

UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

**A COMPARATIVE STUDY OF COMPLICATIONS IN HIV-INFECTED AND HIV-
UNINFECTED WOMEN UNDERGOING CAESAREAN SECTION AT THE
UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.**

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STATEMENT

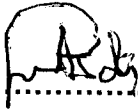
I hereby state that this dissertation is entirely the result of my own personal effort. The various sources to which I am indebted have been clearly indicated in the bibliography and acknowledgements

Signed:

Dr Allan Musonda

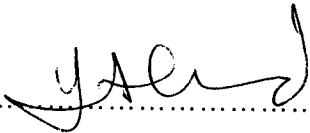
DECLARATION

I declare that this dissertation herein presented for the Degree of Master of Medicine in Obstetrics and Gynaecology has not been previously submitted either wholly or in part for any other Degree at this or any other University nor is it being currently submitted for any other Degree.

Signed:

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Dr. Maureen Chisembe (supervisor).

ABBREVIATIONS

3TC	:	Lamivudine
AIDS	:	Acquired Immunodeficiency Syndrome
APH	:	Ante Partum Haemorrhage
ALT	:	Alanine Aminotransferase
ART	:	Antiretroviral Therapy
ARV	:	Antiretroviral
C/S	:	Caesarean Section
CDC	:	(US) Centers for Disease Control and Prevention
CSO	:	Central Statistics Office
DHMT	:	District Health Management Team
DVT	:	Deep Vein Thrombosis
ELSCS	:	Elective Lower Segment Caesarean Section
HAART	:	Highly Active Antiretroviral Therapy
Hb	:	Haemoglobin
HIV	:	Human Immunodeficiency Virus
JRMO	:	Junior Resident Medical Officer
MTCT	:	Mother to Child Transmission
PG (1,2,3,4)	:	Postgraduate (Masters of Medicine trainee and year)
PLWHA	:	People Living with HIV and AIDS
PMTCT	:	Prevention of Mother to Child Transmission
PPH	:	Postpartum Haemorrhage
SHO	:	Senior House Officer
UTH	:	University Teaching Hospital
VCT	:	Voluntary Counselling and Testing
VL	:	Viral Load
ZDV	:	Zidovudine

ABSTRACT

Background: There is scientific evidence in support of the benefit of caesarean section for the prevention of mother to child transmission of HIV (PMTCT). However, information on the extent of complications and maternal mortality associated with caesarean section in HIV infected women in low resource settings such as at UTH is lacking. Some studies have reported increased risk of maternal complications associated with caesarean section in HIV infected women (particularly sepsis). This study is therefore designed to explore the incidence of maternal complications associated with caesarean section at UTH and compare complications in HIV infected and HIV uninfected women.

Objective: To document the incidence of complications in women undergoing caesarean section at UTH and compare them in HIV infected women and HIV uninfected.

Design and setting: A prospective cohort study documenting complications in women undergoing caesarean section at UTH in Lusaka. In October 2010, 299 consecutive patients undergoing caesarean section at UTH with known HIV status were recruited.

Methods: Consenting participants were followed up for six weeks after the caesarean section. Participants were interviewed and any complications documented. Infectious maternal morbidity such as wound sepsis, endometritis and puerperal pyrexia was the main outcome measure. Analysis was by Chi square and logistic regression. Significance was set at $p < .05$.

Results: Fifty eight (19.4%) HIV positive and 241 (80.6%) HIV negative women were recruited. Apart from age and parity, there were no statistically significant differences between the two groups - HIV negative women were younger and more were nulliparous. Overall 27 (9%) women had sepsis (6 were HIV positive and 21 were HIV negative – 10.3 vs. 8.7% respectively). The unadjusted odds ratio for sepsis in HIV positive vs. HIV negative women was 1.21 (95% CI .46-3.15), $p = .682$ (non-significant). Adjusting for potential confounders for the association between HIV and sepsis (based anecdotally) into a logistic regression model, (and which included: age; whether emergency or elective caesarean; single or multiple skin preparation used; separate blade used for deeper tissues or not; use of pre-operative antibiotics; blood loss greater than 1000ml; duration of operation >45 minutes) did not significantly alter the odds ratio for sepsis in HIV positive vs. HIV negative women – adjusted OR=1.39 (95%CI .5-3.59) $p = .524$.

Conclusion: Sepsis complicates approximately a tenth of caesarean sections though this complication is not independently associated with HIV status. Further studies are needed to address which factors contribute to post-caesarean complications.

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1.0 INTRODUCTION

Elective caesarean section is an effective intervention to prevent perinatal transmission of HIV (Chama 2008). There have been many studies and much discussion and controversy over the use of caesarean section for the prevention of mother to child transmission (PMTCT) of HIV (Panburana, 2008). Importantly, questions still remain regarding the extent of maternal morbidity and complications associated with the procedure.

