RESEARCH THESIS

THE RATE OF HIV SEROCONVERSION DURING PREGNANCY AS SEEN IN WOMEN SEEKING OBSTETRIC SERVICES IN KENYATTA NATIONAL HOSPITAL.

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DEDICATION

This book is dedicated to my lovely husband, Alfonce, our three precious children, Robert, Allan and Lynn; my mother, Teresa and my late father, Longinus.

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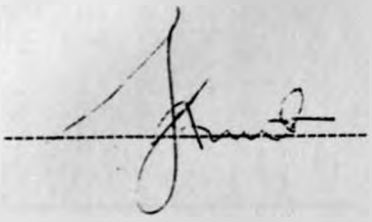
DECLARATION

I declare that the long commentary in this book is my original work and have not been presented for a degree in any other university.

Signed: 

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CERTIFICATION OF THE SUPERVISORS

This is to certify that **Dr. Janerose A. Ambuchi** researched upon the long commentary presented in this book under our guidance and supervision and that this book is submitted with our approval.

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List of abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ARM	Artificial Rupture of Membranes
ARVs	Antiretrovirals
AZT	Azidovudine
CCC	Comprehensive Care Center
DNA	Deoxyribonucleic Acid
ELISA	Enzyme Linked Immunoassay
HIV	Human immunodeficiency virus
KNH	Kenyatta National Hospital
MTCT	Mother – to- child transmission
NACC	National AIDS Control Council
NASCOP	National AIDS and STD Control Programme
PMTCT	Prevention from Mother – to - child transmission
PLWHAs	People Living with HIV/AIDS
RNA	Ribonucleic acid
SPSS	Statistical package for social science
UNAIDS	United Nations Programme on HIV/AIDS
UTI	Urinary tract infection
WHO	World Health Organization

ABSTRACT

Background:

HIV infection is a global pandemic and in Kenya it was declared a national disaster in 1999. To date no cure has been found and prevention of HIV acquisition and transmission remains the mainstay of management. Studies done have shown that there is increased risk of HIV acquisition during pregnancy[10]. However, the incidence of HIV in pregnancy has not been established in our setup.

Objective:

The aim of this study was to determine the rate of HIV seroconversion during pregnancy and factors associated with the seroconversion.

Study site:

Kenyatta National Hospital, Nairobi Kenya.

Methods:

This was a prospective cohort study in which 500 clients seeking antenatal, delivery and postnatal care at KNH were recruited. These women had tested HIV negative at initial testing in early gestation. They were tested again at term using the same kits to determine those who seroconverted. The women who seroconverted were analyzed and their characteristics described. A questionnaire was used to collect individual data.

Data was analyzed using the SPSS computer program.

Results:

Of the 500 women, 4(0.8%) seroconverted. They were all below 30 years of age. 3(75%) of the seroconverted were single, had a secondary level of education and were unemployed. All the seroconverted had single sexual partners, and did not use condoms during the entire pregnancy.

Conclusions:

Pregnant women are at risk of contacting HIV infection, but the rate of seroconversion is low.

Although more of those who seroconverted were single, educated and unemployed the overall number was too small to make statistical conclusions.

Recommendations

A similar study should be conducted in other parts of the country to establish a national outlook for purposes of formulating policies.

INTRODUCTION

Human immunodeficiency virus (HIV) is the cause of the condition termed acquired immunodeficiency syndrome (AIDS).[33] AIDS was first recognized in the United States in 1980-1981 when homosexual men were found to have unusual infections and tumors suggesting an underlying deficiency in their cell mediated immunity.[33] HIV was shown to be the cause of AIDS in 1983-1984. Although evidence exists to show that HIV has been in existence in humans for many years, the exact origin of the virus is not yet known.[34] HIV causes a chronic infection that leads to profound immunosuppression. The hallmark of this process is the depletion of CD4+ lymphocytes, and this predisposes the patient to develop a variety of opportunistic infections and certain tumors.[34]

HIV infection has changed the face of reproductive health especially in the developing countries where the scourge seems to be spreading like bush fire.[1] Scientists are still trying to elucidate the effects of pregnancy on the acquisition of HIV infection. Transmission via sexual contact still remains the commonest mode and increase in sexual desire and enjoyment during the second trimester resulting from the congestion of pelvic vasculature emphasizes the fact that these women could be at increased risk because of increased exposure. This study aimed to show the risk of HIV acquisition during pregnancy and therefore the need to protect pregnant mothers and their babies through practicing safe sex during the antenatal period. For those who seroconvert then there is need to protect the fetus by implementing stringent measures of preventing mother to child transmission of HIV

