EXTENT OF ADHERENCE TO NATIONAL GUIDELINES IN PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV

THESIS IN PARTIAL FULFILMENT OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY
UNIVERSITY OF NAIROBI 2010

SUBMITTED BY .

DR. WYCLIFFE AKIKUVI MUSALIA

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DEDICATION

This book is dedicated to my wife Carol, my daughter Christine and son Musalia Jr whose love and patience has made my work enjoyable.

To my late grandmother Priscillah, whose love and commitment to care for others inspired me to become a doctor.

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As I conclude my masters training in obstetrics and gynaecology, I wish to thank the Almighty God for enabling me to complete my studies.

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To you all and the many others not mentioned, I say Asante sana and may God bless you.

DECLARATION

This is to certify that this thesis study is my original work and has been read by my supervisors.

SIGNATURE.....

DATE.....16·11·09.....

DR. WYCLIFFE AKIKUVI MUSALIA
MBChB
UNIVERSITY OF NAIROBI

CERTIFICATE OF SUPERVISION

This is to certify that Dr. Wycliffe A. Musalia researched upon this thesis under my guidance and supervision and this book is submitted with my approval.

Signature.....

Date.....13/11/09.....

DR. ALICE MUTUNGI
MBCHB, MMED, MPH, MSc. Repro. Biology
SPECIALIST OBSTETRICIAN AND GYNAECOLOGIST
UNIVERSITY OF NAIROBI

CERTIFICATE OF SUPERVISION

This is to certify that Dr. Wycliffe A. Musalia researched upon this thesis under my guidance and supervision and this book is submitted with my approval.

Signature.....

Date.....16-11-09

DR ONESMUS GACHUNO

MBCHB, MMED.

SPECIALIST OBSTETRICIAN AND GYNAECOLOGIST

UNIVERSITY OF NAIROBI

CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Wycliffe A. Musalia, Mmed student registration number H58/7637/06 in Obstetrics and Gynaecology department, University of Nairobi [2006-2010]. The research was carried 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.

Signature..... **Date**.....6th Jan 2010.....

PROF. KOIGI KAMAU
ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNAECOLOGY
CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST
CHAIRMAN,
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
UNIVERSITY OF NAIROBI

LIST OF ABBREVIATIONS

AFASS	AVAILABLE FEASIBLE ACCEPTABLE SAFE SUSTAINABLE
AIDS	ACQUIRED IMMUNE DEFICIENCY SYNDROME
ART	ANTI-RETROVIRAL THERAPY/TREATMENT
ARV	ANTI-RETROVIRAL
AZT	ZIDOVUDINE
DRH	DIVISION OF REPRODUCTIVE HEALTH
HAART	HIGHLY ACTIVE ANTI-RETROVIRAL THERAPY
HIV	HUMAN IMMUNO-DEFICIENCY VIRUS
MTCT	MOTHER TO CHILD TRANSMISSION
NASCOP	NATIONAL AIDS & STI CONTROL PROGRAMME
NVP	NEVIRAPINE
PACTG	PAEDIATRIC AIDS CLINICAL TRIAL GROUP
PCR	POLYMERASE CHAIN REACTION
SD-NVP	SINGLE DOSE NEVIRAPINE
TWG	TECHNICAL WORKING GROUP
UNGASS	UNITED NATIONS GENERAL ASSEMBLY SPECIAL SESSION
WHO	WORLD HEALTH ORGANIZATION

DEFINITION OF TERMS

ARV prophylaxis for PMTCT: The use of anti- retroviral drugs other than for treatment to prevent possible infection of the baby by HIV virus from the mother.

HAART: The life long use of a combination of anti-retroviral drugs to treat an individual infected with the HIV virus.

Optimal PMTCT care: refers to clinical and nursing care offered to the HIV positive pregnant woman that totally adheres to the national guidelines for PMTCT; and is likely to significantly reduce the risk of MTCT of HIV.

Poor PMTCT care: Refers to care that does not adhere to the national guidelines for PMTCT; and has grave omissions that are likely to increase the risk of mother to child transmission of HIV.

Artificial rupture of membranes [ARM]: It is the artificial release of the amniotic fluid from gestational sac by aseptic technique. It can be done manually with the gloved finger during digital vaginal examination or with the aid of Kocher's forceps or an amnicot.

Prolonged rupture of membranes: In the setting of obstetric care for an HIV-positive parturient, rupture of membranes for >4 hours before delivery is prolonged.

ABSTRACT

Background: Mother-to-child transmission [MTCT] of HIV-virus contributes to over 90% of the paediatric HIV infections. Approximately 50% of this vertical transmission occurs during labour and delivery. The national guidelines for PMTCT make recommendations for specific interventions so as to reduce perinatal transmission. Data on adherence to the guidelines by caregivers and quality of PMTCT care is however limited.

Study objective: To evaluate the extent to which PMTCT care offered to HIV positive women admitted for delivery at KNH and PMH adheres to National Guidelines in order to reduce vertical transmission of HIV during labour and delivery.

Study design: Cross-sectional survey.

Study setting: The labour ward at Kenyatta National Hospital and Pumwani Maternity Hospital.

Study population: All consenting HIV positive women admitted to the labour wards at KNH and PMH and planned for delivery.

Study period: Mid January to mid April 2009

Materials and Methods: Data was obtained through observation of care given, direct interviews, and by perusal of clinical records. These information was entered into a structured questionnaire. Data was analysed using SPSS software.

Main outcome measures: Extent to which PMTCT interventions are offered and level of adherence to the National Guidelines.

Results: A total of 370 HIV-positive women were recruited into the study, of whom two hundred and sixty six were from Pumwani Maternity Hospital and one hundred and four

were enrolled at Kenyatta National Hospital. Three hundred and fifty seven [96.4%] of them had been counselled on vertical transmission and while two hundred and five [55.4%] of them had HIV disease staging by CD4 cell count. There were no significant differences between the two study sites in the extent of counselling on MTCT (p=0.398) and HIV disease staging by CD4 testing (p=0.28). Three hundred and forty nine [94.3%] of them were offered varied ARV regimens for PMTCT of whom 101[27.3%] were on HAART. A total of 94 women were given single dose nevirapine and use of efficacious combination prophylaxis was limited. Overall two hundred and sixty eight women [73%] had spontaneous vertex delivery. An episiotomy rate of 7% was observed and no vacuum delivery was recorded. A caesarean section rate of 27.6% was recorded with PMTCT as an indication in almost half of the cases. Significantly more women delivered at KNH were offered HAART (p<0.001) and elective caesarean delivery (p<0.001).

Conclusion: A great majority of HIV positive women admitted for delivery received counseling on vertical transmission. HIV disease staging was however not done routinely and use of HAART and efficacious combination ARV prophylaxis was limited. Although efforts to comply with the recommendation for modified intrapartum care were noted at both facilities, optimization of interventions for PMTCT is significantly more at KNH than at PMH.

Key words: National Guidelines, PMTCT care, HIV-positive.

1.0 BACKGROUND AND LITERATURE REVIEW

1.1 Introduction

HIV/AIDS pandemic is one of the greatest challenges of this century that threatens the health of mankind. In Sub-Saharan Africa where HIV prevalence is highest, women are most affected with an average of 13 infected women for every 10 infected men. This difference is more marked among young people aged 15-24 years with three out of four people living with HIV/AIDS being female [1]. In Kenya there were an estimated 2.3 million people infected with HIV by 2003 [2]. Currently the prevalence of HIV among pregnant women attending antenatal care at various PMTCT sites is approximately 7.8% [3]. Although the Kenya Demographic Health Survey of 2003 had shown a decline in HIV prevalence [4], the Kenya AIDS Indicator Survey [KAIS] 2008 reported a general trend towards a rise in HIV prevalence [5].

In 2005 alone there were 700000 new cases of HIV infection in children under the age of 15 years [6]. About 90% of HIV infected children acquire the virus from their mother during pregnancy and child birth [7, 8]. Each day an estimated 1600 children born to HIV positive women become infected. 1500 of these babies are in sub-Saharan Africa [9].