The indications for caesarean delivery have progressively widened and concern is expressed among health professionals and consumers about its increasing use especially in the advent of HIV/AIDS (Stephenson et al 2003). Caesarean section is a relatively safe surgical procedure though it has well known risks associated with it as well (Bottoms et al 2006). Furthermore, maternal morbidity as well as mortality, is increased with caesarean section regardless of HIV status (Bottoms et al 2006). Data also suggests that caesarean section is associated with increased risk of complications in HIV positive compared to HIV negative women (Bjorklund et al 2005). However, little is known about this risk in Africa in general and Zambia in particular.

The benefit of caesarean section to the fetus is certain while the increased risk to the mother is anticipated. We need systematic studies to document the safety of caesarean sections to the mother in the setting of high HIV prevalence so that counseling for informed consent is based on sound scientific evidence. There is thus a need for more information on the incidence of post caesarean section infections in settings with limited resources, where HIV infection is common and antiretroviral treatment is not generally available due to various challenges.

To date, no such studies have been done at the UTH. Therefore, this study examined the comparative relationship between the incidence of maternal complications in HIV infected and uninfected women undergoing caesarean section at UTH. This study will contribute in shaping appropriate and more careful counseling on delivery plan in HIV infected women in our facilities that are informed by scientific evidence.

2.0 LITERATURE REVIEW

HIV/AIDS still remains a major public health problem all over the world with about 33.4 million people infected with the HIV virus worldwide (UNAIDS 2009). According to the 2007 Zambia Demographic and Health Survey, 16.1% of women of reproductive age (15 – 49 years) are infected with HIV (CSO et al 2009). There is a marked urban – rural difference (23 vs. 11.0%).

HIV positive women continue to be sexually active and the desire for children among HIV infected people is high (Nakayiwa et al, 2006).

HIV prevalence among antenatal mothers in Lusaka is high. In one pilot study of same day voluntary counseling and testing (VCT) in six urban care clinics in Lusaka, of the 84% women that requested the HIV testing, a quarter (25%) of them was HIV positive (Bakari, et al 2000).

The antenatal HIV prevalence in Lusaka has been estimated to be 27.5% (Lusaka DHMT, 2006) ranging between 15 and 30% in the different clinics.

In the midst of the HIV epidemic, increasing attention has been paid to prevention of HIV transmission from mother to her unborn child (PMTCT).

Little attention has been paid to the adverse maternal consequences of some of these interventions especially caesarean sections.

In developing countries HIV positive pregnant women are at high risk for a number of adverse consequences, especially when HIV disease is advanced.

HIV positive women tend to have lower weight gain during pregnancy and may even experience weight loss which is prognostic of maternal mortality (McIntyre 2006).

They are more likely to develop infections especially of the urinary and respiratory tracts. Infections are common postpartum and caesarean section is especially associated with increased infectious morbidity; risks being greatest with women with low CD4 counts. A greater likelihood of postpartum haemorrhage has been reported (Panburana 2008).

HIV infection influence decisions for caesarean section; As such caesarean section rates have increased globally in the era of HIV but the maternal complications could be higher.

Caesarean section is effective in preventing mother to child transmission of HIV (PMTCT) when it is done before labour and before membranes rupture (Villari et al 2008).

However it seems that the primary benefit of this intervention is in women who are not using antiretroviral agents or who are on Zidovudine alone.

More importantly, there is no evidence of benefit after the onset of labour or rupture of membranes. Currently, there is no evidence of benefit in reduction of transmission in women who are on HAART with maximal suppression of viral load.

Before the decision for caesarean delivery, the woman and her partner should be availed of the above information as well as information on the possible increased risk of maternal complications associated with caesarean section.

Caesarean section may be indicated as an obstetric intervention for fetal and/or maternal interest. The benefit to the fetus may be obvious but the risk to the mother may be higher.

Few studies have been conducted in Africa to establish the risk to the mother associated with having a caesarean section in the setting of HIV. The results of these few studies indicate that the risk of post caesarean infection is very high in low resourced settings (Bjorklund et al 2005).

These studies in developing countries have reported increased rates of post operative complications in HIV positive women. In a prospective study in Uganda by Bjorklund and others (2005) comprising 1,526 caesarean sections, the incidence of endometritis in HIV negative/unknown HIV status group was 121 of the 1439 (5.5%), wound infection in 71 of the 1439 (5%), and endometritis and/or wound infection in 154 of the 1439 (10.8%).

The corresponding incidences in the HIV positive group were 49 of 96 (51%), 28 of the 96 (29.2%) and 63 of the 96 (65.5%) respectively. This study did not distinguish between emergency and elective caesarean sections.

Complications are more likely to increase after an emergency rather than an elective section. In a study by Marcollet and Goffinet (2002), postpartum morbidity was highest after emergency rather than elective caesarean section.

In the above study by Marcollet and Goffinet, multivariate analysis which was adjusted for maternal CD4 cell count and antepartum haemorrhage (APH), the relative risk of complications was increased by 1.85 for elective caesarean section compared with vaginal delivery.

