies have shown that antiretroviral prophylaxis given during pregnancy and continued intrapartum greatly reduces transmission rates by lowering the level of viremia.Indeed many antiretroviral drug regimens have been studied and protocols formulated for use as monotherapy, combination therapy or as HAART.

The first major breakthrough in the prevention of MTCT came in 1994 when the Paediatric AIDS Trials Group(PACTG) 076 clinical trial demonstrated that long course Zidovudine(AZT) prophylaxis, given early in pregnancy and intravenously during labour and to the infant for six weeks dramatically reduced transmission by 67%(Connor 1994).Due to its high cost and complexity, other studies were carried out in many low and medium economy countries to evaluate cheaper, shorter simpler yet effective regimes.

A study done in Thailand to investigate safety and efficacy of short course oral Zidovudine administered during late pregnancy and labour, showed the estimated transmission risk to be 9.4% on Zidovudine and 18.9% on placebo. (Shaffer 1999).In this study, all babies were formula fed. The authors concluded that a short course of twice daily oral Zidovudine was safe and well tolerated and, in absence of breastfeeding, can lessen the risk of mother to child transmission by 50%.

A similar study done in West Africa with the aim of assessing the safety and efficacy of short course perinatal oral Zidovudine in reducing MTCT in breastfeeding population showed a reduction in MTCT of HIV by 37% at age of 3 months. (26.1% in the placebo vs.16.5% in the Zidovudine arm). All babies were breastfed. Thus, even in breastfeeding populations, there was significant efficacy of short course perinatal Zidovudine.

Studies by Lallemant et al using Zidovudine at 28 weeks gestation and 6 weeks of treatment in the infant(long-long regime)and Zidovudine from 35 weeks gestation with 3 days treatment of the infant(short-short regime) resulted in higher transmission rates in the latter(5.1%vs 1.6%).

The Petra Study which evaluated the efficacy of short course regimens of Zidovudine and Lamivudine(3TC) in a predominantly breastfeeding population revealed a remarkable reduction in transmission rates at 6 weeks of infants whose mothers were put on the two drugs during prenatal, intrapartum and postpartum periods.However,this risk was reduced at 18 months ostensibly because of breastfeeding.

The HIVNET 012Study in Uganda came to the rescue of resource constrained countries. This landmark study found that a short intrapartum/neonatal regimen of Nevirapine (NVP) given to the mother at onset of labour and to the infant within 72 hours of life reduced the risk of perinatal HIV among breastfeeding women by 47% at 14-16 weeks and by 42% at 18 months compared to a short intrapartum/neonatal regimen of AZT. (Guay et al 1999).

Many workers have compared the efficacy of single agent regimens against combinations of two or more agents. Sequential improvements have been made in the regimens over the past several years. With no intervention,MTCT rate is 22%,with AZT monotherapy 13%,Single dose Nevirapine 12%,Short course AZT/3TC is 9.3%,Short course AZT+sd Nevirapine is 6.5%,short

course AZT+3TC+sd NVP is 4.7% and with triple ART is less than 1%(Mbori-Ngacha PEPFAR 2006).

Initial studies showed that mothers who were delivered by elective caesarean section before onset of labour or rupture of membranes had a lower transmission rate than those who were delivered vaginally(John PA 2001,Boer K 2007).But findings of a recent analysis on deliveries from HIV infected women in the French Perinatal Cohort suggest that HIV infected women on antiretroviral therapy with low viral load less than 1000 copies/ml could safely opt for vaginal delivery in the absence of obstetric factors(Briand et al 2010).

Studies done previously (Ruth Nduati et al 2000, Kiarie et al 2005), showed significant risk of transmission of HIV through breast milk.However,with advent of use of Highly Active Antiretroviral Therapy(HAART) in pregnancy for the mother and throughout the breastfeeding period, the risks are reduced significantly. The Mma Bana Study done in Botswana concluded that the overall transmission rate on HIV infected women who were started on HAART during pregnancy through breastfeeding was 1%till weaning at 6 months.

The Kisumu Breastfeeding Study (KIBS) was a clinical trial that assigned HIV positive pregnant mothers to different regimens of nevirapine and nelfinavir and children to breastfeeding. Results showed that a 12 month infant transmission rate of 5.9%was achieved using maternal HAART from 34 weeks of gestation through 6 months of breastfeeding.

With implementation of recommendation for universal prenatal HIV counselling and testing, antiretroviral treatment (ART) or prophylaxis, safer delivery and infant feeding options, mother to child transmission of HIV has reduced to <2% in resource rich countries (Cooper ER et al 2002).

The Kenya national PMTCT guidelines recommend a comprehensive four pronged approach adopted from WHO, that targets pregnant and non pregnant women, mothers and children. These are primary prevention of HIV infection in women; prevention of unintended pregnancy among HIV infected women; interventions to reduce transmission from HIV infected pregnant and lactating women to their children and care and support of women, children and families infected and affected by HIV(PMTCT plus).

The WHO recommendations for PMTCT of HIV include ARV therapy for all pregnant women. For those with CD4 count less than 350, triple therapy involving a combination of AZT, 3TC, NVP or EFV; or TDF, 3TC, NVP or EFV should be started as soon as possible, at 14 weeks or soon as possible thereafter for life. Infants should be given NVP for 6 weeks.ARV prophylaxes in pregnancy includes two options, both of which should be started in pregnancy at 14 weeks or soon as possible thereafter. Option A involves twice daily AZT for mother and infant prophylaxis with either AZT or NVP for 6 weeks if the infant is not breastfeeding .If the infant is breastfeeding, NVP should be continued for one week after end of breastfeeding period. Option B involves a 3 drug prophylactic regimen for the mother taken during pregnancy and throughout

breastfeeding period as well as infant prophylaxis with NVP for 6 weeks after birth whether or not the infant is breastfeeding.