In Kenya an estimated 141101 births occurred to HIV positive women in 2007. Approximately 45640 of these babies are at risk of acquiring the virus assuming a transmission rate of 40% if there is no intervention [10]. The long term care of these infants is not only a major burden to the health care system but also the affected families. Prevention of new infections is therefore one of the key strategies in the National HIV/AIDS Strategic Plan [11].

1.2 Mother-To- Child Transmission

The risk of mother-to-child transmission (MTCT) of HIV virus during the antenatal period of pregnancy is (5-10%). During breastfeeding the risk is 10-15%. In the intrapartum period the risk is (10-20%). Without interventions to reduce MTCT, the estimated risk of transmission ranges from 15%-25% in non breastfeeding populations and 25%-40% in breastfeeding populations [12].

Up to 40-50% of MTCT occurs during labour and delivery [13]. It is estimated that locally approximately 20000 babies acquire the virus intrapartum. Risk factors for transmission include high levels of maternal viral load, low CD4 level, vaginal delivery with high viral load, prematurity and low birth weight, prolonged rupture of membranes and breastfeeding [14].

Other recognized risk factors include maternal anemia and malnutrition. Presence of genital ulcers or breaks in the skin and mucous membranes including episiotomy all increase the risk of MTCT of HIV virus.

Viral load is the most important risk factor affecting transmission during pregnancy, labour and delivery, and the breastfeeding period. The risk is less than 5% if there are <1000 copies/ml. 15-25% if there are 1000-50000 copies/ml and above 40% if the viral load is >100000 copies/ml [15].

Presence of HIV virus in the genital tract has been shown to be an independent risk factor for MTCT [16]. Studies have reported that the highest level of genital tract HIV shedding are observed among those who would qualify for initiation of antiretroviral therapy based on World Health Organization [WHO] guidelines. Substantial levels of shedding are also observed among asymptomatic women with CD4<350/ml. This poses an increased risk especially among those perceived to be generally healthy and more so those who opt for vaginal delivery without receiving antiretroviral prophylaxis [17].

1.4 Prevention of Mother-to-Child Transmission [PMTCT]

It has been shown that anti-retroviral prophylaxis of any kind given during pregnancy and continued intrapartum greatly reduces transmission rates by lowering the level of viraemia. Indeed many antiretroviral drug regimens have been studied and protocols formulated for use as monotherapy, combination therapy or as HAART [18-24].

With implementation of recommendation for universal prenatal HIV counseling and testing, antiretroviral treatment [ART] and combination prophylaxis, elective caesarean delivery, and avoidance of breastfeeding, MTCT of HIV has decreased to

<2% in resource rich countries [25]. Several studies have also shown that the efficacy of ARV prophylaxis in preventing in-utero and intrapartum transmission is diminished in breastfeeding populations due to postnatal acquisition through breast milk and morbidity associated with mixed feeding [25].

In most resource limited countries especially sub-Saharan Africa, national prevention of MTCT [PMTCT] programs are built around single dose Nevirapine [SD-NVP] to the mother during labour and baby within 72 hours after birth. From a public health standpoint this regimen has been adopted by World Health Organization [WHO] due to ease of administration and its relative high efficacy as monotherapy (47% reduction in perinatal transmission rates). The addition of SD-NVP significantly improves the efficacy of any short-course antiretroviral regimen especially in breastfeeding women [26].

More recent studies have shown significant reduction in risk of MTCT with the use of HAART based regimens initiated antenatally as treatment or prophylaxis and extended to cover the breastfeeding period [27, 28, 29, 30].

1.5 PMTCT Guidelines in Kenya

The Kenya national PMTCT guidelines issued in 2009 recommend a four-pronged approach termed PMTCT-plus [10].

Core interventions include:

- Primary prevention by promotion of safer sexual practices and voluntary HIV counseling and testing
- Prevention of unintended pregnancies among HIV infected women through provision of adequate contraception
- Timely interventions for HIV positive pregnant women to reduce MTCT by use of antiretrovirals, safer delivery and infant feeding practices.
- Care and support of women, children and families affected by HIV/AIDS

The national guidelines recommend on use of HAART during pregnancy when indicated to improve the health of the woman in addition to reducing vertical transmission while ARV prophylaxis is offered to women who do not need treatment.

This recommendation is based on the fact that untreated and advanced HIV infection is known to cause infected women to suffer increased risk morbidity and mortality from opportunistic infections more so as the CD4 cell count falls to < 300. Advanced HIV infection with low CD4 cell counts also negatively influences pregnancy outcomes. Studies have shown that there is an increased incidence of abortion, chorioamnionitis and premature rupture of membranes among HIV infected pregnant women especially those with stage III and IV disease who are not on treatment with HAART. There is also increased risk of poor fetal outcomes including prematurity, low birth weight, intrauterine growth restriction and perinatal death among these women [43-49].

However with use of HAART and treatment of opportunistic infections there is significant improvement in the health status, maternal survival and birth outcomes of the infected women [25].

The national guidelines therefore recommend on HIV disease staging of all positive women in order to provide comprehensive clinical care. If laboratory facilities are available or accessible, baseline CD4 cell count testing should be done. Although the W.H.O clinical staging system is recommended in resource constrained settings studies have shown that when used alone up to 11.8% of patients with CD4 cell count <200 are missed out [31]. Combining the clinical staging system with laboratory CD4 testing is therefore preferred. All pregnant women with WHO clinical stage I and II disease with CD4 cell count of 350 or lower should be started on treatment with HAART. All pregnant women with WHO clinical stage III or IV disease should be put on treatment irrespective of CD4 cell count.

Combination ARV prophylaxis is recommended for PMTCT as it has been shown to be superior to monotherapy. HIV positive women attending the antenatal care clinic should therefore have disease staging and subsequently offered appropriate ARV regimen.

One of the ARV prophylaxis regimen recommended is AZT 300mg twice daily starting at 28 weeks or soon thereafter as possible. This is to be continued intrapartum at 300mg every 3 hours until delivery or as 600 mg stat dose. In either case the addition of SD-NVP 200mg at onset of labour is recommended to improve efficacy. The infant should receive NVP 2mg/kg stat immediately or within 72 hours of delivery+ AZT 4mg/kg twice daily for 6 weeks.

Women tested late in pregnancy or intrapartum and confirmed positive should be offered the SD-NVP regimen and 2mg/kg to the baby immediately after birth or within 72 hours.

1.5 Intrapartum PMTCT Interventions

Two aspects of obstetric care are critical to the success of intrapartum PMTCT interventions [10, 32].

The first aspect is the optimal uptake of ARV regimen peripartum. Correct use of antiretroviral drugs either as prophylaxis or treatment requires adherence/compliance to the recommended dosage schedule. Occasional missed doses, late dose or drug holidays all contribute to non compliance. Kiarie et al in a study on compliance with the ARV regimen for PMTCT at Kenyatta National Hospital reports that compliance was better with antenatal zidovudine (80%) than intrapartum zidovudine (44%) [33] Such non compliance results in sub-therapeutic concentrations with increased risk of MTCT and development of drug resistant viral strains.

The second critical aspect is the modification of routine intrapartum obstetric care. The practice of safe delivery in the setting of HIV/AIDS requires not only a skilled attendant at birth but timely and cautious intervention with the highest level of universal precaution. This is in view of the fact that obstetric complications like prolonged rupture of membranes (>4hours before delivery), chorioamnionitis and repeated vaginal examinations increase the transmission rates. It has been shown that women with prolonged rupture of membranes have an increased risk of vertical transmission regardless of whether they received AZT or combination therapy [34]. Unduly prolonged labour with attendant birth asphyxia and birth injuries also compromises the natural defenses of the neonate increasing the risk of transmission.

Elective caesarean delivery is recommended as it has been shown to reduce MTCT independently of other factors. Locally elective caesarean delivery is not readily available in most health facilities. The national guidelines however do recommend that in situations in which labour is expected to be prolonged or induced, consideration should be given for elective caesarean delivery [10].