Since caesarean section rates have increased globally (Mola, 2006) maternal safety should always be discussed as part of informed consent. At UTH, the institutional caesarean section rate was 18.5% in 2008 (UTH Labour Ward Records, 2008). The Zambia Demographic and Health Survey of 2001 – 2000 showed an overall caesarean section rate for Zambia of 2.1% and it was estimated at 3.0% in the 2007 ZDHS (CSO et al 2003; CSO et al 2009). The WHO target is a caesarean rate not exceeding 15%.

In the setting of high HIV prevalence, women undergoing caesarean sections need to know whether the HIV positive status increases the risk for post caesarean complications.

However, this data is lacking at UTH. This question has not been addressed in the context of UTH. This study was therefore designed to address this information gap so that the findings can be used in the provision of counseling to HIV infected women with regards to the delivery plan. If HIV infection is a great risk for maternal complications following caesarean section, we will identify those independent correlates which can be modified to prevent the complications.

3.0 STATEMENT OF THE PROBLEM

Caesarean section delivery is a common and important surgical procedure. Data on caesarean section usage in developed countries show that caesarean section is relatively safe even for HIV-infected women. This may not be the same in developing countries with limited resources e.g. antibiotic prophylaxis may not always be available, limited theatre space, limited human resources and lack of access to antiretroviral therapy early in pregnancy for PMTCT prophylaxis or treatment.

Information on the safety of caesarean sections in HIV-infected women in resource limited settings such as UTH is lacking.

Hence, this study proposed to explore the risk of complications associated with caesarean section and also study the difference in HIV positive women compared with HIV negative women at UTH in Lusaka.

3.1 STUDY JUSTIFICATION

HIV prevalence is high in Lusaka. Many HIV positive women present to antenatal clinics in need of obstetric interventions including caesarean section.

Studies report that infections and other complications are more likely after caesarean section in HIV positive women compared to HIV negative women. This information is lacking in the context of UTH and hence this study aims to address this information gap.

3.2 RESEARCH QUESTION

What is the extent of post operative complications after caesarean section and how is this higher in HIV positive women compared to HIV negative women at UTH?

3.3 HYPOTHESIS

Null hypothesis (H_0): There is no difference in incidence of complications between HIV positive and HIV negative women after caesarean section.

3.4 OBJECTIVES

3.4.1 General objective

To compare the extent of complications in HIV positive and HIV negative women undergoing caesarean section at the University Teaching Hospital in Lusaka.

3.4.2 Specific objectives

1. To compare the incidence of complications associated with caesarean section in HIV positive and negative women at the UTH.
2. To determine socio-demographic, pre-operative (antenatal), intra-operative, and post-operative factors associated with increased post caesarean section morbidity.

4.0 RESEARCH METHODOLOGY

4.1 Research design

This study was a comparative prospective cohort study of the association between HIV status and risk of postpartum complications (infectious morbidity and need for transfusion) following caesarean delivery at the University Teaching Hospital (UTH) in Lusaka.

4.2 Study site

The study site was the Department of Obstetrics and Gynaecology at the University Teaching Hospital, Lusaka, Zambia.

4.3 Target population

The pregnant population in Lusaka during the study period was the target population. UTH was chosen as the site as it is the only public hospital offering caesarean section delivery in Lusaka.

4.4 Study group

Pregnant women who underwent caesarean section at UTH commencing 1st September 2010 until the sample size was reached constituted the study group.

4.5 Inclusion criteria

To be eligible participants:-

1. Should have been advised to undergo caesarean section by their doctors during the study period.
2. Should have been of known HIV status at the time of recruitment.
3. Should have been someone who was likely to remain in Lusaka during the six weeks follow up period.

4. Should have consented to return for follow up when she had an appointment
5. Was required to have consented to the caesarean section – the patient would have already consented to the caesarean section (elective or emergency).

4.6 Exclusion criteria

Participant was excluded if:-

1. Their HIV status was not known.
2. They had not consented to caesarean section
3. They had delivered already but needed other operations e.g. hysterectomy for postpartum hemorrhage, repair of cervical tear etc.
4. They would not remain in Lusaka during the six weeks follow-up period and they were not willing to return for follow-up visits

4.7 Sampling method

Convenience sampling methods were used as all consecutive patients who underwent caesarean section from the start of the study until the target was reached were invited to participate in the study.

4.7.1 Sample size

Group of interest: HIV positive women undergoing caesarean section for any indication including PMTCT.

Comparison group: HIV negative women undergoing caesarean section for various indications.