LITERATURE REVIEW

HIV/AIDS has become a pandemic with devastating global health and socio-economic issues. The Joint United Nations Programme on AIDS (UNAIDS) and World Health Organization (WHO) estimates indicate that by the end of 2005, 40.3 million people were living with HIV/AIDS and about 4.9 million new infections occurred. Majority of the people living with HIV/AIDS (PLWHAS), 95% of the global total, live in the developing countries[1]. Sub-Saharan Africa has 70% of the global total. Interventions have been instituted by leaders of the world and individual countries to curb the scourge. Kenya as depicted by NACC yearly updates has shown a downward trend of HIV prevalence; 6.1% in 2004, 5.9% in 2005 an incidence of 85,000 in 2004 and 60,000 in 2006[2]. HIV prevalence in women in the reproductive age group (15 – 49) is 8.7% while for men of the same age group it is 4.6%. Urban residents have a significantly higher risk of HIV infection (10%) than the rural residents (6%).[3] The downward trend could be due to the interventions carried out after the Government in 1999 declared HIV/AIDS a national disaster and established the National AIDS Control Council (NACC) to provide a policy and strategic framework for mobilizing and coordinating resources for prevention of HIV transmission, and provision of care and support to the infected and affected people in Kenya. NACC consequently formulated the 2000 – 2005 National HIV/AIDS Strategic Plan[4].

The HIV Virus

The Human Immunodeficiency Virus (HIV) was isolated in 1985 four years after the AIDS clinical definition had been made in 1981[5]. There are two types of HIV; HIV-1 and HIV-2. HIV-1 is more widespread and virulent than the HIV-2, which is predominantly found in West Africa.[6] HIV-1 is further sub-classified into serotypes A, B, C, D, etc.

The predominant sero-type in East Africa is A. The virus is about 100 nm in diameter and bears an RNA genome.

HIV is an obligate intracellular virus with many sub-types and has ability to undergo mutations. The many sub-types and the fact that it undergoes rapid mutations have made vaccine development difficult.

Transmission occurs when HIV bearing human body fluids such as semen, blood from an infected person enters the bloodstream of uninfected individual.

Specifically, its cytopathic effect begins with the entry into the CD4 antigen bearing cells such as T-helper lymphocytes, macrophages and placental trophoblasts cells, among others. Other antigens such as CD26 and CCR3 have been postulated as receptors for HIV leading to infection of the gut, bone marrow cell progenitors and placental trophoblast respectively[7]

Once gut and bone marrow cell progenitors and placental tr inside the cell, an enzyme, reverse transcriptase, converts RNA into DNA, which is then incorporated into the victims DNA and transcribed into virions. The transmembrane release of these virions causes cytopathic injury and/or death, hence the reason for reduction of CD4 T-lymphocytes. These lymphocytes, through lymphokines and other chemical substances, play a central role in coordinating both cellular and humoral immunity[7]

There are several ways of HIV transmission including intimate sexual contact (heterosexual and homosexual), mother to child transmission, transfusion with contaminated blood and being pricked or cut with contaminated instruments, as is the case with drug abusers[5].

Pregnancy and HIV Virus

Studies done have shown that there is increased risk of HIV acquisition during pregnancy. In Malawi [8], an observational study showed that rates of HIV acquisition are significantly higher during pregnancy than the postpartum period. The findings were a 2.19 fold higher rate of HIV incidence during pregnancy (incidence rate 7.9 per 100 person years) compared to non pregnant population.

Investigators in Rwanda[9] also reported higher HIV incidence rates during the early postpartum period than at later time remote from puerperium indicating seroconversion during pregnancy

In Rakai Uganda[10], a prospective cohort study done showed that there is increased acquisition of HIV infection during pregnancy mainly because of the effects of hormones of pregnancy have on the genital tract and the immunological factors.