1.8 Monitoring and Evaluation of PMTCT services in Kenya

PMTCT services in Kenya are monitored through specific registers that provide details on number of clients served. Examples of these are: antenatal client register, counseling register, ARV register and delivery register. Data from these registers is submitted to NASCOP on a quarterly basis for compilation of national figures.

The National PMTCT Programme recognizes the need for evaluation of the PMTCT service so as to attain and maintain quality, acceptability, efficiency and effectiveness. A national impact evaluation of PMTCT service requires enormous resources [manpower, time, equipment and capital]; however inferences can be drawn from operational research.

2.0 STUDY JUSTIFICATION

In the 26th United Nations General Assembly Special Session on AIDS [UNGASS], monitoring and evaluation [M&E] of PMTCT services was emphasized. Majority of the countries reported that monitoring and evaluation of national activities was still a challenge due to limitations of capacity and information systems.

Locally, although there has been rapid scale up of PMTCT services over the last four years, the program still faces many challenges of commodity logistics, manpower and inadequate documentation of interventions offered by caregivers to reduce MTCT. Data available on the program though providing figures on service coverage is still limited in scope as it does not provide details on quality of care at each PMTCT site.

This study evaluated the PMTCT care offered at Kenyatta National Hospital and Pumwani Maternity Hospital in order to document the extent to which specific interventions are offered to reduce perinatal HIV transmission. Inferences are also

made on the quality of PMTCT care at these facilities.

The two hospitals are leading model institutions for the PMTCT program and were among the first public health facilities to initiate PMTCT services based on the National Guidelines for PMTCT. Evaluation of PMTCT care offered to HIV positive women admitted for delivery at these facilities provided an opportunity to determine the impact of the program at patient management level.

It is hoped that the results of this study and its recommendations will be used to formulate policies for improvement of PMTCT services at these facilities and others in the country.

2.1 Study Question

To what extent is PMTCT care offered to HIV positive women admitted for delivery at KNH and Pumwani Maternity Hospital in line with national guidelines for PMTCT in order to reduce perinatal HIV transmission?

3.0 STUDY OBJECTIVES

3.1 Broad objective

To evaluate the extent to which PMTCT care offered to HIV positive women admitted for delivery at KNH and PMH adheres to National Guidelines in order to reduce mother to child HIV transmission.

3.2 Specific objectives.

1. To determine the extent to which HIV positive women are offered counseling on vertical transmission.
2. To determine the preferred options on mode of delivery and infant feeding after counseling on mother-to-child transmission.
3. To determine the extent of clinical or laboratory HIV disease staging among HIV positive pregnant women admitted for delivery.
4. To determine the extent to which HIV positive women are offered ARVs for prevention of vertical transmission and the specific regimen used.
5. To determine the extent to which appropriate obstetric interventions are practiced in order to facilitate safe delivery of HIV positive women.

4.0 METHODS AND MATERIALS

4.1 STUDY DESIGN

This was a cross sectional survey in which all consenting HIV positive pregnant women presenting for delivery at the study sites for delivery were enrolled into the study at the earliest opportunity. It was both a process and outcome evaluation that reviewed the PMTCT care offered through direct interviews, review of clinical records and direct observation. The specific interventions offered to reduce vertical transmission were determined and degree of compliance and adherence with specific recommendations for modified intrapartum care assessed. Errors of omission and lapses in clinical care resulting in suboptimal care are described.

4.2 STUDY AREA

This study was conducted at Kenyatta National Hospital and Pumwani Maternity Hospital. The two were chosen because of their high volume of deliveries that allowed the research to attain the desired sample size. Both are public health facilities that have implemented the PMTCT programme following the national guidelines.

4.2.1 Kenyatta National Hospital [KNH]

Kenyatta National Hospital is the largest referral hospital of the Republic of Kenya. It is a 1400 bed teaching hospital for the College of Health Sciences, University of Nairobi and the Kenya Medical Training College. In 2007, 6850 women delivered in Kenyatta of whom~ 500 were HIV positive.

PMTCT services at Kenyatta Hospital

PMTCT services are offered based on the national guidelines for PMTCT. Voluntary HIV counseling and testing service is offered to all pregnant mothers on an opt-out basis. HIV positive mothers attending ANC at this faccility are offered HAART as prophylaxis or treatment based on CD4 cell count. Counseling on mode of delivery and infant feeding is also offered. At 38 weeks gestation, those opting for elective caesarean section are admitted for delivery. Those opting for vaginal delivery are advised to come when in labour.

Use of single dose Nevirapine [SD-NVP]:

Single dose Nevirapine is limited to women who present after 38weeks or those

counseled and tested in early labour.

Intrapartum care

All mothers are managed as per national guidelines **[appendix III].**

4.2.2 Pumwani Maternity Hospital

Pumwani Maternity Hospital is located in Nairobi, the capital city of Kenya. It is the largest maternity hospital in East and Central Africa and is run by the Nairobi City Council. In 2007, 18225 deliveries were conducted in this hospital; approximately 1200 were to HIV positive women.

PMTCT services at Pumwani Hospital

PMTCT services at Pumwani Maternity Hospital follow the National Guidelines for PMTCT. Like at Kenyatta, mothers are counseled and tested at the 1st antenatal visit on an opt-out basis.Those testing positive are further informed of the available options for preventing vertical transmission.

CD4 cell count test is subsequently done and those qualifying for ART treatment are started on it. Those who require ARV prophylaxis are started on AZT from 28weeks or soon after. Further counseling on mode of delivery and infant feeding is offered. Elective caesarean section delivery is however not offered routinely. Mothers are subsequently followed up in the ante-natal clinic until at term gestation when they are advised to take the single dose 200mg Nevirapine tablet when labour pains start or drainage of liquor amnii is noted. They are then required to report to hospital immediately.

Intrapartum obstetric care

Like at Kenyatta National Hospital, intrapartum obstetric care follows the National PMTCT Guidelines [see appendix III]

4.3 STUDY POPULATION

The study population was composed of consenting HIV positive pregnant women admitted to the labour ward at Pumwani Maternity and Kenyatta National Hospital for delivery.

4.4 EXCLUSION CRITERIA

i) HIV positive women who delivered before arriving to hospital.

ii) HIV positive pregnant women with preterm labour or preterm premature rupture of membranes not planned for immediate delivery.

iii) HIV positive women admitted with other medical conditions and not planned for immediate delivery.

iv) HIV positive women who were too sick to consent.

4.5 SAMPLE SIZE

Sample size was calculated using the formula

$$n = \frac{Z^2 a/_2 \times P(1-P)}{d^2}$$

Where:

n = minimal number of parturient to be included in the study

$Za/2$ = the cut off points along the x-axis of the standard normal probability distribution that represents probabilities matching the 95% confidence interval (1.96).

P = proportion of HIV-positive pregnant women offered optimal PMTCT care [40%]. This is based on other studies that have reported ~40% adherence to the recommended PMTCT care [36,37,39]

d = Minimum acceptable error margin of 5 %, (± 0.05).

Substituting the values in the formulae above, the target sample size was

n=369 parturients

4.6 Distribution of sample size

In 2007 approximately6850 women delivered at KNH, while 18225 women delivered at Pumwani Maternity Hospital giving a volume of deliveries ratio of ~ 1:2.6

To avoid bias and ensure the sample was evenly distributed, eligible clients were recruited simultaneously at K.N.H and Pumwani Maternity Hospital with weighted target 1:2.6. Using this formula a total 370 HIV-positive women were recruited into the study, 104 women at KNH and 266 at Pumwani Maternity.

4.7 Study period: This study was carried out from mid January to mid April 2009 when the target sample size was attained.

4.8 DATA COLLECTION

Data was collected on 24-hour basis by the principal researcher and four research assistants.

4.8.1 DATA COLLECTION TOOLS

Data was collected by means of a structured open ended questionnaire [appendix I]. The main parts of the questionnaire were:

a] Social demographic

b] Obstetric history

c] Health status and ARV uptake on admission.

d] Obstetric evaluation on admission

e] Monitoring of labour

f] Conduct of delivery

g] Maternal outcome

h] Partogragh

To avoid repetition all the questionnaires were serialized from 01 to 370

4.8.2 DATA COLLECTION PROCEDURE

Each day during the study period the research team reported to the assigned labour ward on a 12-hour shift commencing at 8.00am. The HIV status of every woman admitted for delivery was ascertained after perusal of the labour ward admissions register, the individual clients' file/antenatal card and nursing cardex. In cases where there was no record of HIV sero- status, the primary nurse was consulted for confirmation.