Modified obstetric practices include avoidance of multiple digital examinations, artificial rupture of membranes with reduction of time between rupture of membranes and delivery to less than 4 hours; unnecessary episiotomies, milking of cord, suctioning of baby and invasive procedures.

Prevention of mother to child transmission of HIV infection is dependent on various factors which are interrelated. These include policy regulation organization which encompasses even distribution of health facilities, 4 ANC visits, access to ARVS, infant feeding and prophylaxis and adequate provision of health workers. Predisposing factors include age, income, and poverty and literacy level. There are reinforcing factors like free counselling and testing services, Provider Initiated Testing and counselling(PITC) with opt out strategy,HIV kit and lab reagent supply, free ARVs,support for infant feeding options, health workers supportive attitude, family support and treatment of STIs.The enabling factors include male involvement couple counselling and community participation. Behavioural factors include poor health seeking behaviour and non adherence on ARV therapy.

Effective provision of PMTCT interventions improves maternal health and infant HIV free survival.PMTCT is a key component of overall HIV prevention efforts and represents a critical opportunity in stemming the tide of the HIV epidemic. To successfully reduce mother to child transmission of HIV, population-level efforts to prevent HIV infection among women of child bearing age must be realized. For the individual woman, a comprehensive, coordinated continuum of services must be provided beginning with increased access to counselling, testing and primary prevention services as well as reproductive health choices enabling either prevention of unintended pregnancies or appropriate planning for future intended pregnancies for people living with HIV.

For the HIV positive women who become pregnant, access to and follow through on effective interventions to prevent transmission to the infant and to provide treatment for herself and the child if infected must be provided to maximize maternal health and infant HIV free survival.

There have been efforts countrywide in health facilities to scale up PMTCT services using various ways. This study seeks to determine what gaps exist in this endeavour which needs to be filled in order to reduce MTCT hence ensure an AIDS free generation.

JUSTIFICATION

The Abuja declaration committed countries with high HIV paediatric burden to reducing the transmission by 90% by 2015 to less than 5% among breastfeeding populations. Whereas elimination of MTCT of HIV has been achieved in developed countries, some factors still hinder attainment of this goal in developing countries. Majority of the paediatric HIV infections still occur in Sub-Saharan Africa and are mainly due to perinatal transmission. This problem has serious morbidity and mortality if no intervention is undertaken and this has an effect not only on the families but on the nation as a whole through erosion of civil order and economic growth. By determining the factors that are associated with perinatal transmission, innovative strategies can be drawn to overcome these bottlenecks. This study can also form a hypothetical basis for future research.