High levels of oestrogen and progesterone during pregnancy affects a woman's susceptibility to HIV infection by inducing structural changes in the genital tract mucosa that promote viral penetration, [11,12] or by immunological effects.[13, 14]

Pregnancy causes increased ectopy because of hyperplasia of the columnar epithelium and glands, hyperaemia and stromal oedema, which could also increase susceptibility to HIV.[15]

Upper genital tract epithelial cells express HIV-1 co-receptors, which are under hormonal regulation and these cells can be productively infected by HIV.[16,17]

The fetal trophoblast is thought to induce stimulation of CD4+ T- helper cells and suppression of cytotoxic natural killer cells, which might increase susceptibility to acquisition of HIV.[14] In summary, immunological changes during pregnancy could increase susceptibility to HIV infection but the evidence is inconclusive

There is an increase in sexual desire and enjoyment during the second trimester which result from the congestion of pelvic vasculature thus many pregnant women could have frequent sexual intercourse at this time[29]. Increased sexual exposure experienced by these women could put them at risk of acquiring the HIV virus if their partners are HIV infected.

Roonggisuthipong et al[21] conducted a prospective study at Siriraj hospital Mahidol university Bangkok Thailand and found an increase in the percentage of those who seroconverted from 1.4 % to 2% incidence rates

Qolohle[28] and his colleagues in Durban South Africa retested women for HIV when they came in labour. These women were initially negative when they were first tested in early gestation. They found a 2.2%% HIV seroconversion rate. (9 women out of the 418 they tested had positive HIV results.)

Mother to child HIV transmission (MTCT)

Unfortunately a child can acquire the deadly virus from their infected mothers. Without any intervention an infected pregnant woman has 14% to 50% cumulative chance of transmitting the virus to her baby depending on her health and socio-economic status[22]. MTCT occurs antenatally (5 to 8%), during labour and delivery (10 to 20%) and through breastfeeding (10 to 50%). Many studies[22,23,24,25,26] done in various parts of the world have shown that an infected mother can transmit HIV-1 to her baby.

Cost-effectiveness of doing two HIV test during the antenatal period

Studies done in the United States [27,28,29] the United Kingdom [30], and South Africa[31,32] on the cost-effectiveness of doing two HIV tests, the first in early gestation and the second one at the middle of the third trimester have all shown that it is cost effective to do these two tests as opposed to cost incurred in managing children infected by their mothers, during the antenatal period or immediately postpartum

There are also the long term implications on the economy of the country. Their recommendations were that in high prevalence areas with infection rate of 1 per 1000 person years a second HIV test is worthwhile.

JUSTIFICATION

Studies done elsewhere as indicated above have shown that rates of HIV acquisition may be higher during pregnancy either because of behavioral factors or the effect of hormones on the genital tract. Irrespective of the mechanism of heightened risk, these findings have important implications for HIV prevention, both to protect mothers from primary HIV infection during pregnancy and to potentially prevent mother- to- child HIV transmission which can be increased by the rise in HIV-1 viraemia associated with recent maternal infection.

By testing HIV negative pregnant mothers again at term or during labour those who would have seroconverted will be detected.

It would be prudent to warn women of this potential risk of HIV acquisition during pregnancy and promote safer sex (ie monogamy and condom use) or sexual abstinence where feasible.

With all this overwhelming evidence there is still no policy in place directing pregnant mothers to be retested for HIV during the antenatal period and this study aimed to establish whether this need exists.

OBJECTIVES

Broad objective

To determine the rate of HIV seroconversion in pregnancy and associated factors as seen in mothers seeking obstetric services at Kenyatta National Hospital.

Specific objectives

1 To determine the seroconversion rate of HIV in pregnancy in women seen in KNH.

2 To describe the sociodemographic characteristics of pregnant women seen in KNH.

3 To determine the factors associated with the HIV seroconversion in pregnancy in women seen in KNH.

METHODOLOGY

Research question

What is the rate of HIV seroconversion in pregnant women seeking obstetric services in KNH?

Are there any factors associated with the seroconversion?

Study design

This was a prospective cohort study.

Study site

The study was conducted at the obstetric unit of Kenyatta national hospital. KNH is the largest hospital in Kenya situated in Nairobi, 3KM from the city center and serves as a referral center for the country as well as serving the population within and around the city.

Study population

A cohort of 500 pregnant women who had tested HIV negative in early gestation (12-28 weeks) using the standard HIV test kits were followed up and retested at between 38weeks and first week postpartum using the same kits to determine those who seroconverted.

INCLUSION CRITERIA

1. Pregnant mothers at term who tested HIV negative at initial testing antenataly and had consented to be retested for HIV
2. Mothers in labour who came for delivery at KNH and had their first test done in accordance to guidelines on HIV testing.
3. Mothers who tested HIV negative at first testing and were in immediate postpartum period in the wards or attended PNC at KNH.