A record of all HIV positive women admitted in labour ward each day and planned for delivery was maintained by the principal researcher or his assistant. This record was handed over at every shift as new entries were entered with subsequent admissions. HIV-positive pregnant women admitted for delivery, who met study criteria and gave an informed consent were enrolled into the study by principal researcher or assistant.

Parturients tested intrapartum and in early labour [latent phase] and confirmed HIV positive were identified in consultation with the nurse assigned to counseling and testing duty who provided details of the sero-status of clients attended to in her register. Subsequently informed consent to participate in the study was obtained from the individual client.

Each study participant was identified by a number corresponding to the serial number of the questionarre. She was then interviewed by the principal researcher or the research assistant. Relevant demographic and antenatal care data including counseling on vertical transmission, mode of delivery and infant feeding, and disclosure of HIV status was entered into the questionnaire.

Data on clinical staging of HIV disease by the primary care giver was obtained from the antenatal card and admission notes. Laboratory CD4 cell count if done was also documented. The ARV regimen taken was recorded with exact times of last dose taken. Availability of a prescription of the ARV regimen on the treatment sheet for continuation intrapartum was determined. Data on non compliance with ARV dosage schedule was also documented.

All enrolled parturients were followed up through the labour monitoring period till delivery for direct observation of care given. A description of PMTCT care offered intrapartum was entered into the study questionnaire. No interventions were given or attempts made by the principal researcher or his assistants to influence the care given to the HIV positive parturient. After delivery the mother and baby were observed for one hour to document any complication.

To avoid undue interruption of clinical care; each parturient was visited on a 4-hourly basis for documentation of care offered. Where events occurred in the absence of the research assistant or the principal researcher; the partogragh record, clinical notes and mid-wives' confirmation was sought.

This study continued at the two study sites till the sample size was attained to allow for data analysis.

4.9 MAIN OUTCOME MEASURES

- Extent to which counseling on vertical transmission was offered
- Extent of HIV disease staging
- Extent to which ARVs were offered ARVs PMTCT
- Uptake of elective caesarean for PMTCT
- Episiotomy rate
- Duration of labour with ruptured membranes before delivery

5.0 DATA MANAGEMENT AND ANALYSIS

At the end of each day the filled questionnaires were cross checked for completeness and any missing entries corrected. The filled questionnaires were then kept in a safe place ready for data entry and confidentially of the patients' details.

A data base was designed in MS Access which allowed the research to set controls and validate the variables. On completion of the data entry exercise, the data was exported in a Statistical Package for Social Science research (SPSS - Version 12.0) and subsequently analyzed.

The results are presented in tables and figures. Comparison between the two facilities is made using p values. P-value of <0.05 is considered significant.

6.0 ETHICAL CONSIDERATIONS

Clearance to conduct the study was obtained from the department of obstetrics and gynaecology after presentation of the research proposal.

Subsequently permission to carry out the study was sought from the Kenyatta National Hospital Research and Ethical Committee as well as the Pumwani Maternity Hospital Ethical Committee. Written informed consent to participate in the study was obtained from all the study participants.

The interviews and observation of PMTCT care given were carried out in the privacy of the labour ward examination rooms. Throughout the study period all participating mothers received their treatment and observations by the clinical and nursing staff as scheduled. No client was denied care for failure to consent. Equally no parturient was given preferential treatment for participating in the study.

To maintain confidentiality all the study participants were only identified by the assigned serial number and their names were not written on any of the research forms.

7.0STUDY LIMITATIONS

This study being a cross-sectional survey by design it was prone to selection and information bias. Selection bias was however minimized as the inclusion criteria was formulated to capture all HIV positive women admitted to the study site and planned for delivery. The exclusion criteria was also designed to allow for maximum enrolment of eligible women without bias from the research team.

Information bias was minimal as the research team had no influence on the extent to which interventions for PMTCT were offered at each study site.

8.0 RESULTS OF THE STUDY

A total of 370 HIV-positive women were recruited into the study, 104 at Kenyatta National Hospital [KNH] and 266 at Pumwani Maternity Hospital [PMH].

Social demographics

Table 1 shows the social demographic characteristics of the study population by study site. Approximately 80% of them were aged between 20-35 years and married. 92% were of primary or secondary level of education. Majority [>60%] had no income of their own and thus were dependant on their partners.

Characteristic	STUDY SITE		Total No.(%) N=370	p-value
	KNH No.(%) N=104	Pumwani No.(%) N=266		
Age				
- 15-19	2 (1.9%)	26 (9.8%)	28 (7.6%)	0.059
- 20-24	24 (23.1%)	76 (28.5%)	100 (27.0%)	
- 25-29	37 (35.6%)	87 (32.8%)	124 (33.5%)	
- 30-34	24 (23.1%)	52 (19.5%)	76 (20.5%)	
- 35-39	14 (13.5%)	20 (7.4%)	34 (9.2%)	
- >=40	3 (2.9%)	5 (2.2%)	8 (2.2%)	
Education				
- pri	35 (33.7%)	160(60.3%)	195 (52.6%)	<0.001
- Secondary	48 (46.2%)	97(36.6%)	145 (39.3%)	
- post secondary	21 (20.2%)	9(3.1%)	30 (8.0%)	
Marital status				
- monogamous	85 (81.7%)	197 (73.9%)	282 (76.2%)	0.451
- polygamous	5 (4.8%)	19 (7.0%)	24(6.4%)	
- single	12(11.5%)	45 (17.1%)	57 (15.5%)	
- divorced/separated	2 (1.9%)	5 (1.9%)	7(1.9%)	
Occupation				
- salaried job	21 (20.2%)	36(13.6%)	57(15.5%)	0.300
- self-employed	27 (26.0%)	63 (23.7%)	90 (24.3%)	
- housewife	52 (50.0%)	156(58.4%)	208 (56.2%)	
- unemployed	4 (3.8%)	11(4.3%)	15 (4.0%)	
Partners education level				
- Primary	11 (12.3%)	71 (32.9%)	82 (26.8%)	<0.001
- sec	49 (54.4%)	133 (61.5%)	182 (59.5%)	
- post sec	30 (33.3%)	12 (5.6%)	42 (13.7%)	
Partners occupation				
- salaried job	51 (57.0%)	97 (45.0%)	148 (48.4%)	0.98
- self-employed	32 (35.5%)	105 (48.8%)	137 (44.7%)	
- unemployed	7 (7.5%)	14 (6.2%)	21(6.9%)	

Aspects of antenatal care, HIV disease staging and counseling on vertical transmission

Table 2 shows some aspects of antenatal care, HIV disease staging and counseling on MTCT. Three hundred and forty six [93.6%] of the HIV positive women admitted for delivery had received some antenatal care; although majority 249 (64.6%) attended other facilities outside the study site. Counseling on mother to child transmission of HIV had been offered to three hundred and fifty six [96.4%] of the women. Two hundred and five [55.4%] of the study participants had CD4 cell count, and <1% had been staged clinically either in the clinic or at admission to labour ward.