4.7.2 Sample size estimation

$$N = \frac{Z^2 \times P \times Q}{D^2}$$

Where Z = confidence interval (1.96)

D = specified margin of error (5%)

P = Estimate of population with characteristics of interest:
assume 20% complications of any type and magnitude. (10% to 60% in Uganda – Bjorklund 2005)

$$Q = 1 - P$$

At 80% power, Alpha 5%

$$N = 246$$

Adjusting for non response and incomplete data at 15%,
N=276

4.8 Participant recruitment and study procedures

All the women who were to have a caesarean section delivery at the start of the study (from 1st October 2010) at UTH were told of the study just before the operation and were invited to join the cohort. (The caesarean section protocol at UTH is outlined in Appendix I). They were seen by the study staff while in labour ward and other wards before the operation. The participant information sheet (Appendix II) was read to them and details of the study explained.

The research assistant (a midwife/psychosocial counselor) met all the women before caesarean section and obtained consent for participation in the study. No extra tests were required for the study and only routine test data was collected, if available, from the medical records. This included tests for HIV, CD4 count, viral load. At the time of recruitment, the protocol and procedures of the study was explained to all the women in the language they preferred to use.

After the caesarean section, the women were seen the following day and the protocol and purpose of the study explained to them again as contained in the participant information sheet (Appendix II). All consenting women were then followed up until six weeks after the caesarean section taking note of any adverse events especially infections, puerperal sepsis, wound sepsis, endometritis, need for transfusion, etc.

After obtaining informed consent, all the consenting participants' demographic and medical details were noted. If not available in the medical records, these were asked for from the patient. Also obtained from the medical records were: the time the decision was made for the caesarean section, indication for caesarean section, laboratory data such as last haemoglobin, CD4 cell count, HIV status etc. Laboratory tests were not ordered as part of this study unless ordered by attending doctors for purposes of patient care. Information was extracted from antenatal records and patient obstetric record book. All information was entered in part I of the data collection instrument (Appendix III).

In theatre, the surgeon that performed the caesarean section filled in part II of the data collection instrument to obtain intrapartum data and data related to the caesarean procedure. The patient was interviewed the day after the caesarean section for any socio-demographic details and other baseline health information that may have been previously missed or was unavailable earlier.

After caesarean section, participants were followed up according to the visit schedule (daily to discharge, then week 2 and week 6) and clinical information was extracted from their medical records into the data collection instrument.

4.9 MEASURING EXPOSURE AND OUTCOME

4.9.1 The exposure

An important exposure to be studied was the HIV status of the women undergoing caesarean section. Similarly, maternal demographic, antenatal, procedure related characteristics were considered variables important in determining which ones may be relevant in the development of the outcome (see below).

4.9.2 The outcome measure

The main outcome measure was '**sepsis**' defined as febrile illness, wound sepsis and/or endometritis arising after the caesarean section during the six (6) weeks follow-up period. Any other adverse event or morbidity attributable to the caesarean section, for example: wound dehiscence, need for blood transfusion and maternal death was also recorded.

Febrile illness - Puerperal pyrexia was defined as axillary temperature of 38 degrees Celsius on two occasions one hour apart without abnormal cervical or vaginal mucopurulent discharge, cervical motion tenderness. (This may also be due to pneumonia, urinary tract infection etc).

Wound sepsis, for purposes of this study, was defined by a reddened, tender area, deep to the incision, which may be surrounded by induration, with purulent wound discharge, wound breakdown with or without fever, chills and rigors.

Postpartum endometritis was determined clinically as any participant presenting with fever, purulent vaginal discharge and uterine tenderness developing after the caesarean section.

4.10 DATA COLLECTION AND ANALYSIS

Data was collected using a pre-tested interviewer-administered questionnaire (Appendix III). The author of this dissertation, under supervision, compiled the study design, obtained relevant authorizations, pilot-tested the instruments, oversaw the research assistant and data collection, checked the data, and compiled the results and final dissertation.

Data was collected by interviewing the participants (Part 1) and by checking in the medical records to extract data related to demographics, past history, antenatal care, HIV status etc. All the Doctors performing caesarean sections filled in Part II of the data collection tool which related to indication for caesarean section, surgeon level, date of operation, prophylactic antibiotic use, blood loss during operation, complications during operation, etc. The research assistant then followed up all the consenting participants in the postnatal wards to discharge and at two and six weeks post-delivery.

All the information collected was stored on the data capture sheet in Epi-info software and subsequently exported to SPSS. Data entry was checked for consistency by using double entry checks by two people entering the data. Discordant data was corrected accordingly.

All statistical procedures were done using SPSS for Windows Version 18. All tests were two tailed and a significance level of $P < 0.05$ was accepted as statistically significant.

In order to determine whether there were any differences between the two groups of women based on HIV status, different characteristic variables were compared using Chi square test.

Crude odds ratios were calculated to obtain the odds of complications in HIV positive and HIV negative participants and under different circumstances based on the women's demographic, antenatal and caesarean procedure characteristics.

Development of logistic regression model: A logistic regression model was developed using plausible variables (for sepsis) to get a best-fit model taking care to check if any of the selected variables were confounders of the main study association between HIV and sepsis. A p-value of 0.05 was taken as significant.