EXCLUSION CRITERIA

1. Mothers with no clear record of their HIV status ie. no ANC card with conclusive results
2. Mothers who refused to consent for a second testing.
3. Mothers who came in labour with unknown HIV status.

SAMPLE SIZE

The minimum sample size was calculated using the formular .....

$$n = \frac{Z^2pq}{d^2}$$

z = 1.96 which was the value assuming a 95% confidence limit

n = the desired sample size

p = the probable seroconversion rate during pregnancy. No study of this nature has been done in our set up and thus 50% rate was taken. Thus p was 0.5.

q = 1 - p

d = degree of accuracy with which p was determined was taken as 0.05

$$n = \frac{1.96^2 \times 0.5 \times 0.5}{(0.05)^2} = 384$$

A sample size of 500 women was taken to increase the power of the study.

MATERIALS AND METHODS

RECRUITMENT, DATA COLLECTION AND ANALYSIS

The participants were recruited from antenatal clinic, antenatal and postnatal wards of KNH. They were recruited by the principal investigator assisted by two nurses who were already providing counseling and testing services for KNH PMTCT program. In order to maintain confidentiality, private rooms in ANC, labor ward and postnatal wards were used. A total of 500 clients who met the criteria were recruited. General information regarding the research was explained to each of the participants. Those who accepted were counseled by the investigator and the nurses and they then signed an informed consent form.

The participant was interviewed using a questionnaire to obtain data on demographic characteristics, sexual behavior; illness such as genital ulcerative disease, severe malaria and malnutrition resulting from severe vomiting and so on. Knowledge on HIV transmission and views about two HIV tests during the antenatal period were also sought. A second HIV test was then performed using rapid test kits after drawing blood from her using needle prick on her finger. The test kits used were Determine for screening and Unigold for confirming the results of the screening test for those who seroconverted. There was provision for indeterminate results to be verified at Kenya Medical Research Institute (KEMRI) by sending the blood sample there for Tie Breaker test. However, none of the participants had indeterminate results. Determine screening test has a sensitivity of 98.5% to 100% and a specificity of 97.6%, while Unigold's sensitivity and specificity are 95% and 97.9% respectively. The illustrations for performing the two tests are provided in the Appendix III. The results were released to the participants who were counseled accordingly.

Those found to have seroconverted were counseled and immediately linked to the [illegible] program for PMTCT and the high risk clinic for care and support. They were encouraged to notify their spouses and encourage them to undergo testing.

The raw data from the questionnaires was then verified, compiled and entered into the computer. Data analysis was done using the SPSS program. Results were presented in frequency distributions and descriptive statistics.

STUDY LIMITATIONS

1 Some of the mothers may have been missed out if they seroconverted at or after the second testing during the antenatal period.

ETHICAL CONSIDERATIONS

HIV infection and AIDS have profound implications on socioeconomic and health issues once the diagnosis has been made.

The study was approved by the ethics review committee.

The study participants were informed of the nature of the study and its intended use and confidentiality was maintained.

On accepting to participate in the study the participants filled a consent form and were then counseled by a trained counselor.

The counseling focused on issues of mother to child transmission of the virus, breastfeeding, safer sex practices, follow up and treatment.

To reduce the risk of mother- to- child transmission of HIV the seroconverted mothers were subjected to PMTCT protocol of KNH and were encouraged to be followed up at the KNH high risk clinic after the study in order to benefit maximally from the health services available in KNH.

There was no financial inducement to participate in the study and participants had a right to decline to participate and still received medical attention unconditionally.

RESULTS

Table 1: Socio-demographic and obstetric characteristics

Characteristic	n (%)
Age of client (yrs) n=500	
15-19	40 (8)
20-24	155 (31)
25-29	175 (35)
30-34	97 (19.4)
35-39	30 (6)
40–44	3 (0.6)
45–49	0 (0)
Marital status. n=500	
Single	67 (13.4)
Married	427 (85.4)
Widow	5 (1.0)
Divorced	1 (0.2)
Level education. n=500	
None	11 (2.2)
Primary	132 (26.4)
Secondary	237 (47.4)
College	120 (24)
Employment. n=500	
None/housewife/student	68 (13.6%)
Salaried/self	432 (86.4%)
Income (Kshs). n=500	
≤5,000	176 (35.2)
5,000–	324 (64.8)
Parity. n=500	
Primigravida	124 (24.8)
2-3	351 (70.2)
4–	25 (5.0)
Living children. n=500	
None	159 (31.8)
1-3	314 (62.8)
4+	27 (5.4)
No. of Sexual Partners for the woman during index pregnancy. n=500	
1	497 (99.4)
2+	3 (0.6)
Mean monthly sexual frequency during index pregnancy.	
1st trimester	14
2nd trimester	8.2
3rd trimester	2.6
Condom use. n=500	
None	437 (87.4)
Always or irregularly	63 (12.6)
Seroconversion during index pregnancy n=500	4 (0.8%)