Table 2: Aspects of antenatal care offered by study site

Aspects of antenatal care	STUDY SITE		Total No.(%) N=370	p-value
	KNH No. (%) N=104	Pumwani No. (%) N=266		
Any ANC visit				
- Yes	92(88.5%)	254 (95.5%)	346(93.6%)	
- No	12(11.5%)	12 (4.5%)	24 (6.4%)	0.024
Facility attended				
- KNH	38 (36.0%)	4 (1.6%)	42(11.6%)	<0.001
- PMH	5(5.0%)	84(31.6%)	89 (23.8%)	
- Others	61(59.0%)	178 (66.8%)	249 (64.6%)	
Counselled on MTCT				
- Yes	99(95. 2%)	257(96.6%)	356(96.4%)	0.398
- No	5(4.8%)	9(3.4%)	14(3.6%)	
CD4 test done				
- Yes	53 (51.0%)	153(57.2%)	206 (55.4%)	0.280
- No	51 (49.0%)	113 (42.8%)	164 (44.6%)	
Clinical staging done				
Yes	1 (1.0%)	3 (.8%)	4(.9%)	0.750
No	103(99.0%)	263 (99.2%)	366 (99.1%)	

Extent to which counselling on MTCT was offered and the preferred options on mode of delivery and infant feeding by study site

Table 3 shows the extent to which counseling on mother to child transmission was offered by study site. A total of 344[92.9%] HIV positive women were counseled on mode of delivery. Three hundred and four [82.9%] had opted for vaginal delivery and 17.1% for elective caesarean delivery. Significantly more women at KNH opted for elective cesarean delivery than at PMH ($p<0.001$). Although majority of the women opted to breast feed after counseling on infant feeding, there was a marginal significant difference of women counseled at KNH opting for replacement feeding ($p=0.034$)

Table 3: Extent to which counselling on MTCT was offered

Extent of counselling	STUDY SITE		Total No.(%) N=370	p-val
	KNH No.(%) N=104	Pumwani No.(%) N=266		
counselled on mode of delivery				
- yes	95(91.2%)	249 (93.6%)	344 (92.9%)	0.416
- no	9 (8.8%)	17(6.4%)	26 (7.1%)	
counselled on infant feeding				
- yes	103 (98.9%)	259 (97.2%)	361 (97.6%)	0.377
- no	1 (1.1%)	7 (2.8%)	9(2.4%)	
Opted for mode of delivery				
- Vaginal	59 (57.4%)	245 (92.2%)	304 (82.9%)	<0.00
- Elective cs	45 (42.6%)	21 (7.8%)	66 (17.1%)	
Opted for feeding practise				
- exclusive bf	78 (75.0%)	225 (84.6%)	303 (81.9%)	0.034
- replacement	26 (25.0%)	41(15.4%)	67 (18.1%)	

Extent of use of antiretroviral as prophylaxis/treatment

Table 4 shows the extent to which ARVs were offered as prophylaxis by study site in order to reduce vertical transmission during labour and delivery. A total of three hundred and forty nine [94%] HIV positive women were offered ARVs for PMTCT. One hundred and one [29.6%] were on HAART while the rest received varied short course regimens including single-dose nevirapine. Significantly more women at KNH were on HAART than at PMH ($p<0.001$). Twenty one women [6%] received no ARV prophylaxis. Only 149[42.6%] had a prescription of the ARV regimen on their treatment sheet for continuation intrapartum. Zidovudine was commonly taken as 300mg bid rather than 600mg stat.

Table 4: Extent to which ARVs were offered as prophylaxis/treatment

Extent of ARV offered	STUDY SITE		Total No.(%) N=370	p-value
	KNH No.(%) N=104	Pumwani No.(%) N=266		
Any ARV Regimen				
- Yes	96 (92.3%)	253 (95.1%)	349 (94.3%)	0.304
- No	8 (7.7%)	13 (4.9%)	21 (5.7%)	
Specific ARV regimen				
- HAART	45(43.3%)	56(21.0%)	101(27.3%)	
- NVP+AZT	19(19.8%)	111(43.9%)	130(37%)	<0.001
- SD-NVP	25(26%)	69(27.3%)	94(26.9%)	
- AZT only	7(7.3%)	17(6.6%)	25(7.1%)	
ARV prescribed				
- Yes	17 (17.7%)	132 (52.2%)	149 (42.6%)	<0.001
- No	79 (82.3%)	121 (47.8%)	200 (57.4%)	
Ever missed drug				
- Yes	12 (12.5%)	25 (9.9%)	37 (10.6%)	0.410
- No	84(87.5%)	228 (90.1%)	312 (89.4%)	

Aspects of obstetric management

Table 5 shows some aspects of obstetric management by study site to ensure safe delivery of the HIV positive women admitted for delivery. A total of three hundred and seven women [94%] women had labour that was spontaneous in onset while nineteen [5.8%] were induced. Eighty five [23.9%] had ruptured membranes spontaneously at the time of admission while 48 [13%] had active rapture of

membranes before 7cms cervical dilatation. Eighty six paturients [26%] were augmented with syntocinon and two women [0.9%] had more than 24 hours of labour with ruptured membranes before delivery. Almost half of them 178 [49.9%], were monitored with a partograph. The mean duration of labour in hours since admission to time of delivery was 8.9 hours.

Table 5: Aspects of obstetric management

Aspect of Management	STUDY SITE		Total No.(%)	p-value
	KNH No. (%)	Pumwani No.(%)		
Onset of labour				
- Spontaneous	76 (90.5%)	231 (95.5%)	307 (94.2%)	0.093
- Induced	8 (9.5%)	11 (4.5%)	19 (5.8%)	
State of membrane on admission				
- ruptured	24 (23.8%)	61 (23.9%)	85 (23.9%)	0.975
- not ruptured	77 (76.2%)	194 (76.1%)	271 (76.1%)	
Partograph use				<0.001
– Yes	81 (80.2%)	97 (37.9%)	178 (49.9%)	
– No	20 (19.8%)	159 (62.1%)	179 (50.1%)	
No. of VEs				
– Once	85 (81.7%)	94 (36.6%)	179 (49.6%)	
– Twice	14 (13.5%)	107 (41.6%)	121 (33.5%)	<0.001
– Thrice	5 (4.8%)	56 (21.8%)	61 (16.9%)	
Mean total duration of labour with ruptured membranes.	3.99 (2.61, 5.37)	4.80 (3.82, 5.79)	4.62 (3.80, 5.43)	0.41
Total duration of labour before delivery	7.8(6.5.9.1)	9.3(8.3,10.3)	8.9(8.1,9.7)	0.092

Table 6 shows some aspects of delivery care offered by each study site in order to optimize on prevention of mother to child transmission. In total of 267 [72%] women had spontaneous vertex delivery. all conducted by a skilled attendant. of whom 26 [7%] were given episiotomy. No vacuum assisted delivery was documented. Cord milking and routine suction without meconium staining was observed in<0.01%

cases. Most of the babies [99%] were wiped of maternal secretions immediately after delivery. Forty nine women had cesarean delivery with PMTCT as the indication, thirty two [65%] of whom were delivered at KNH. Overall the cesarean section delivery rate in the study group was 27.6%. Thirty five women had a lower genital tract injury while two maternal deaths were reported at KNH, one due to amniotic fluid embolism and the other due to viral encephalitis

Table 6: Aspects of delivery care by study site

Aspects of care	STUDY SITE		Total N (%) N=370	p-value
	KNH N (%) N=104	Pumwani N (%) N=266		
Vaginal delivery - vertex - breech	62 (59.7%) 0 (.0%)	205 (77.7%) 1 (0.4%)	267(72.2%) 1 (0.3%)	0.584
All CS - EmCS+ Elective CS	42 (40.3%)	60 (22.5%)	102(27.5%)	0.028
CS for PMTCT	32(30.8%)	17(6.4%)	49(13.2%)	<0.001
Episiotomy given - Yes - No	0(0.0%) 104(100.0%)	26(9.8%) 240(90.2%)	26(7.0%) 344(93.0%)	0.004
Cord milking - Yes - No	0 (.0%) 104(100.0%)	1 (.4%) 265 (99.6%)	1 (.3%) 369(99.7%)	0.588
R suction -without meconium -with meconium	5 (4.8%) 6 (5.7%)	0 (.0%) 82 (100.0%)	5 (1.3%) 88 (23.8%)	<0.001
Wiping - Yes - No	97 (99.0%) 1 (1.0%)	242 (98.8%) 3 (1.2%)	339 (98.8%) 4 (1.2%)	0.874
Maternal outcome - No complication - Genital injury - Death	97(93.3%) 5(4.8%) 2(1.9%)	236(88.7%) 30(11.3%) 0(0.0%)	333(90.0%) 35(9.5%) 2(0.5%)	0.110