4.11 RETENTION PROTOCOL

Loss to follow up can reduce statistical power to detect a difference between the two study groups. If there is a differential loss to follow up between the two groups, this may also introduce bias. As such, certain measures were put in place to improve retention:-

1. The participants were mainly from Lusaka town
2. Participants were encouraged to come back for review and did not experience any additional waiting time compared to their counterparts that were not enrolled in our study as there was a dedicated study midwife allocated to attend to them.
3. With permission, we documented telephone numbers to be able to contact in the event of loss to follow-up.

4.12. ETHICAL CONSIDERATIONS

Apart from asking questions, there was no interference to the participant with the general standard of care at UTH. Written informed consent was obtained from all participants.

Permission to conduct the study was obtained from the UTH management through the Head, Department of Obstetrics and Gynaecology. Ethical approval was obtained from the University of Zambia Research Ethics Committee.

There were no personal identifiers on the data collection instruments, and data was kept in a lockable cabinet under lock and key.

5.0 RESULTS

A total of 305 consecutive patients were recruited into the study in October 2010. Six were excluded from the analysis because their HIV status was unknown. Of the remaining 299 patients 58 (19.4%) were HIV positive while 241 (80.6%) were HIV negative.

The socio-demographic and antenatal characteristics of the 299 respondents are shown in Table 1 stratified by HIV status. Apart from age, parity, and difference in presence of any medical condition in pregnancy, there were no significant differences between the HIV positive and HIV negative patients.

The difference in age and parity is reflected by more HIV negative women being younger and of nulliparity before the caesarean. The existence of medical conditions was also significantly different between the two comparison groups ($P = 0.015$). Eight of 58 HIV positive women (13.8%) had hypertensive disorders in pregnancy while only 17 of 241 HIV negative women (7.1%) had hypertensive disorders in pregnancy. TB was present in 2 (3.4%) of HIV positive patients compared to none in HIV negative women

Prenatal management of HIV positive women

Of the 58 women that were HIV positive, 13 (22.4%) were on life-long Antiretroviral Therapy (ART) for more than 1 year, one woman (1.7%) had been on ART for less than 1 year, while the majority ($n=40$, 69%) were only on short course ARVs for PMTCT. Four of the 58 women were not on any management plan.

TABLE 1: Characteristics of women undergoing caesarean classified by HIV status

Characteristics		HIV Positive n (%)	HIV Negative n (%)	All N (%)	2-sided p value*
All		58 (19.4)	241 (80.6)	299 (100)	
Age (years)	19 or less 20-34 35+ (Mean 30.2)	1 (1.7) 43 (74.1) 14 (24.1) (Mean 30.2)	38 (15.8) 169 (70.1) 34 (14.1) (Mean 26.3)	39 (13.0) 213 (71.2) 47 (15.7)	.006
Marital status	Single Married Widowed	8 (13.8) 49 (84.5) 1 (1.7)	30 (12.4) 211 (87.6) 0 (0)	38 (12.7) 260 (87.0) 1 (.3)	0.222
Education	None Primary Secondary Tertiary	3 (5.2) 20 (34.5) 21 (36.2) 14 (24.1)	8 (3.3) 60 (24.9) 110 (45.6) 63 (26.1)	11 (3.7) 80 (26.8) 131 (43.8) 77 (25.8)	0.382
Occupation	Unemployed Formal Informal	44 (75.9) 11 (19.0) 3 (5.2)	184 (76.3) 52 (21.6) 5 (2.1)	228 (76.3) 63 (21.1) 8 (2.7)	0.401
Religion	Christian Muslim	58 (100) 0 (0)	237 (98.3) 4 (1.7)	295 (98.7) 4 (1.3)	1.000
Residence	High density Medium density Low density Rural	37 (63.8) 11 (19.0) 7 (12.1) 3 (5.2)	135 (56.0) 43 (17.8) 29 (12.0) 34 (14.1)	172 (57.5) 54 (18.1) 36 (12.0) 37 (12.4)	0.316
Parity	0 1-4 >5	6 (10.3) 46 (79.3) 6 (10.3)	85 (35.3) 139 (57.7) 17 (7.1)	91 (30.4) 185 (61.9) 23 (7.7)	0.001
Gestation (weeks)	<28 28-36 37-42 >42	0 (0) 9 (15.5) 49 (84.5) 0 (0)	3 (1.2) 44 (18.3) 192 (79.7) 2 (0.8)	3 (1.0) 53 (17.7) 241 (80.6) 2 (0.7)	0.900
RPR status	Reactive Non-reactive indeterminate	1 (1.7) 56 (96.6) 1 (1.7)	5 (2.1) 229 (95.0) 7 (2.9)	6 (2.0) 285 (95.3) 8 (2.7)	.999
Medical condition in pregnancy	Diabetes Mellitus Hypertensive disorder TB Anaemia None	1 (1.7) 8 (13.8) 2 (3.4) 0 (0) 47 (81.0)	1 (0.4) 17 (7.1) 0 (0) 3 (1.2) 220 (91.3)	2 (0.7) 25 (8.4) 2 (0.7) 3 (1.0) 267 (89.3)	.015
HIV status and prenatal management	On ART > 1 year On ART < 1 year Short course ARVs None	13 (22.4) 1 (1.7) 40 (69.0) 4 (6.9)	N/A	13 (22.4) 1 (1.7) 40 (69.0) 4 (6.9)	N/A