Out of 500 pregnant women 4(0.8%) seroconverted during pregnancy.

Majority of the women in this cohort were in the age group 25 – 29 years (35%), married (85.4%), had secondary level of education (47.4%) and had some form of income generation (86.4%).

Highest monthly mean sexual frequency was noted to occur in the first trimester (14) and majority of them did not use condoms during the entire pregnancy (87.4%).

Table 4: Relationship between socio-demographic and obstetric with seroconversion

Characteristics (n=4)	n (%)
Age (years)	
Below 30	4 (100)
30–	0 (0)
Marital status (n=4)	
Married	1 (25)
Single/divorced/widowed	3 (75)
Level of education (n=4)	
Primary and below	1 (25)
Secondary and above	3 (75)
Employment (n=4)	
None/housewife/student	3 (75)
Salaried/self employed	1 (25)
Parity (n=4)	
Nulliparous	1 (25)
1-3	3 (75)
Illness during pregnancy (n=4)	
Ill	1 (25)
Not ill	3 (75)
Number of sexual partners for pregnant woman (n=4)	
1	4 (100)
2–	0 (0)
Number of sexual partners for spouse (n=4)	
1	0 (0)
2–	1 (25)
Unknown	3 (75)
HIV status of spouse (n=4)	
Negative	1 (25)
Positive	0 (0)
Unknown	3 (75)

All of the seroconverted women were below 30 years of age.

Although more of them 3(75%) had secondary level of education, majority were unemployed and had no knowledge of their spouses HIV status and number of sexual partners their spouses had during index pregnancy.

Table 3: Factors associated with seroconversion

Factor	positives	negatives
Illness during pregnancy (n=500)		
Presence of genital ulcerative disease (n=18)	0 (0.0)	18(100)
Severe nausea and vomiting (n=52)	0 (0.0)	52(100)
Illness such as malaria, UTI (n=39)	1 (2.6)	38(97.4)
None (n=391)	3 (0.8)	388(99.2)

No positive case was found in the pregnant women who had genital ulcerative disease or severe nausea and vomiting. Only one case (2.6%) of those who had malaria and other illnesses was positive. 3 (0.8%) of those who had uneventfully pregnancy seroconverted.

Table 4: Knowledge of those who were positive

Modality of HIV transmission	Positives n = 4(%)
Know HIV can be transmitted through unprotected sex.	4 (100)
Know HIV can be transmitted through blood transfusion.	4 (100)
Know MTCT	4 (100)

All those who seroconverted the modalities through which HIV is transmitted.

DISCUSSION

This study found that 4 out of 500 pregnant mothers receiving obstetric services in KNH seroconverted during pregnancy giving a proportion of 0.8%. This is low compared to rates of 2.2% and 2% found in South Africa and Bangkok respectively.[21,31] HIV prevalence in Kenya is on the decline as demonstrated in the reports from Kenya Demographic and Health Survey (KDHS) and Sentinel Surveillance of HIV in pregnant women.[3] HIV prevalence peaked in the late 1990s when a 15% rate was estimated. It then started declining to 6.7% in 2003, 6.1% in 2004, 5.9% in 2005 and 5.1% in 2005. The incidence has also been on the decline from 85,000 in 2004, 60,000 in 2005 to 55,000 in 2006.[3] As much as it is comforting to have these declining rates, the world is still at risk and exposed mothers will continue to seroconvert unless a permanent solution is found.

The study found out that all the seroconverted women were below 30 years of age including 1(25%) teenager. This correlates to the fact that women in this age group are also more sexually active and thus are more exposed than other age groups.[20]

Single women were found to be more at risk when 3(4.5%) of them were found to have seroconverted as compared to 1(0.2%) of the married counterparts.