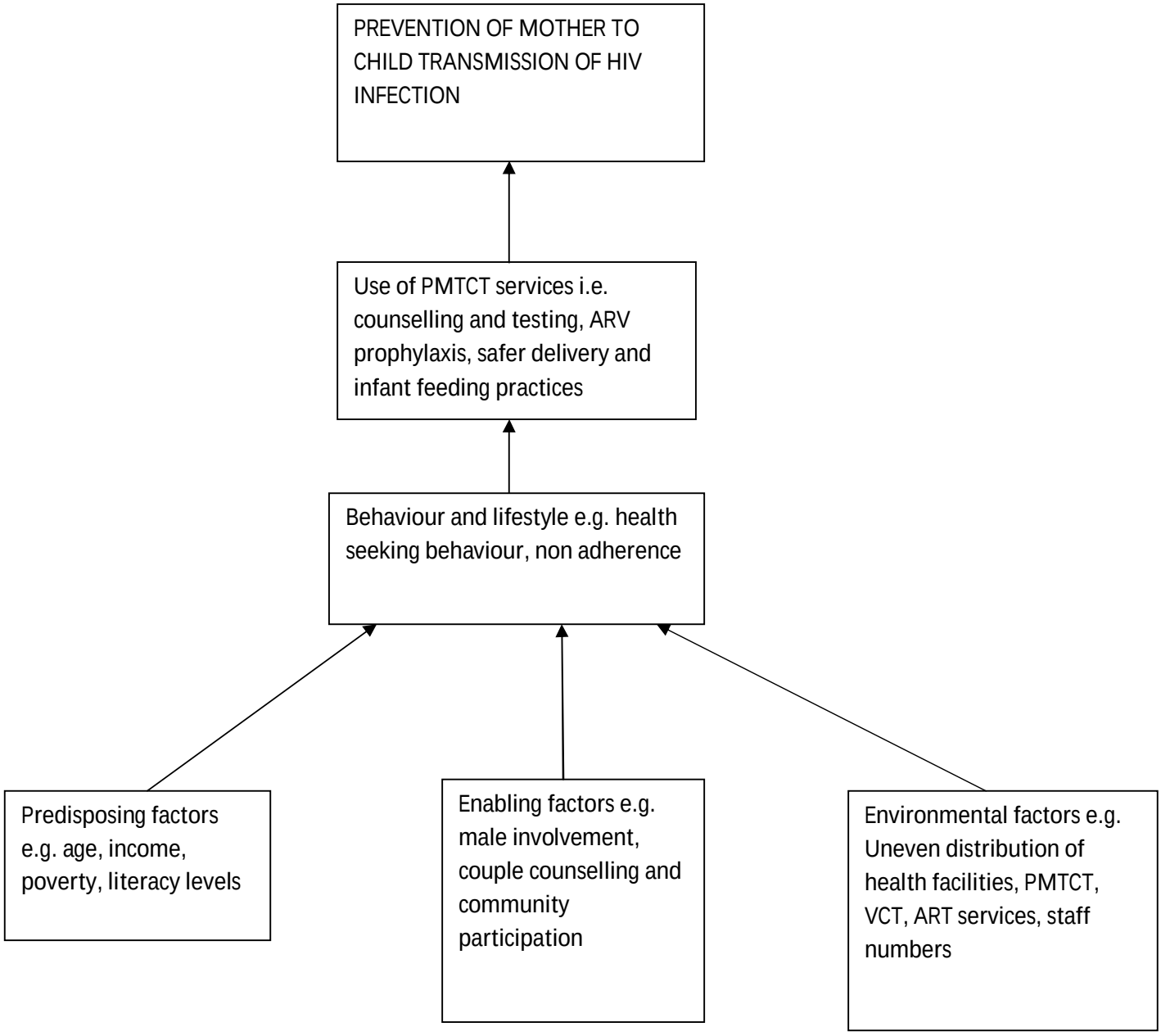
CONCEPTUAL FRAMEWORK

HIV/AIDS is a major public concern especially in Sub-Saharan region. Without intervention, it contributes to morbidity and mortality of the population. Pregnant mothers are especially vulnerable as there is aggravated lowering of immunity thus an upsurge of opportunistic infections. Moreover, there is a high risk of transmitting the virus to the fetus.This is compounded by predisposing, enabling and environmental factors. The conceptual framework illustrates these factors which contribute to perinatal HIV transmission and their relationship with each other.

The schematic presentation of the conceptual framework is as shown:

Conceptual framework

Schematic presentation



RESEARCH QUESTION

What is the proportion of HIV exposed children on care who have acquired HIV and what are their mother's characteristics?

OBJECTIVES

BROAD

To determine the proportion of HIV exposed children who have acquired HIV and their mother's characteristics.

SPECIFIC

1. To describe the sociodemographic characteristics of the HIV positive women.

2. To determine the proportion of HIV exposed infants on care who have acquired HIV.

3. To determine the maternal characteristics associated with Mother to Child Transmission (MTCT) of HIV.

METHODOLOGY

STUDY DESIGN

This was a cross-sectional study where all consenting HIV positive mothers with 2 year old confirmed HIV positive or negative children were presenting for routine Comprehensive Care Clinic visits.

STUDY SITE

The study was conducted at Thika Level 5 Hospital Comprehensive Care Clinic (CCC).

HIV positive mothers are followed up in the MCH clinic in the facility up to delivery and thereafter, together with their babies, until the child is 18 months of age when antibody test is done. All HIV negative children are discharged to continue with the normal MCH clinic whereas the HIV positive ones are enrolled to continue care at the paediatric section of the CCC.The facility also receives HIV infected babies from the periphery for continuity of care postnatally, together with their mothers.

STUDY POPULATION

The study population was composed of consenting HIV positive mothers with their 2 year old children.

Inclusion Criteria

1. Those who signed informed consent

2. Children whose ELISA test results were available.

Exclusion criteria

1. Mothers whose children had died or were hospitalized.

SAMPLE SIZE DETERMINATION

The sample size was calculated using the following formula by Fisher:

$$N = \frac{z^2 \times p(1-p)}{d^2}$$

N=minimum sample size required

z=confidence interval at 95% (standard value of 1.96)

p=the average rate of MTCT with intervention. The most commonly used regimen in Kenya for PMTCT is AZT which is commenced from 28 weeks of gestation with the infant given Nevirapine for 6 weeks. The transmission rate observed at 6 weeks, in a randomized trial, with use of this regimen was 8 %(Chung MH et al 2005).We therefore used 8 %.

d=0.05

$$N = \frac{(1.96)^2 \times 0.08(1-0.08)}{(0.05)^2}$$

The minimum sample size for this study was 114 mother-child pairs.

SAMPLING PROCEDURE

There were 2 research assistants sourced from the CCC who were trained by the principal investigator for 3 days prior to commencement of the study. The training entailed explaining to them the objectives of the study, how to obtain and record patient details in the data collection form and how to maintain patient confidentiality.

The training also entailed getting consent from the participants, administering the questionnaire and going through their files and antenatal cards to verify some of the information obtained. It was carried out in the CCC where the investigator demonstrated the patient flow and showed the assistants where to position themselves when administering the questionnaire. This was after the patients had been seen by the clinicians and received treatment.

After training of the research assistants, the questionnaire was rechecked in order to determine its applicability. The questionnaire was examined for clarity, ambiguity, time taken to fill out and analyzability. Appropriate adjustments were made.

DATA COLLECTION

Data was collected by the principal investigator with the help of 2 research assistants at the CCC. The clinic runs daily from Monday to Friday, 8a.m till 2 p.m. Identification of clients who fit the inclusion criteria was done daily using records from the clinic. After the clients had been reviewed in the routine CCC clinic and received treatment, the research assistants introduced themselves and informed consent was obtained. Sequential enrolment was done until the sample size was obtained. The questionnaire, which only contained serial numbers and was close ended, was administered in a private room provided to ensure confidentiality. Information on antenatal care including CD4 count, ARV initiation, intrapartum history, infant feeding, ARV for prophylaxis and ELISA test results of the child were documented. Some of the information was verified by records (outpatient card, antenatal card, discharge summary or patient files).Clients whose information could not be verified by records due to missing data were not included in the study. The information obtained was entered in the questionnaire (Appendix I).

DATA MANAGEMENT

At the end of each day, each questionnaire was checked for completeness, consistency and accuracy and locked up safely in a cabinet ready for data entry. Confidentiality of the patients' details was upheld. Data was entered into a password protected Microsoft Access database managed in consultation with the statistician. Once data entry was complete, it was compared with data on hardcopy forms to ensure accuracy. Inconsistency was detected by running simple frequencies and correlations and those identified were addressed before commencement of data analysis.

DATA ANALYSIS

Data was transferred into a coded sheet for computer analysis using SPSS package with help from the statistician. The data was presented in tables. Parametric tests were used to determine whether there was any significant association between two continuous variables while chi-square test was used to establish the significant association between categorical variables. A p value <0.05 was considered significant. All the factors that were significantly associated with HIV transmission were then subjected to logistic regression model to find out which factors were independently associated with perinatal HIV transmission.

ETHICAL CONSIDERATIONS

The proposal was submitted to KNH/UON research and ethics committee for review and approval prior to data collection.