DISCUSSION

One of the priority areas of the Kenya National AIDS Strategic plan [2000-2010] and National Health Strategic Plan II is adherence to set clinical and public health standards in order to provide quality care to those infected and affected: and to reduce the number of new infections. This study evaluated the PMTCT care offered to HIV positive women admitted for delivery at KNH and Pumwani Maternity Hospital so as to determine quality of care offered and the level of adherence and compliance to the national guidelines for PMTCT. A total of 370 HIV- positive women admitted for delivery at the two hospitals were enrolled into the study. 104 at KNH and 266 at PMH. Majority were aged between 20-35 years. married and with no income of their own and were therefore totally dependent on their partner for support. Those delivering at KNH were of significantly higher education level than those at PMH ($p<0.001$)

With regard to antenatal care. the national guidelines recommend that HIV positive pregnant mothers should be offered individualized counseling on risks of MTCT. They should also be provided with information on the opportunities available for prevention of vertical transmission [10]. In this study three hundred and forty six [93.6%] of the HIV positive women admitted for delivery had received antenatal care. More than 90% of them reported having received counseling on vertical transmission. mode of delivery and safe infant feeding. Significantly more women admitted at KNH had opted for elective cesarean delivery than PMH ($p<0.001$). Overall (80%) had opted for vaginal delivery and exclusive breastfeeding. Previous studies have also reported a similar high uptake of counseling services [36, 37]. This is commendable as counseling plays an integral role in implementation and uptake of PMTCT interventions.

HIV disease staging is an important step in the comprehensive care and clinical management of the infected client. The national guidelines recommend that all HIV positive women should have their disease staged clinically and by CD4 cell count. Based on the disease stage the use of ARVs is initiated as treatment or prophylaxis [10].

In this study only 55% of the HIV positive mothers admitted for delivery had a CD cell count. Less than 1% of them had been staged clinically by the WHO clinical staging system either at admission or antenatally. There was no significant variation in extent of HIV disease staging between the two study sites ($p=0.28$ for CD4 test and $p=0.75$ for clinical staging). Previous studies have reported similar low levels of disease staging [38].

With no HIV disease staging, most of these women were therefore not offered optimal care as it is possible that some of those given ARV prophylaxis would have benefited from use of HAART for their own health and for effective PMTCT.

Use of antiretroviral drugs as prophylaxis or treatment has been shown to be the most effective intervention for PMTCT [18-24]. The national guidelines recommend that all HIV positive pregnant women should be offered HAART when eligible. For those ineligible, short courses of combination prophylaxis are recommended for greater efficacy; and to minimize the development of resistance associated with monotherapy especially to nevirapine.
In this study three hundred and forty nine HIV-positive women [94.3%] were put on antiretroviral drugs either as prophylaxis or treatment. HAART was offered to one hundred and one [27.3%] of the HIV positive mothers. Significantly more women delivered at KNH were on HAART than at Pumwani Maternity Hospital ($p<0.001$). Nevirapine and Zidovudine monotherapy was observed in 30% of the cases.

These findings correlate with the other studies done before which showed that although there has been progressive improvement in ARV uptake, use of HAART or efficacious combination prophylaxis is still low. Many women are still put on single dose nevirapine despite the availability of more superior ARV regimens [38, 40]. Further research should be done to determine the possible barriers to access to HAART and combination prophylaxis

With regard to mode of delivery, the national guidelines recommend that women opting for vaginal delivery should be offered modified intrapartum care including delayed ARM and limited number of digital vaginal examinations [10]. Additionaly the partograph should be used to monitor the progress of labour.

In this study forty eight women [13%] opting for vaginal delivery had active rupture of membranes at <7 cms cervical dilatation. Most of the women were however allowed to labour with intact membranes up to the second stage when spontaneous rupture occurred or ARM was done to facilitate expulsion of the baby. Use of partograph was poor, particularly at Pumwani Maternity Hospital where only 37.8% of the women were monitored with this tool.

No vacuum delivery either by rubber or metal cup was observed. The episiotomy rate in this study was 7% which is four times less than that reported by Guled in his study [41]. No significant differences were observed between the two study sites with regard to mean total duration of labour before delivery ($p=0.092$) and maternal outcomes including genital tract injury ($p=0.110$). The results of this study thus indicate that though there are efforts by care givers to adhere to the recommended practice of modified intrapartum care, more still needs to be done especially on partograph use at PMH.

Amniotic fluid embolism is a known rare but fatal complication that may occur during labour or immediately after delivery [43]. The risk factors include precipitate labour or tumultuous labour with hyperstimulation in cases where syntocinon or other uterotonics are in use. The national guidelines recommend that ARM be done in all cases before augumentation of labour with syntocinon to reduce the risk of amniotic fluid embolism. One maternal death was observed in this study due to amniotic fluid embolism. Care givers should therefore adhere to the national guideline in all cases by performing ARM before labour augmentation in order to avoid this rare but life threatening complication as happened in this case.

Studies have also shown that elective cesarean delivery is a safe and efficacious intervention for PMTCT [42]. The national guidelines recommend that HIV positive pregnant women be offered elective cesarean delivery where feasible. In this study, 82.9% of the HIV positive women had opted for vaginal delivery after counseling while 17.1% preferred elective cesarean delivery. Overall only forty nine HIV positive women [13.1%] had cesarean delivery for PMTCT. Significantly more women delivered at KNH had caesarean delivery for PMTCT ($p<0.001$).

The low uptake of this intervention is unsatisfactory considering that most of the women opting for vaginal delivery are on single dose nevirapine and thus at greater risk of vertical transmission than those on combination prophylaxis.

Clients should therefore be offered adequate counseling and more information on safety and efficacy of cesarean delivery in prevention of MTCT. Issues of capacity limitations at the facility level and cost of surgery should be addressed by the national program.

The findings of this study and results from previous studies thus indicate that only a small percentage of HIV positive women receive optimal care with a complete package of interventions that have been shown to effectively reduce the vertical transmission of HIV. Majority of the women are offered sub-optimal care with varied levels of limited interventions thus still at risk of perinatal transmission. The PMTCT program therefore still has a long way to go in offering optimal PMTCT care to every HIV positive woman despite the rising prevalence of HIV infection [35].

CONCLUSIONS

1. A great majority of the HIV positive women receive counseling on vertical transmission, mode of delivery and infant feeding.
2. Clinical or laboratory HIV disease staging is not done routinely.
3. Majority of the HIV positive women are offered ARVs for PMTCT, but use of HAART and more efficacious combination prophylaxis is limited.
4. Although efforts to comply with the recommendation for modified intrapartum care were noted at both facilities, optimization of interventions for PMTCT is significantly more at KNH than at PMH.

RECOMMENDATIONS

1. HIV disease staging by clinical or CD4 cell count should be done routinely.
2. Use of HAART for PMTCT should be done more objectively and frequently.
3. There is need for more research on quality of care offered to women delivered in our facilities.