3(75%) of the seroconverted had attained a secondary school education while 3(75%) of them were unemployed.

Those with income lower than Ksh 5000 had proportionally higher seroconversion rate 2(1.1%) compared with those with higher income 2(0.6%). This echoes the global scenario where higher HIV prevalence rates (70%) are found in poor sub Saharan Africa.[1]

All of those who seroconverted did not use condoms during the entire pregnancy. Correct and consistent use of condoms has been shown to protect against STIs including HIV

According to the study done by Masters and Johnson, pregnant women tend to have more sex during the second trimester but from this study the mean frequency of sexual intercourse per month during pregnancy was highest in overall terms (14) in the first trimester and lowest (2.6) in the third trimester. where as it was 8.2 in the second trimester indicating a decreasing trend.

Although presence of genital ulcerative disease has been associated with increased HIV acquisition[10], none of the seroconverted had genital ulcerative disease. Only 1(2.6%) of those who suffered from malaria and other illnesses seroconverted. Majority of the seroconverted had uneventful pregnancy.

Ironically, all the seroconverted knew that HIV can be transmitted through unprotected sex, transfusion of contaminated blood and even vertical transmission from mother to child.

CONCLUSIONS

1. This study has shown that HIV negative pregnant women seroconverted during pregnancy but the rate is low (0.8%)
2. Although 3 of the 4 seroconverted women were single, educated and unemployed, the overall number of women who seroconverted was too small to make statistical conclusions.

RECOMMENDATIONS

1. Despite the low HIV seroconversion rate found in pregnancy in a subset of women in Kenyatta national hospital, it will be prudent to conduct a similar study in other areas of the country to establish a national outlook.

2. A study on cost-effectiveness on doing two HIV tests, one in early gestation and another in late gestation and involvement of sexual partners at the same time should be done in future.

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APPENDIX I: INFORMATION GIVEN TO THE PARTICIPANT

This research forms part of my thesis for the masters degree in obstetrics and gynaecology. The aim of the research is to find out the rate of seroconversion of HIV infection during pregnancy. HIV disease is of global concern and research has shown that pregnant women are at higher risk of acquiring HIV infection during pregnancy because of the lowered immunity and the effects of the pregnancy hormones on the genital tract. It is not known how many women seroconvert during pregnancy in our set up and the results of this research will enable us to strengthen our policies on prevention of HIV acquisition especially during pregnancy

You are therefore requested to voluntarily participate in this research in order to generate information in this area of study. This research will inflict no harm to yourself or to your baby. Your participation and the information you provide will be highly appreciated and treated with utmost confidentiality. If you are found to have seroconverted, measures will be taken to reduce the risk of your baby acquiring the virus from you and you will be linked to the programme dealing with HIV positive clients. By participating in this research you will have given crucial information to the scientists of this country on how to plan for better health delivery systems. This information may be published and appear in scientific journals. You also have a right to refuse to participate in this research and this will in no way affect your current or future treatment in this hospital.

Yours faithfully.

Dr Janerose Amoit Amcuchi.
Postgraduate student.
Department of obs Gyn.
University of Nairobi.
Telephone 0722833313

APPENDIX II: CONSENT FORM

I ---------- do consent to participate in the research and to have my blood tested for HIV a second time. I understand that this research is for educational purposes only and I do not stand to gain financially from it. I consent to have been adequately counseled on the risks of acquisition of HIV during the period of pregnancy and the implications on myself and my baby. I do understand that it is my right to decline to participate in this study and this will not in any way affect my current or future treatment in this hospital.

SIGNATURE OF PARTICIPANT / LEFT THUMB PRINT ----------

DATE ----------

SIGNATURE OF THE WITNESS ----------

DATE ----------

Mimi ---------- ninakubali kujihusisha na utafiti huu niliofafanuliwa. Ninakubali damu yangu kupimwa virusi vya ukimwi kwa mara ya pili. Pia ninaelewa ya kwamba utafiti huu ni kwasababu ya maswali na shaka na pesa zozote kutokana na utafiti huu. Ninakubali nimeelezewa kuhusu uwezekano wa kuhambukizwa virusi vya ukimwi hasa wakati wa mimba na madhara yake kwangu na mtoto wangu. Ninaelewa ya kwamba ni haki yangu kukataa kujihusisha na utafiti huu na uamuzi wangu hautadhuru matibabu yangu ya sasa na ya baadaye katika hospitali hii.