*Chi square (or Fisher exact test when values <5)

Indications for caesarean section

The indications for caesarean section are illustrated in table 2, stratified by HIV status. The three commonest indications were: one or more previous caesarean (86, 28.8%), cephalopelvic disproportion (67, 22.4%) and fetal distress (31, 10.4%). There were proportionally more HIV negative women with the first two indications and likely reflecting nulliparity. Numbers of cases for other indications are too small to make substantial inferences between the two groups of women.

TABLE 2: Indications for caesarean section by HIV status

Indication	HIV Positive n (%)	HIV Negative n (%)	All N (% of 299)
>1 previous caesarean (or scarred uterus)	19 (22.1)	67 (77.9)	86 (28.8)
Cephalopelvic disproportion	10 (14.9)	57 (85.1)	67 (22.4)
Fetal distress	6 (19.4)	25 (80.6)	31 (10.4)
Breech presentation	4 (18.2)	18 (81.8)	22 (7.4)
Hypertensive disorders of pregnancy	7 (36.8)	12 (63.2)	19 (6.4)
Multiple pregnancy	3 (25.0)	9 (75.0)	12 (4.0)
Placenta praevia	6 (54.5)	5 (45.5)	11 (3.7)
Failed induction	1 (11.1)	8 (88.9)	9 (3.0)
Abruptio placenta	1 (12.5)	7 (87.5)	8 (2.7)
Ruptured uterus	2 (33.3)	4 (66.7)	6 (2.0)
Cord prolapse	5 (100)	0 (0)	5 (1.7)
Face presentation	1 (25)	3 (75)	4 (1.3)
Transverse lie	0 (0)	4 (100)	4 (1.3)
Antepartum haemorrhage	3 (100)	0 (0)	3 (1.0)
Premature rupture of membranes	1 (33.3)	2 (66.7)	3 (1.0)
PMTCT only	1 (100)	-	1 (.3)
Other (Bad obstetric history, TB spine, compound pres ⁿ , hand prolapse)	2 (22.2)	7 (77.8)	9 (3.0)
All	58 (19.4)	241 (80.6)	299 (100)

Caesarean section procedures by HIV status

Table 3 illustrates the various caesarean section procedures and the corresponding p values. Caesarean section procedures were statistically similar in the HIV positive and HIV negative groups. Type of caesarean (i.e. emergency or elective), type of anesthesia, surgeon level, skin preparation solutions, type of skin incision, use of separate blade for deeper tissue, use of prophylactic antibiotics, estimated blood loss, need for transfusion in theatre, sutures used on sheath and skin, type of skin closure, complications at caesarean, operation duration etc, did not differ significantly across the two HIV status groups. However, HIV positive status was significantly associated with important intra operative findings such as adhesions, fibroid uterus, poorly formed lower segment ($P=0.003$).