Permission to carry out the study was sought from the medical superintendent of Thika Level 5 Hospital as well as the in charge of the CCC.

Informed written consent was sought from each woman and only those who consented were included in the study. The study was voluntary and no inducements were offered.

Confidentiality was maintained on information regarding the patient since no clients' names were sought and the information was not traceable to medical personnel or the patients themselves. The questionnaires had serial numbers instead. Data and information obtained was solely used for the official intended purpose and was locked in a cabinet .The computer used for analysis was password protected.

Information on the researcher and the KNH and University of Nairobi Ethics and Research Committee (KNH/UoN ERC) and their telephone numbers were availed to the participants in case they needed to contact them at any time.

STUDY LIMITATIONS

This being a cross sectional study was prone to recall bias. This was minimized by verifying some of the information given by the patients in the questionnaires from their records.

The study respondents were both from the facility and also neighbouring health facilities. This may have had an impact on validity of the results as the ones who had been on follow up in the facility and the ones referred from the peripheral facilities may have had different background characteristics. However, sequential recruitment of the HIV positive mothers was done daily as they came to the clinic regardless of the original facility of antenatal care.

RESULTS

A total of 114 HIV positive mothers with 2 year old children were recruited into the study between March and August 2013.

Table 1: Sociodemographic characteristics of the HIV positive mothers. (n=114)

Variable	Frequency (%)
Age	
Less than 20 years	5.3
21-30 years	43.0
31-40 years	46.5
More than 40 years	4.4
Missing	0.9
Marital status	
Single	19.3
Married monogamous	73.7
Married polygamous	1.8
Divorced/Separated	4.4
Widowed	0.9
Education level	
None	0.9
Primary	57.0
Secondary	29.8
Tertiary	10.5
Missing	1.8
Occupation	
Unemployed	39.5
Casual worker	10.5
Formal employment	15.8
Self-employed	33.3
Missing	0.9
Parity	
01-2	51.8
03-4	41.2
More than 4	7.0
Number of children alive	
All	87.7
Most	9.6
Some	2.6

Table 1 is a frequency distribution of the sociodemographic characteristics of the women in the study .The number of mothers 30 years and below and above 30 years was same. Majority of the

mothers were married, had attained primary school level and had some form of employment at 75.5%, 57%and 60% respectively.

Table 2: Association between obstetric factors and perinatal transmission of HIV

Variable	ELISA result of child at 18 months		OR (95% CI)	P value
	HIV Positive	HIV Negative		
Antenatal clinic attendance				
Yes	27 (25.5%)	79 (74.5%)	0.1 (0.0 – 0.6)	0.010
No	6 (75.0%)	2 (25.0%)	1.0	
When maternal HIV test was done				
Before pregnancy	12 (17.6%)	56 (82.4%)	1.0	0.001
During ANC and delivery	20 (45.5%)	24 (54.5%)	3.9 (1.6 – 9.2)	
Place of delivery				
Home	12 (57.9%)	8 (42.1%)	5.5 (2.0 – 15.2)	0.001
Health facility	20 (17.9%)	73 (82.1%)	1.0	

Table 2 presents the association between obstetric factors and perinatal transmission of HIV.Antenatal clinic attendance was significantly protective [O.R 0.1; 95% C.I 0.0-0.6; p value 0.010].HIV test done during ANC and delivery was significantly associated with higher perinatal HIV transmission as compared to before pregnancy [O.R 3.9; 95%C.I 1.6-9.2; p value 0.001].Home delivery was significantly associated with perinatal transmission [O.R 5.5; 95%C.I 2.0-15.2; p value 0.001]

(OR 1.0 is used as the reference point.)

Table 3: Association between counselling package and perinatal transmission of HIV

Variable	ELISA result of child at 18 months		OR(95% CI)	P value
	HIV Positive	HIV Negative		
Information about vertical transmission				
Yes	21 (21.9%)	75 (78.1%)	0.1 (0.0-0.4)	0.001
No	11 (68.8%)	5 (31.3%)	1.0	
Use of condoms in pregnancy to prevent co-infection				
Yes	22 (24.2%)	69 (75.8%)	0.3 (0.1 – 0.7)	0.010
No	10 (55.6%)	8 (44.4%)	1.0	
Minimum counselling package				
Yes	13 (14.9%)	74 (85.1%)	0.1 (0.0-0.2)	<0.001
No	19 (79.2%)	5 (20.8%)	1.0	

Table 3 shows the association between counselling package and perinatal transmission of HIV.HIV positive mothers who were given information on vertical transmission were significantly less likely to transmit the virus to their children [OR 0.1;95%C.I 0.0-0.4; p value 0.001].Counselling on use of condoms in pregnancy to prevent co-infection was significantly associated with lesser perinatal transmission [OR 0.3;95% C.I 0.1-0.7; p value0.010].Minimum counselling package was significantly associated with less perinatal transmission[O.R 0.1;C.I 0.0-0.2; p value<0.001]