SAHIHI YA MUHUSIKA / ALAMA YA KIDOLE GUMBA YA

KUSHOTO ----------TAREHE ----------

SAHIH YA SHAHIDI ---------- TAREHE ----------

APPENDIX III : QUESTIONNAIRE

Socio-demographic data

1 Serial number ---------- b) Client's Antenatal number ----------

2 Age of the client in years a) 15 – 19 [ ]
b) 20 - 24 [ ]
c) 25- 29 [ ]
d) 30 – 34 [ ]
e) 35 - 39 [ ]
f) 40 - 44 [ ]
g) 45 – 49 [ ]

3 Marital status a) Single [ ]
b) Married [ ]
c) Widow [ ]
d) Divorced [ ]

4 Parity

5 Number of living children (i) males [ ]
(ii) females [ ]

6 Level of education a) None [ ]
b) Primary [ ]
c) Secondary [ ]
d) College [ ]

7 Occupation a) None housewife [ ]
b) Self employed [ ]
c) Salaried formal [ ]

d) Student [ ]

8 Average monthly income (Ksh) a) < 1000 [ ]

b) 1000 –2000 [ ]

c) 2000 – 5000 [ ]

d) 5000 – 10000 [ ]

e) > 10000 [ ]

f) none NA [ ]

9 Residence ----------

Sexual History

10 Number of sexual partners during current pregnancy [ ]

11 Frequency of sexual intercourse (per month) (1) First trimester ----------

(2) Second trimester ----------

(3) Third trimester ----------

12 Condom use during coitus

(i) None [ ]

(ii) Irregular [ ]

(iii) Always [ ]

13 Knowledge about mode of HIV transmission

a) Unprotected sexual intercourse [ ]
b) MTCT [ ]
c) Sharing razors / sharps [ ]
d) Transfusion with infected blood [ ]

Others (specify) ----------

14 Number of sexual partners for spouse a) 1 [ ]
b) 2 [ ]
c) 3 [ ]
d) Unknown [ ]

Contributing factors

a) Presence of genital ulcerative disease [ ]
b) Severe nausea and vomiting [ ]
c) Illnesses such as malaria, UTI ----------
d) Others specify ----------

HIV Testing

15 Views about testing pregnant women twice antenatally

a) Acceptable [ ]

b) It is important [ ]

c) No need [ ]

d) Not sure [ ]

16 Gestation at a) first testing (Wks) [ ]

17 Test used a) Rapid [ ]

b) ELISA [ ]

Other (specify) ----------

18 Second HIV testing (a) Gestation (Wks) [ ]

(b) Days postpartum [ ]

19 Results a) Negative [ ]

b) Positive [ ]

20 Spouse HIV status a) Negative [ ]

b) Positive [ ]

c) Unknown [ ]

APPENDIX IV: PROCEDURE FOR RAPID HIV TESTING \

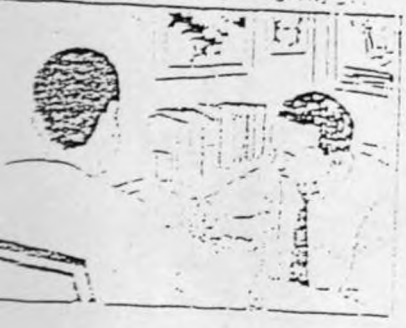
Steps to Perform the Finger-Stick Procedure

1. Wash hands with soap and water.

2. Put on latex gloves.

3. Remove test strip and cotton pouches of test.

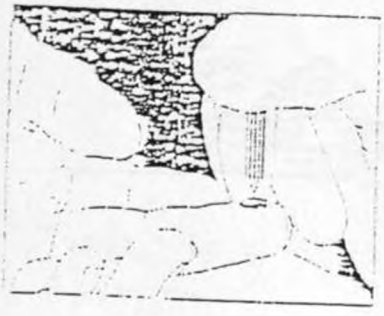
4. Label test in front of client with his or her unique identification number.