TABLE 3: Caesarean section procedures by HIV status

		HIV Positive n (%)	HIV Negative n (%)	All N (%)	p value*
		58	241	299	
Type of caesarean	Emergency	50 (86.2)	222 (92.1)	272 (91.0)	.159
	Elective	8 (13.8)	19 (7.9)	27 (9.0)	
Type of anaesthesia	General	57 (98.3)	229 (95.0)	286 (95.7)	.372
	Spinal/epidural	1 (1.7)	12 (5.0)	13 (4.3)	
Surgeon level	JRMO	2 (3.4)	8 (3.3)	10 (3.3)	.367
	PG1	21 (36.2)	89 (36.9)	110 (36.8)	
	PG2	7 (12.1)	55 (22.8)	62 (20.7)	
	PG3	1 (1.7)	5 (2.1)	6 (2.0)	
	PG4	21 (36.2)	67 (27.8)	88 (29.4)	
	Senior Registrar	6 (10.3)	13 (5.4)	19 (6.4)	
	Consultant	0 (0)	4 (1.7)	4 (1.3)	
Skin preparation	Savlon, iodine, spirit	1 (1.7)	9 (3.7)	10 (3.3)	.736
	Savlon with iodine/spirit	40 (69.0)	175 (72.6)	215 (89.2)	
	Savlon only	14 (24.1)	48 (19.1)	62 (25.7)	
	Spirit only	3 (5.2)	9 (3.7)	12 (5.0)	
Skin incision	Transverse	56 (96.6)	227 (94.2)	283 (94.6)	.473
	vertical	2 (3.4)	14 (5.8)	16 (5.4)	
Separate blade for deeper tissue	Yes	5 (8.6)	33 (13.7)	38 (12.7)	.298
	No	53 (91.4)	208 (86.3)	261 (87.3)	
Prophylactic antibiotics used	None	43 (74.1)	173 (71.8)	216 (72.2)	.719
	Any	15 (25.9)	68 (28.2)	83 (27.8)	
	Pre-op	11 (73.3)	46 (67.6)	57 (68.7)	
	Per-op	4 (26.7)	22 (32.4)	26 (31.3)	
Intraop findings (patient can have more than 1 finding)	Adhesions	19 (29.2)	57 (22.4)	76 (23.8)	.003
	Fibroids	5 (7.7)	11 (4.3)	16 (5.0)	
	Poorly formed lower segment	10 (15.4)	10 (3.9)	20 (6.3)	
	Other*8	2 (3.1)	16 (6.3)	18 (5.6)	
	None	29 (44.6)	160 (63.0)	189 (59.2)	
	(total)	65 (100)	254 (100)	319 (100)	
Blood loss (estimated)	<500	15 (25.9)	89 (36.9)	104 (34.8)	.247
	500-1000	37 (63.8)	126 (52.3)	163 (54.5)	
	>1000	6 (10.3)	26 (10.8)	32 (10.7)	
Transfused	Yes	4 (7.0)	13 (5.4)	17 (5.7)	.643
	No	54 (93.0)	228 (94.6)	282 (94.3)	
Sutures (sheath)	Nylon	3 (5.2)	15 (6.2)	18 (6.0)	.657
	Chromic catgut	49 (84.5)	191 (79.3)	240 (80.3)	
	Vicryl	6 (10.3)	35 (14.5)	41 (13.7)	
Sutures (skin)	Nylon	10 (17.2)	30 (12.4)	40 (13.4)	.459
	Chromic catgut	2 (3.4)	12 (5.0)	14 (4.7)	
	Silk	43 (74.1)	173 (71.8)	216 (72.2)	
	Vicryl	3 (5.2)	26 (10.8)	29 (9.7)	
Skin closure	Subcuticular	6 (10.3)	37 (15.4)	43 (14.4)	.329
	Interrupted	52 (89.7)	204 (84.6)	256 (85.6)	
Complications at caesarean**	Nil	52 (89.7)	214 (88.8)	266 (89.0)	.851
	Other (bleeding, extension)	6 (10.3)	27 (11.2)	33 (11.0)	
Operation duration	<30	23 (39.7)	119 (49.4)	142 (47.5)	.354
	30-44	30 (51.7)	92 (38.2)	122 (40.8)	
	45-59	3 (5.2)	19 (7.9)	22 (7.4)	
	60+	2 (3.4)	11 (4.6)	13 (4.3)	

* Chi square (or Fisher exact test when values <5)

** includes presence of meconium, vascular lower segment, retroplacental clot.

*** adhesions, extension of lower segment incision, difficulty in achieving haemostatis, bladder damage.

Outcome measures

The main outcome measure for this study (complication) was sepsis (defined as febrile illness, septic wound or endometritis). By week 6, 6 of 58 (10.3%) HIV positive women had sepsis as did 21 of 241 (8.7%) HIV negative women (overall 9.0%) (table 4). **Sepsis by week 6 was used as the primary outcome in subsequent analysis.**

Similarly, the proportion needing blood transfusion (another complication and outcome) was 6.9% and 5.4% respectively. There were two maternal deaths.

Table 4: Sepsis and blood transfusion as outcomes

	HIV Positive (58 women) n (row %) (column %)	HIV Negative (241 women) n (%) (column %)	All (299 women) N (%) (column %)
Sepsis (feb, sep, endo) by week 1	5 (41.7) (8.6)	7 (58.3) (2.9)	12 (100) (4.0)
Sepsis (feb, sep, endo) by week 2	6 (22.2) (10.3)	21 (77.8) (8.7)	27 (100) (9.0)
Sepsis (feb, sep, endo) by wk 6 (no new cases from week 2)	6 (22.2) (10.3)	21 (77.8) (8.7)	27 (100) (9.0)
No sepsis by 6 weeks	52(89.7)	220(91.3)	272(91%)
Need for blood transfusion	4 (23.5) (6.9)	13 (76.5) (5.4)	17 (100) (5.7)
Died	2	0	2

Summaries of maternal deaths

Case 1: 28year old, para1, 38weeks gestation, HIV positive, no current illness, on short course ARVs, had an emergency caesarean section for ruptured uterus, did not have pre-operative antibiotics, 1500ml blood loss and was transfused, had peritonitis, relaparotomy and hysterectomy. Died 2 weeks post caesarean.

Case 2: 29year old, para 4, 40weeks gestation, HIV positive, Clinical Stage 2, no current illness, had been on ART for 2 years, suspected features of Stevens Johnson syndrome, had an emergency caesarean section for abruption placenta, 700 ml blood loss. Died soon after caesarean.