Table 4: Association between ARV initiation and perinatal transmission of HIV

Variable	ELISA result of child at 18 months		OR(95% CI)	P value
	HIV Positive	HIV Negative		
CD4 count during pregnancy/first contact				
Less than 350	17 (29.3%)	41 (70.7%)	1.0	
More than 350	9 (19.1%)	38 (80.9%)	0.6 (0.2-1.4)	0.230
Not known	7 (77.8%)	2 (22.2%)	8.4 (1.6–44.8)	0.005
WHO staging during pregnancy/first contact				
Stage 1	11 (24.4%)	34 (75.6%)	1.0	
Stage 2	8 (22.2%)	28 (77.8%)	0.9 (0.3 – 2.5)	0.815
Stage 3	6 (33.3%)	12 (66.7%)	1.5 (0.5 –5.1)	0.474
Stage 4	2 (66.7%)	1 (33.3%)	6.2 (0.5 – 74.9)	0.152
Not known/documented	6 (50.0%)	6 (50.0%)	3.1 (0.8 – 11.6)	0.094
Timing of ARV initiation				
Before pregnancy	6 (15.0%)	34 (85.0%)	1.0	
First trimester	1 (8.3%)	11 (91.7%)	0.5 (0.1 – 4.8)	0.559
Second trimester	2 (28.6%)	5 (71.4%)	2.3 (0.4 – 14.5)	0.387
After delivery	13 (92.9%)	1 (7.1%)	73.7(8.1– 672.4)	<0.001
Not known	11 (26.8%)	30 (73.2%)	2.1 (0.7 – 6.3)	0.196
Gestational age ARVs were initiated	9 (15.3%)	50 (84.7%)	1.0	
During pregnancy	13 (92.9%)	1 (7.1%)	72.2 (8.4– 622.7)	<0.001
After delivery	11 (26.8%)	30 (73.2%)	2.1 (0.8 – 5.5)	0.196
Not known				
ARV regimens				
Monotherapy	12 (60.0%)	32 (40.0%)	2.3 (0.8-6.1)	0.107
Triple therapy	8 (40.0%)	48 (60.0%)	1.0	

Table 4 shows association between ARV initiation and perinatal transmission of HIV.Women with stage 4 disease and WHO staging not known or documented were more likely to transmit the virus perinatally than earlier stages though not statistically significant. [OR 6.2; 95% C.I 0.5-74.9; p value 0.152].Initiation of ARVs after delivery was significantly associated with perinatal HIV transmission [OR 72.2; 95%C.I 8.4-672.4; p <0.001].Use of monotherapy (AZT or single dose NVP was associated with perinatal transmission though not statistically significant [OR 2.3; 95%C.I 0.8-6.1; p value 0.107].

Table 5: Association between intrapartum factors and perinatal transmission of HIV

Variable	ELISA positive	ELISA negative	O.R(95% C.I)	P value
Duration of labour				
Less than 6 hours	22 (26.5%)	61 (73.5%)	1.0	0.424
More than 6 hours	9 (34.6%)	17 (65.4%)	1.5 (0.6 – 3.8)	
Presence of PROM				
Yes	22 (33.8%)	43 (66.2%)	2.1 (0.8 – 5.3)	0.110
No	8 (19.5%)	33 (80.5%)	1.0	
Episiotomy				
Yes	8 (24.2%)	25 (75.8%)	0.8 (0.3 – 1.9)	0.559
No	22 (29.7%)	52 (70.3%)	1.0	
Mode of delivery				
Caesarean section	5 (20.0%)	20 (80.0%)	1.0	0.372
Vaginal delivery	25 (29.1%)	61 (70.9%)	1.6 (0.6 – 4.9)	

Table 5 presents association between intrapartum factors and perinatal transmission of HIV.Duration of labour more than 6 hours was likely to be associated with perinatal HIV transmission [OR 1.5;95%C.I 0.6-3.8;p value 0.424].Presence of PROM was also likely to be associated with perinatal transmission[OR 2.1;95%C.I 0.8-5.3;p value 0.110],as was mode of delivery[OR 1.6;95%C.I 0.6-4.9;p value 0.372]Interestingly, episiotomy was associated with less perinatal transmission[OR 0.8 95%C.I 0.3-1.9;p value 0.559]None of the variables were statistically significant.

Table 6: Association between infant prophylaxis and feeding and perinatal HIV transmission.

Variable	Positive	Negative	OR (95% CI)	P value
Duration of infant NVP				
Less than 6 weeks	2 (8.3%)	4 (5.0%)	2.8 (0.5-17.3)	0.246
6 weeks	11 (45.8%)	62 (77.5%)	1.0	
>6 weeks	3 (12.5%)	9 (11.3%)	1.9 (0.4-8.1)	0.390
Non compliant	8 (33.3%)	5 (6.3%)	9.0 (2.5-32.7)	<0.001
Mode of feeding				
Exclusive breast milk	22 (68.8%)	36 (45.0%)	1.0	
Formula milk	8 (25.0%)	44 (55.0%)	0.3 (0.1-0.7)	0.008
Other feeds	2 (6.3%)	0 (0.0%)	-	

Table 6 shows the association between infant prophylaxis and feeding and perinatal HIV transmission. Duration of infant prophylaxis of less than 6 weeks [OR 2.8; 95% C.I 0.5-17.3; p value 0.246] and non compliance [OR 9.0; 95%C.I 2.5-32.7; p value <0.001] were associated with perinatal HIV transmission, non compliance being statistically significant. Formula milk was significantly associated with reduced perinatal HIV transmission [O.R 0.3; 95%C.I 0.1-0.7; p value 0.008]

Table 7: Factors independently associated with perinatal transmission of HIV

Variable	OR (95% CI)	P value
Gestational age ARVs were initiated		
During pregnancy	1.0	
After delivery	19.1 (1.9-194.2)	0.013
Not known	1.6 (0.5-4.9)	0.408
Counselling package		
Yes	0.1 (0.0-0.5)	0.003
No	1.0	

Table 7 presents factors independently associated with perinatal transmission of HIV.All the factors that were significantly associated with HIV infection in the association tests were subjected to logistic regression model. Delayed initiation of ARVs [O.R 19.1; 95%C.I1.9-194.2; p value0.013] and few counselling packages [O.R 0.195%C.I 0.0-0.5; p value0.003] were found to be factors independently associated with perinatal HIV transmission.

DISCUSSION

This was a study to determine the proportion of children who acquired HIV infection and the maternal characteristics associated with perinatal transmission of HIV.

A total of 114 HIV mother child pairs were recruited into the study. The number of mothers 30 years and below and above 30 years was same. Majority of the mothers were married, had attained primary school level and had some form of employment at 75.5%, 57%and 60% respectively. About a third (28.9%) of the 2 year old children in the sample size (33) was HIV positive. There were significant associations between delayed and few attendance of antenatal care, delayed mother ARV initiation and infant prophylaxis and mixed feeding with perinatal HIV acquisition. Multiple logistic regression analysis revealed predictors of perinatal transmission as delayed initiation of ARVs (p value 0.013) and few counselling packages (p value 0.003).