5. Holding the palm up, choose the least calloused fingertip of client's middle three fingers.

6. Clean client's fleshy area of fingertip with alcohol and cotton pad.

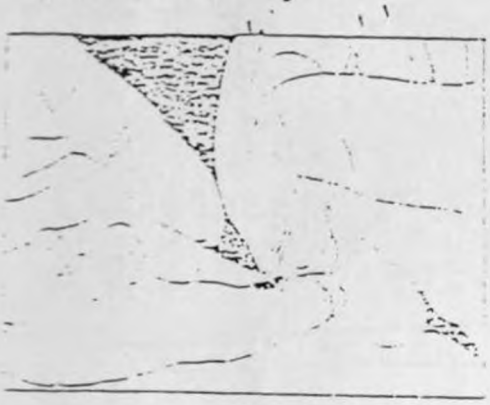
7. Tell client that you are going to prick his or her finger and it may be uncomfortable. Hold finger lower than elbow. Prick clean finger with lancet (finger prick device). Use a new lancet when pricking client's finger. A quicker prick is less uncomfortable for the client.

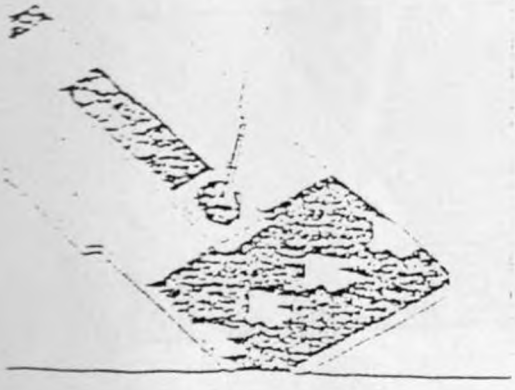


8. Place lancet in puncture-resistant container. Never reuse the lancet.

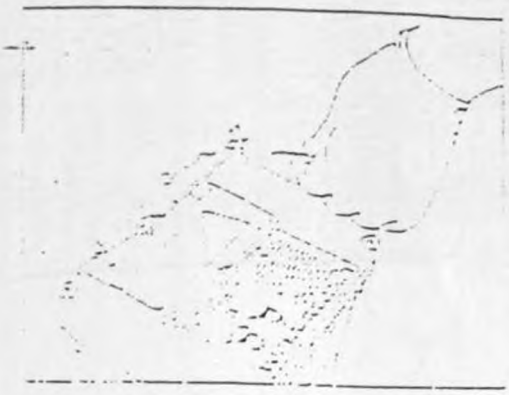
APPENDIX V: HIV TESTING (DETERMINE)

1. Take clean micro-filter tube and place gently on finger. Keep your thumb on the tube and gently tap so tube can fill up with blood.





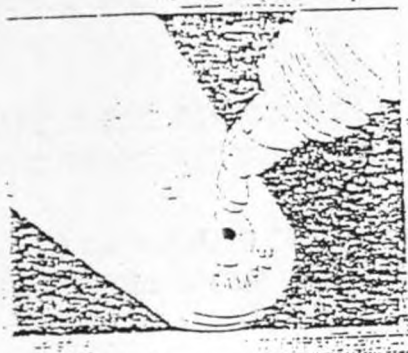
3. Put tube in puncture-resistant

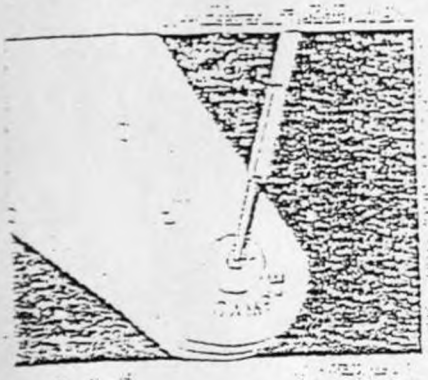


APPENDIX V

HIV TESTING (UNIGOLD)

Steps for Conducting the Uni-Gold HIV Rapid Test





RESEARCH APPROVAL BY ETHICAL COMMITTEE

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3rd October 2006

Dr. Jeremiah A. Amolo
Dept. of Obstetrics & Gynaecology
Faculty of Medicine
University of Nairobi

Dear Dr. Amolo

RESEARCH PROPOSAL: "A STUDY TO DETERMINE THE RATE OF HIV SEROCONVERSION IN PREGNANCY AND ASSOCIATED FACTORS AMONG MOTHERS ATTENDING ANTENATAL CARE AND DELIVERY SERVICES AT K.N.H" (P168/08/2006)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved revised version of your above cited research proposal for the period 3rd October 2006 – 2nd October 2007.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the date given.

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

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

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH-ERC

c.c. Prof. A.M.Breen, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, Faculty of Medicine, UoN
The Chairman, Dept. of Obs & Gyn
The Head, Social Services