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APPENDIX I: STUDY QUESTIONNAIRE

1.0 DEMOGRAPHIC DATA

1. Age [ ] years.

2. How many years of school did you complete? [ ] years.

3. Highest education level attained?
a) None
b) Primary
c) Secondary
d) College (Post-secondary)

4. Marital status (Tick one)
a) Married (Monogamous)
b) Married (Polygamous)
c) Single
d) Divorced/Separated

5. Employment (Tick one)
a) Salaried job
b) Self-employed
c) Housewife
d) Unemployed

8. How old was your husband/partner on his last birthday? [ ] Years

9. How many years of school did your partner complete? [ ]

10. What is the highest education level attained by your partner?
a) None [ ] b) Primary [ ] c) Secondary[ ]
d) College (Post-secondary)

11. What is the employment of your partner? (Tick one)
a) Salaried job [ ] b) Self employed [ ] c) Unemployed [ ]

2.0 OBSTETRIC HISTORY.

2.1 Parity [ ]

2.2Current pregnancy
Facility attended: KNH [ ] Pumwani Hospital [ ] Others [ ]

Is antenatal card available Yes[ ] No[ ]
Number of antenatal visits [ ]
Gestation at first antenatal visit (weeks) [ ]
Antenatal Laboratory tests
Haemoglobin [ ]
Blood group [ ]
VDRL [ ]
Rhesus factor [ ]
HIV [ ]
CD4

2.3 Informed/shared results on HIV status with partner Yes [ ] No [ ]

2.4 Counseled on vertical transmission and the risks of MTCT Yes [ ] [ ]

2.5 Counseled and made decision on mode of delivery Yes [ ] No [ ]

2.6 Opted for mode of delivery: vaginal [ ] elective caesarean delivery [ ]

2.7 Infant feeding practise opted for: Exclusive Breastfeeding [ ]
Replacement formula feed [ ]

3.0 HEALTH STATUS

3.1 Duration since HIV diagnosis (Months) [ ]

3.2 Findings on physical examination by primary care giver as per clinical records: assign 1, 2,or 3 accordingly
N.B 1 [recorded +ve finding on clinical notes/antenatal card]
2. [recorded-ve finding
3.[NO record-ve/+ve]
I. Weight (kg) [ ]
2. Oral thrush [ ]
3. Lymphadenopathy [ ]
4. Pallor [ ]

3.3 WHO clinical staging by primary caregiver Yes[ ]No[ ]

3.4 If yes in 3.4 give stage[ ]

4.0 ANTI RETROVIRAL PROPHYLAXIS

4.1 Has the mother been put on any ARV regimen Yes [ ] No [ ]

4.2 On which regimen is the client HAART [ ] ARV prophylaxis [ ]

4.3 Gestation in weeks at initiation of ARVs [ ]

4.2 Is the ARV regimen prescribed on the treatment sheet Yes [ ] No [ ]

4.4 Fill in the table below the drugs taken, dose and relevant times.

Drug	Dosage	Time taken	Duration in hrs between doses
Nevirapine			
Zidovudine			
AZT+3TC			
HAART			
Others			

4.2Have you missed any of the drugs in the last 7 days
Yes [ ] Number of days missed [ ] . No [ ]

4.3 Reason for missing dose
1. Forgot [ ]
2. Side effects [ ]
3. Drugs got finished [ ]
4.Severe illness[ ]
5.Regimen complexity [ ]
6.Others[ ]

5.0 ADMISSION STATUS

5.1 Time on admission [ ]
5.2 Estimated Gestation age at admission [[

5.3 Stage of labour [tick one]
Not in labour [ ]
Latent phase of labour [ ]
Active phase of labour [ ]

5.4 Cervical dilatation in cms [ ] Time [ ]

5.5 Onset of labour: 1. Spontaneous [ ]
2. Induced [ ]
specify method.....

5.5 State of membranes on admission
1. Ruptured. [ ] Approximate duration in hours.....
2. Not ruptured [ ]

IF FOR ELECTIVE C/S DELIVERY PROCEED TO 7.0

6.0 LABOUR MONITORING

6.1 Primary caregiver monitoring progress of labour

- None
- Nurse/midwife
- Medical or Nursing student
- Medical officer/Resident
- Obstetrician

6.2 Vaginal examinations

VE no	Health worker	Time	Antiseptic used

6.4 Time of active rupture of membrane [ ]

6.5 Cervical dilatation at ARM [ ]

6.6 Augumentation with syntocinon Yes [ ] No [

6.7 Duration of second stage of labour in hours [ ]
6.8 Duration in hours with ruptured membranes before delivery [ ]

7.0 DELIVERY

7.1 Time of delivery [ ]

7.2 Care giver/attendant at delivery

a) None [ ]
b)Medical student/Nursing student [ ]
c)Nurse/midwife [ ]
d)Medical officer [ ]
e)Obstetrician [ ]

7.3 Mode of delivery and neonatal care

a)Vaginal spontaneous –Vertex or breech
b)Vaginal assisted: vacuum with rubber cap [ ] metal cap/forceps [ ]
d)Use of episiotomy Yes [ ] No [ ]
e)Caesarean section Emergency [ ] Elective [ ]
f)Cord milking Yes [ ] No [ ]
g)Routine suction of baby: without Meconium [ ] with Meconium [ ]
h) Wiping or cleaning of baby of maternal secretions and blood:
Yes [ ] No [ ]

7.4 Indication for caesarean section [tick as appropriate]

a) Cephalopelvic disproportion (CPD)
b) Neglected CPD

c) Uterine dystocia
d) Fetal distress
e) PMTCT
f) Others specifiy .....

8.0 FETAL MATERNAL OUTCOME

8.1 Fetal outcomes

a) Stillbirth [ ]
b) Live birth [ ]
c) Premature [ ]
d) Fetal weight
e) Apgar score at 1min [ ] 5mm [ ]

8.2 Maternal outcome

i. No complication[ ]
ii.Perineal and genital tract injuries (Include episiotomy)[ ]
iii.Retained placenta[ ]
iv.Antepartum haemorrhage (APH)[ ]
v.Postpartum haemorrhage (PPH)[ ]
vi.Maternal death[ ]
vii. Others[ ]

8.3Use of partograph Yes [ ] No [ ]
Adequecy of partograph record complete [ ] incomplete [

APPENDIX II

DATA COLLECTION CONSENT FORM

University of Nairobi-Department of Obstetrics and Gynaecology

CONSENT TO PARTICIPATE IN EVALUATION OF INTRAPARTUM OBSTETRIC CARE OFFERED TO HIV SERO-POSITIVE WOMEN

Study Title: An evaluation of PMTCT care offered to HIV –positive women presenting for delivery at Kenyatta National Hospital and Pumwani Maternity Hospital for delivery.

Principle Investigator: Dr. Wycliffe Akikuvi Musalia

General Information

This consent form contains information about the research named above. In order to be sure that you are informed about being in this research study, we are asking you to read (or have read to you) this consent form. You will also be asked to sign it (or make your mark in front of a witness).

The Ethics and Research committee of Kenyatta National Hospital and University of Nairobi have approved the study. We will give you a copy of this form. This consent form might contain unfamiliar words. Please ask us to explain anything you may not understand.

What is the purpose of the Study?

Mother-to-child transmission of HIV can be prevented by use of ARVs, through modification of intrapartum obstetric care and breastfeeding practices. The Kenya National PMTCT Programme has issued guidelines to health workers on PMTCT.

This study aims at documenting and describing the clinical care you will be offered being HIV positive in order to reduce the risk of you transmitting the virus to the baby as you deliver.

How the Research will be Done And the Part You Will Play

This study will be conducted on 369 HIV-positive women admitted for delivery at both Kenyatta National Hospital and Pumwani Maternity Hospital. If you agree to take part you will be asked some questions about yourself, the antenatal care and your HIV status. You will subsequently be visited on a 4-hourly basis for documentation of the clinical obstetric care you are being offered until you deliver. During this time your care will not be interrupted or modified because of the study.

Risks and Benefits

There are no major risks associated with taking part in this study. Some of the questions you will be asked will touch on your personal life: which you may find uncomfortable. You may refuse to answer any of the questions and this will not affect your intrapartum care. You may not benefit directly from this study. However the results of this study will be made available to both Kenyatta and Pumwani hospital and this may be used to improve on PMTCT services.

Confidentiality

We will protect information about you and your taking part in this research to the best

of our ability. We will not write your name on the research forms.
If the results of this research are published, your name will not be shown. However, the Kenyatta National Hospital/University of Nairobi Ethics and Research committee may sometimes look at the records of those who take part in the research study.

Compensation
You will not be paid for taking part in this study. However you will get all the care that is necessary for your safe delivery.

Staying in or Leaving the Research Study
You may choose to stay in or leave the study at any time. If you decide to leave, please tell the research doctor/nurse you wish to leave and you will be allowed to do so.

Also you may be asked to leave the research if:

- The research doctor/nurse feels it is best for you; or
- You are not able to follow the research procedures; or
- The research is stopped.

When you are no longer in the research, you will still be able to receive your maternity services as required.

Contact for Questions
Please contact Dr Wycliffe. A. Musalia, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Nairobi, P.O Box 19676, Nairobi; mobile phone number +254721646183; e-mail musaliawa@yahoo.com if you have any problems or questions about this research.