Fewer children whose mothers received antenatal care were likely to be HIV infected (25.5%) compared to the ones who did not attend clinic (75%), [OR 0.1; 95% CI 0.0-0.6; p value 0.010].This may have been due to early intervention through initiation of ARV prophylaxis or treatment for the mothers. Majority of the mothers in the study (90%) attended Antenatal clinic. This compares well with the KAIS report of 2012,where 96% of mothers had attended ANC. Kenya's health facility data indicates that 73% of pregnant women had attended at least one antenatal (ANC) visit in 2010 but survey data indicates that fewer will access at least 4 visits as recommended by WHO. According to a KDHS survey, 92% attended at least 1 ANC visit but only 47% attended at least 4 visits (KDHS 2008-2009).

Majority of the children whose mothers were initiated ARVs after delivery were more likely to acquire HIV infection compared to those whose mothers were initiated during pregnancy [OR 73.7; 95% C.I 8.4-622.7; p value <0.001].This may be as a result of no ARV protection during pregnancy and delivery hence a high risk of transplacental and intrapartum transmission of HIV.This may have been attributed to late or non attendance of ANC hence late ARV initiation.

Mothers who were started on monotherapy (either AZT during pregnancy or NVP during labour) were more likely to transmit the virus to their children compared to those who were started on triple therapy though the association was not statistically significant [OR 2.3; 95% C.I 0.8-6.1; p value 0.107]. This could be attributed to enhanced effectiveness in reducing maternal serum and breast milk HIVviral load, the strongest determinant of HIV transmission via breast milk (Mbori Ngacha 2001). This is comparable to the Kesho Bora Study, a randomized control trial which was conducted in Kenya, South Africa and Burkina Faso. It was investigating whether giving HAART to women whose CD4 count between 200-500 during pregnancy, labour and through 6

months of breastfeeding could reduce HIV transmission to the infant compared to short course therapy from 28 to 36 weeks gestation through one week post delivery .It found no difference in transmission rates from birth through the first week of life but found a significant reduction in risk of transmission by one year of age in the HAART group(6.1% vs.11.1% in the short course arm).This suggests that triple therapy could be incorporated into the PMTCT programmes in all health facilities in order to reduce MTCT of HIV.

Majority of the mothers who got information about vertical transmission of HIV were less likely to have HIV positive children than those who did not have information and the association was statistically significant [OR 0.1; 95% C.I 0.0-0.4; p value 0.001]. Similarly, mothers who received services package that included couple counselling and testing, infant feeding and nutritional counselling were less likely to have HIV infected children (14.9%) compared to their counterparts who did not receive the services (79.2%), [OR 0.1;95% C.I 0.0-0.2; p value <0.001].This may have been due to understanding the importance and ensuring compliance in taking the ARVs, prevention of co-infection by use of condoms, delivery under skilled birth attendants, infant prophylaxis and safer infant feeding methods. This is similar to a study done to determine the effect of partner involvement and couple counselling on uptake of interventions to prevent HIV-1 transmission at a Nairobi antenatal clinic (Farquhar et al 2004).The results showed that partner participation in VCT and couple counselling increased uptake of Nevirapine and formula feeding and couple counselling may be a useful strategy to promote HIV-1 prevention interventions.

The intrapartum factors associated with perinatal transmission of HIV included duration of labour, presence of premature rupture of membranes and vaginal delivery. Although the associations were not statistically significant, duration of labour was 1.5 times likely to be associated with perinatal HIV transmission; whereas presence of PROM was twice likely to be associated with transmission of HIV.A retrospective cohort study was done in Spain to determine the effect of duration of ruptured membranes(more than 6 hours)and prolonged labour(more than 5 hours).The results concluded that an increased duration of ruptured membranes increased perinatal HIV transmission when it was associated with prolonged labour.(Garcia T et al 2003).Moreover, results from a meta-analysis from 15 prospective cohort studies by the International Perinatal HIV group supported the importance of duration of membrane rupture as a risk factor for perinatal transmission.

Mode of delivery was related to risk of transmission, though the association was not statistically significant. Vaginal delivery had a slight increased risk of transmission of the HIV infection [OR 1.6;95% C.I 0.6-4.9]This may have been due to non practice of safer intrapartum measures considering some mothers had home deliveries. Studies have shown that with effective ARV treatment for prophylaxis antenatally, vaginal delivery can be undertaken as the risks of transmission are reduced due to low viral load levels in the blood (Shah 2006, Briand et al 2010).

More than half of children who were delivered at home were HIV infected (57.9%) compared to those that delivered in the health facility (17.9%), [OR 5.5; 95% CI 2.0-15.2; p value 0.001].This was despite majority of them having received antenatal care. This was similar to the national trend, where less than half of pregnant women (43%) delivered with a skilled birth attendant

(KDHS 2008-2009). This results in minimal practice of safer delivery practices therefore enhancing transmission of the HIV virus to the infant.

Non compliance in giving the infant prophylaxis with nevirapine was 9 times associated with perinatal transmission of HIV ,the association being significant[O.R 9.0;95% C.I 2.5-32.7;p value<0.001].HIV transmission in breastfeeding mothers is 20-25% without any intervention.Nevirapine,commenced after delivery of the infant confers protection against transmission of the HIV infection especially in the breastfeeding period. The HIVNET 012 study marked the beginning of use of infant prophylaxis with Nevirapine. It demonstrated that a short intrapartum/neonatal dosage of nevirapine reduced the risk of transmission in breastfeeding by47% at 14-16weeksand by 42% at 18 months compared to a short intrapartum/neonatal regimen of AZT.Several other studies have evaluated longer term daily Nevirapine prophylaxis to the infant an all show that extended nevirapine prophylaxis for breastfeeding infants is more effective than single dose Nevirapine in reducing both HIV infection and infant mortaliy,especially in those infants whose mothers are not receiving antiretroviral therapy.(Bedri A et al 2008,Kumwenda N.I et al 2008,Chasela CS et al 2010).Hence, there is need for infant prophylaxis with Nevirapine to reduce postnatal transmission rates even though the mother is not on antiretroviral treatment.

In this study, infant feeding using formula milk was associated with lower risk of perinatal transmission of HIV ,the association being statistically significant[O.R 0.3;95% C.I0.1-0.7;p value 0.008].This could be attributed to the absence of risk of transmission through breastfeeding. Initial studies had shown formula feeding was associated with lesser risk of mother to child transmission of HIV than breast milk. However, the effectiveness of ARVs to reduce transmission through breastfeeding has resulted in major changes in this regard. The Mitra Study was a non randomized prospective cohort study on HIV positive breastfeeding women, who were were treated with triple therapy consisting of Zidovudine, Lamivudine and Nevirapine for 6 months with abrupt weaning. The results showed that HAART given in late pregnancy and during breastfeeding resulted in a low postnatal HIV transmission. (Kilewo C et al 2009). The WHO recommends breastfeeding exclusively for the first 6 months of life, introduce complementary foods thereafter and continue breastfeeding for the first 12 months of life. Avoidance of breastfeeding should only be recommended for HIV infected women if replacement feeding is affordable, feasible, acceptable, safe and sustainable (AFASS).

From the logistic regression, delayed initiation of ARVs was a predictor of perinatal HIV transmission, [OR 19.1; 95% C.I 1.9-194.2; p value 0.013]. Similarly, giving comprehensive counselling was a predictor of HIV free outcome, OR 0.1 (95% CI 0.0-0.5). All the other factors were not independently associated with perinatal HIV transmission.

During the study, there were some limitations that were encountered. The study respondents were both from the facility and also neighbouring health facilities. This may have had an impact on validity of the results as the ones who had been on follow up in the facility and the ones referred from the peripheral facilities may have had different background characteristics. However, sequential recruitment of the HIV positive mothers was done daily as without prior information on whether they were originally from the facility or were referrals from other health facilities.

During analysis of the results, some variables had wide confidence intervals meaning the sample size was not sufficient to give a precise Odds Ratio. However; this does not invalidate the findings.

CONCLUSION

There was significantly less transmission of HIV to children whose mothers were initiated ARVs before or during early pregnancy and received counselling on infant prophylaxis and nutrition, couple testing and use of condoms during pregnancy to prevent co infection.

RECOMMENDATIONS

The findings in this study are aimed to put more emphasis on empowering all health facilities with PMTCT programmes which ensure early initiation of ART to HIV positive pregnant mothers, more comprehensive counselling package and follow up postnatally in the same facilities for continuity of care.

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APPENDIX 1

QUESTIONNAIRE ON MATERNAL PREDICTORS OF PERINATAL TRANSMISSION OF HIV AT THIKA LEVEL 5 HOSPITALS.

DATE *(did/mm/by)* ……../……/……. Serial Number……

PCR of child……..

SECTION A: BIODATA

1. Age ☐ (in complete years)

1. Less than 20 years 2.21-30 years 3.31-40 years 4.more than 40 years

2. Marital Status ☐

1. Single 2.married monogamous 3.married polygamous 4.divorced/separated 5.widowed

3. Education level ☐

1. None 2.primary 3.secondary 4.tertiary

4. Occupation ☐

1. Unemployed 2.casual worker 3.formal employment 4.self employed

5. Parity ☐

1.1-2 2.3-4 3.more than 4

6. Number of children alive ☐

1. All 2.most 3.some 4.none

SECTION B: PARTNER HISTORY

7. Age of partner ☐ years Not known ☐

8. Partners highest level of education ☐

1. None 2.primary 3.secondary 4.college/post secondary 5.not known

9. Partners main source of income ☐

1. Salaried job 2.self employed 3.farming 4.other (specify) 5.Don`t know

10. Partner testing ☐

1. Seropositive 2.seronegative 3.not tested 4.not known

SECTION C: ANTENATAL CARE AND DELIVERY

11. Any antenatal care received during this pregnancy?

☐ Yes ☐ No

12. Place antennal care received ☐

1. Own home 2.government hospital 3.government dispensary 4.mission/church hosp/clinic

5. nursing/maternity home 6.someone else`s home 7.Govt.health centre/clinic

7. Other public 8.private hospital/clinic 9.other (specify)

13. Place of delivery ☐

1. Home 2.government hospital 3.government dispensary 4.mission/church hosp/clinic

5. nursing/maternity home 6.someone else`s home 7.govt health centre/clinic 8

8. Private hospital/clinic 9.othr private medical 10.other (specify)

14. Time taken to reach delivery facility

☐ Hour's ☐ minutes

15. If delivery not in a health facility, assisted by ☐

1. A nurse/doctor 2.Traditiona birth attendant 3.communtiy health worker 4.unassissted

5. Other (specify)

16. Mode of delivery ☐

1. Caesarean section 2.vaginal delivery

SECTION D: PMTCT CARE RECEIVED

17. CD4 count during pregnancy/first contact ☐

1. Less than 350 2.350-500 3.more than 500 4.not known

18. Viral load during pregnancy/ at 36 wks ☐

1. Less than 1000copies/ml 2.more than 1000copies /ml 3.not known

19. WHO staging during pregnancy /first contact ☐

1. Stage 1 2.stage 2 3.stage 3 4.stage 4 5.not known/documented

20. At what gestational age ARVS were initiated ☐

1. before pregnancy 2.first trimester 3.second trimester 4.third trimester 5.during delivery 6.after delivery