If you have any question about your rights while you are in the research, you may contact: The Chair, Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, P.O Box 20723, Nairobi

UNIVERSITY OF NAIROBI
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

CONSENT TO PARTICIPATE IN STUDY ON EVALUATION OF INTRAPARTUM OBSTETRIC CARE OFFERED TO HIV-POSITIVE WOMEN

VOLUNTEER AGREEMENT

The data collection consent form outlining the purpose. risks and benefits of above study has been read and explained to me. I agree to participate as a volunteer.

....
Date Signature or mark of volunteer

If a volunteer cannot read the form herself, a witness must sign here.

I was present while the benefits. risks and procedures of this study were read to the volunteer. All the questions were answered and the volunteer has agreed to take part in the research.

....
Date Signature of witness

I certify that the nature and purpose of this study; the potential risks and benefits associated with participating in this research has been explained to the above individual.

....
Date Signature of person who obtained consent

Appendix III: National Guidelines for PMTCT Intrapartum care

1.1Modification of Routine care During Labour and Delivery

Women with HIV should not be isolated or treated differently from other women in labour. Universal precautions (see table 8 for details) should be used by health workers on all women in labour irrespective of their HIV status.

Factors Associated with Intrapartum MTCT

- Prolonged rupture of membranes: Each hour of rupture membranes increases risk of transmission
- Episiotomy: Routine episiotomies may increase the risk of HIV transmission.
- Mode of delivery: Vaginal delivery has a higher risk of transmission than elective caesarean section delivery
- Intrapartum haemorrhage: Intrapartum haemorrhage has been associated with increased transmission in some studies.
- Invasive foetal monitoring procedures: Invasive procedures such as penetrating scalp electrodes and foetal blood sampling may be associated with increased foetal transmission risk.
- Instrumental delivery: Vacuum extraction and forceps increase the risk of injuring the infant
- Twin deliveries: First twin have higher risk of transmission than second born twins.

Intrapartum Interventions

a) Use of partogram

Proper and consistent use of the partogram in the monitoring progress of labour

b) Vaginal cleansing

Vaginal cleansing with Hibitane (chlorhexidine 0.25%) solution reduces the risk of puerperal and neonatal sepsis. It may also have some effect on HIV transmission where membranes are ruptured for more than 4 hours.

After every vaginal examination, the birth canal is wiped with gauze or cotton

wool, soaked in Hibitane solution. Number of vaginal examinations should be kept to a minimum required.

c) Artificial Rupture of Membranes (ARM)

ARM is practised routinely in many settings although it should be reserved for women with abnormal labour progress. Rupture of membranes of more than four (4) hours duration is associated with an increased risk of HIV transmission. Therefore ARM should be reserved for those with foetal distress or abnormal progress. ARM can be done if cervical dilatation is 7 cm or more.

d) Routine episiotomies

Routine episiotomies have been shown to have no obstetric benefit. The procedures should be used only for specific obstetric indications.

e) Counselling and Testing in the Labour Ward

Midwifes should confirm the HIV status of all women who are admitted to the labour ward by checking on the mother's card and/ or by asking mother whether she has been tested for HIV infection. The management of those who are HIV positive is discussed in section 1.2 below.

Those who have not received counselling and testing (CT) during pregnancy and are in early labour or being admitted for other conditions may be candidates for counselling and rapid testing for HIV in the labour ward. If this is not appropriate because of active labour or other reasons, the midwife should plan to provide counselling and offer testing at the earliest possible time after delivery. Since the intrapartum period is the most risky for transmission of HIV from mother to child, identifying HIV-infected women and appropriate management should be instituted.

1.2 Specific Management of HIV Positive Pregnant Women

a) Prophylactic Antiretroviral therapies

Nevirapine and other ARVs are most effective when given early in labour (refer to appendix or given regimes). The midwife should ask whether the HIV positive

pregnant woman received a dose of nevirapine during antenatal care and whether she took it before admission. If she has not, she should receive a nevirapine tablet (200mgs) during labour or at least 4 hours before an elective caesarean section. If oral zidovudine is the HIV regimen used, 300mgs should be given on a 3 hourly basis from the onset of labour.

Testing after delivery can be carried out on a cord blood. This will give an opportunity to administer post exposure prophylaxis of ARV to the baby, but it should be combined with counselling and testing after delivery so that mothers will know how to protect themselves and their partners in future and to decide on the infant feeding method.

b) Mode of delivery

Elective caesarean section (C/S):

Elective C/S reduces the risk of transmission by 50% as compared to vaginal delivery, but is not available in many settings. Where C/S is performed (elective or emergency) in HIV positive women, they should receive prophylactic antibiotics. If C/S is performed after prolonged labour prolonged rupture of membranes, longer courses of antibiotics should be considered.

Although elective C/S will not be readily available in most health facilities in Kenya as a routine for HIV positive women, there may be some cases that merit consideration for C/S. These include pregnancies where labour is expected to be prolonged or where other obstetric complications may be associated with increased risk of transmission (e.g abruptio placenta, placenta previa, pre-term rupture of membranes). Depending on the situation the above may apply to women with previous C/S or breech presentation.

Vaginal delivery:

i)Management of labour:

Labour management should follow normal obstetric guidelines in most respects. Women do not need to be isolated, but staff must use universal precautions with all patients (see modifications of routine labour care above).

Analgesia should be given in labour, if required and epidural analgesia is not contraindicated.

ii) Support during labour:

Emotional support during labour is important for all women, and may be even more necessary for an HIV positive woman who is concerned about her condition and risk of transmission to the child. This may be made worse by her fears of stigmatisation and discrimination by medical staff, or because she has not disclosed her status to her partner or family members.

Whenever possible, during labour, HIV positive women should have the option to have a companion of their choice who knows their HIV status and can provide supportive companionship. Where this is not possible labour ward staff must be sensitive to the fears and concerns of the HIV positive mother about her infection, and how much she had told any of her companions.

iii) Induction of labour:

Labour is always induced by one or a combination of the following: Oil and enema, ARM, oxytocin therapy, and prostaglandins. As prolonged rupture of membranes is associated with increased risk of transmission, ARM may be dangerous in HIV positive women. Careful assessment of need for and desirability of induction rather than C/S is necessary. Where induction of labour is chosen, membranes should be left intact for as long as possible. Syntocinon should not be used with intact membranes.

iv) Delivery:

Delivery should be conducted using standard practice while avoiding unnecessary trauma or prolongation of the second stage.

Table 8: Activities to perform when conducting a safe vaginal delivery

Activities for the mother

- Perform vaginal cleansing with Hibitane (chlorhexidine 0.25%)
- Avoid episiotomies unless absolutely necessary
- If assisted delivery is required it should involve as little trauma as possible e.g use of plastic cup vacuum extractor or low pressure.
  Episiotomies may not be required for all forceps deliveries or vacuum extraction.
- Clamp the cord immediately after the baby is delivered and avoid milking the cord.
- Cut cord under cover of a lightly wrapped gauze swab to avoid blood spurting.
- If the mother has decided not to breastfeed, place the baby on the mother's body for skin-to-skin contact.

Activities for the baby:

- Wipe baby's mouth and nostrils with gauze at delivery of the head.
- All babies, regardless of HIV status of mother should be handled with gloves until maternal blood and secretions are washed off.
- All babies, irrespective of their HIV status should be kept warm after delivery.
- Immediately after birth, baby should be washed with warm chlorhexidine solution or wiped dry with a towel or surgical cloth to remove maternal body fluids.
- There should be no suction of the newborn with a nasogastric tube unless there is meconium stained liquor. Where suctioning is required, it is better to use a mechanical suction unit (at a pressure below 100mmHg) or bulb suction, if possible, rather than mouth operated suction.
- Vitamin K and BCG should be administered, ensuring injection safety.
- Infant should receive 1% tetracycline eye ointment or 1% silver nitrate eye ointment as prophylaxis against opthalmia neonatorum.
- If the mother is HIV positive, avoid putting the baby to the mother's breast unless the decision to breastfeed was made before hand.