21. Duration of labour ☐

1. Less than 6 hrs 2.6-12 hours 3.12-24 hours 4.more than 24 hours

22. Presence of PROM ☐

1. Yes 2.no 3, not known

23. Presence of choriamnionitis ☐

1. Yes 2.no 3.not known

24. Episiotomy ☐

1. Yes 2. No 3.not known

25. Drugs taken during pregnancy, labour to prevent mother to child transmission of HIV ☐

1. Nevirapine 2.zidovudine 3lamivudine 4.combivir 5.kaletra 6.nelfinavir 7.efavirenz 8.stavudine 9.didanosine 10. AZT/3TC/EFV 11.AZT/3TC/NVP

26. Infant prophylaxis with ARVS ☐

1. Yes 2.no 3.not known/documented

27. If yes, which drugs?

Nevirapine 1.yes 2.no ☐

AZT 1.yes 2.no ☐

Septrin prophylaxis 1, yes 2.no ☐

Multivitamins 1yes 2.no ☐

28. Duration which ARVS for infant prophylaxis were taken ☐

1. Once 2.7 days 3.4 weeks 4.6 weeks 5.other

SECTION E: NEONATAL HISTORY

29. Date of delivery

Dd……. Mm…… yyyy …….

30. Mode of feeding after delivery ☐

1. Exclusive breast milk 2.formula milk 3.cow milk 4water 5.other feeds

31. Frequency if breastfeeding ☐

1. on demand/more than 6 times 2. 4-6 times 3.2-3 times 4.less than 2 times

SECTION F: FAMILY PLANNING HISTORY

32. Method used before this pregnancy ☐

1. OCPS 2.IUD 3.injections 4.implant 5male condom 6.female condom

7. Natural method 8.withdrawal 9.other

33. FP method after delivery ☐

1. Female sterilization 2.male sterilization 3.pill 4.IUD 5.injections 6.implant 7.male condom 8.female condom 9.natural method 10.withdrawal 11.other (specify)

34. Reason for pregnancy if HIV positive status known prior to pregnancy ☐

1. Choice 2.inability to access FP 3.FP method failure

SECTION G: HIV COUNSELLING, TESTING AND EDUCATION

35. When status was discovered ☐

1. before pregnancy 2.during ANC 3.during delivery 4.after delivery

36. Place testing done ☐

1. ANC 2.labour ward 3.postnatal ward 4.postnatal clinic 5.FPclinic 6.Child welfare clinic 7.VCT 8.wards 9.door to door 10.other place (specify)

37. Information in pregnancy or after delivery about:

Vertical transmission 1.yes 2.no ☐

Syphilis testing 1.yes 2.no ☐

Use of condoms in pregnancy to prevent co-infection 1.yes 2.no ☐

38. Services received during pregnancy or within 3 days after delivery ☐

1. Yes 2.no

Couple HIV counselling and testing

Infant feeding counselling

Presumptive malaria treatment

Insecticide treated nets

Testing for syphilis

Treatment for sexually transmitted infection

Nutritional counselling

Screening for TB (asked if coughing, CXR done or sputum taken)

APPENDIX 2

CONSENT FORM FOR PARTICIPATION IN A STUDY ON MATERNAL PREDICTORS OF PERINATAL TRANSMISSION OF HIV AT THIKA LEVEL 5 HOSPITAL.

Study No. …….

I am Dr Mary Ingabo,a, a postgraduate student at the University of Nairobi, Department of Obstetrics and Gynaecology.Iam carrying out a study to determine factors influencing perinatal HIV acquisition and will use this information to help us manage patients in future. I hope you will feel free to discuss certain information with me and all the information you will provide will not be divulged to anyone else nor will there be penalty for refusing to respond to any of the questions. This study will not cost you any money and no material benefit will be given in case you participate. Declining to participate in the study will not affect you or your child's quest to seek for treatment in this hospital. I hope that you will help me gather the information I require.

I, study number……having been informed about the study/read all the above and what it entails, do wilfully consent to participate in the study.

Client signature/Right thumb print…… Date……

Investigator signature…….. Date……

In case you have any questions or need further information, please contact the following persons:

1. Principal investigator-

Dr. Mary Ingabo,

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3. KNH/UoN Ethics and Research Board

Kenyatta National Hospital

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APPENDIX 3

KUKUBALI/KUKATAA KUSHIRIKI KATIKA UCHUNGUZI

Mimi ni Daktari Mary Ingabo;mkufunzi wa masomo ya juu katika idara ya afya ya wanawake katika Chuo Kikuu cha Nairobi.

Nafanya utafiti kuhusu chanzo cha watoto kuambukizwa virusi vya ukimvi yaani HIV kutoka kwa mama zao wakati wanapozaliwa.Huu atafiti utatuwezesha kupata taarifaambayoitatumika kuelekeza nuamuzi na utengenezaji wa miundo msingi ya kusaidia kupunguza idadi ya watoto wanaoambukizwa virusi vya ukimwi nyakati zijazo.Utafanywa kwa njia ya kuuliza maswali ambayo yameandikwa kwenye karatasi na majibu tutakayopata yatawekwa siri.

Kushiriki kwenye atafiti huu ni hiari, kwa hivyo, hakuna atakayekulazimu kushiriki.Hakuna malipo yoyote utakayotozwa au kulipwa kwa kushiriki.Kukataa kushiriki kwa uchunguzi huu hakutasababisha wewe au mtoto wako kunyimwa huduma au kutengwa kwa njia yoyote ile.

Mimi, nambari ya uchunguzi…….. nimesoma/nimeelezwa yaliyomo kwenye kibali hiki,na ninakubali kushiriki kwenye utafiti huu kwa hiari yangu.

Sahihi ya mshiriki …….. Tarehe ……

Shahidi …… Tarehe ……..

Kwa maswali au maelezo zaidi,wasiliana na wahusika wa utafiti huu kupitia nambari hizi:-

Mchunguzi mkuu

Daktari Mary Ingabo

0720218819

Wasimamizi

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3.Jopo la usimamizi wa uchunguzi wa kisayansi la Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi

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