Characteristics of the women undergoing caesarean section classified by presence or absence of sepsis

Table 5 shows the socio-demographic and antenatal characteristics of the women undergoing caesarean section classified by outcome (sepsis). In this study sample, being HIV positive was not associated with sepsis (OR1.21; 95%CI .46-3.15; p=.682). None of the other listed antenatal or demographic variables were statistically associated with sepsis.

TABLE 5: Characteristics of women undergoing caesarean classified by outcome (sepsis)

Characteristic		sepsis n (%)	No sepsis n (%)	All N (%)	Unadjusted odds ratio (95% CI) p value
Any		27 (9.0)	272(91)	299 (100)	
HIV status	Positive	6 (22.2)	52 (19.1)	58 (19.4)	1.21 (.46-3.15) .682
	Negative	21 (77.8)	220 (80.9)	241 (80.6)	
Age (years)	Up to 18	3 (11.1)	17 (6.3)	28 (6.7)	1.88 (.33-7.15) .406
	>18	24 (88.9)	255 (93.7)	279 (93.3)	
Marital status	Single	4 (14.8)	35 (12.9)	39 (13.0)	1.18 (.28-3.74) .765
	Married	23 (85.2)	237 (87.1)	260 (87.0)	
Residence	High density/rural	19 (70.4)	190 (70.0)	209 (69.9)	1.03 (.44-2.57) .487
	Medium density	8 (29.6)	82 (30.0)	90 (30.1)	
Parity	0	10 (37.0)	81 (29.8)	91 (30.4)	1.39 (.59-3.15) .44
	1+	17 (63.0)	191 (70.2)	208 (69.6)	
Gestation (weeks)	37+	24 (88.9)	219 (80.5)	243 (81.3)	1.94 (.55-10.4) .437
	24-36	3 (11.1)	53 (19.5)	56 (18.7)	
Medical condition in pregnancy	Diabetes Mellitus, Hypertensive disorder, TB, Anaemia	3 (11.1)	29 (10.7)	32 (10.7)	0.95 (.22-3.1) .984
	None	24 (88.9)	220 (89.3)	267 (89.3)	

Caesarean section procedure by outcome (sepsis)

When caesarean section procedures were compared across the two groups of women i.e. those with sepsis and those without sepsis, there was no significant association with sepsis in any of the procedures. Hence type of caesarean, type of anaesthesia, surgeon level, skin preparation, use of separate blade for deeper tissues, prophylactic antibiotic use etc were not independently associated with increased post operative sepsis. (Table 6).

TABLE 6: Caesarean section procedures by outcome (sepsis)

		sepsis	No sepsis		
		n=27 (%)	n=272 (%)	N=299 (%)	odds ratio (95% CI) p value
Type of caesarean	Emergency	25 (92.6)	247 (90.8)	272 (91.0)	1.27 (0.29-11.65) .999
	Elective	2 (7.4)	25 (9.2)	27 (9.0)	
Type of anaesthesia	General	26 (96.3)	260 (95.6)	286 (95.7)	1.2 (0.16- 53.2).999
	Spinal/epidural	1 (3.7)	12 (4.4)	13 (4.3)	
Surgeon level	JRMO+PG1	10 (37.0)	110 (40.4)	120 (40.1)	.87 (.34-2.1) .838
	PG2,3,4, SR, Cons	17 (63.0)	162 (59.6)	179 (59.9)	
Skin preparation	Savlon OR Spirit	10 (37.0)	81 (29.8)	91 (30.4)	1.39 (.59-3.15) .44
	Savlon + other	17 (63.0)	191 (70.2)	208 (69.6)	
Skin incision	Transverse	27 (100)	256 (94.1)	283 (94.6)	N/A
	vertical	0 (0)	16 (5.9)	16 (5.4)	
Separate blade for deeper tissue	No	26 (96.3)	235 (86.4)	261 (87.3)	4.1 (.63-172.3) .223
	Yes	1 (3.7)	37 (13.6)	38 (12.7)	
Prophylactic antibiotics used	None	22 (81.5)	194 (71.3)	216 (72.2)	1.77 (.63-6.19) 0.368
	Any	5 (18.5)	78 (28.7)	83 (27.8)	
Intraop findings (can have >1)	Adhesions, fibroids etc	10 (37.0)	100 (36.8)	110 (36.8)	1.01 (.43-2.29) >.999
	None	17 (63.0)	172 (63.2)	189 (63.2)	
Blood loss (estimated)	>1000 ml	5 (18.5)	27 (9.9)	32 (10.7)	2.06 (.65-5.68) .199
	<1000 ml	22 (21.5)	245 (90.1)	267 (89.3)	
Transfused	Yes	5 (18.5)	12 (4.4)	17 (5.7)	4.92 (1.23-16.7) .01
	No	22 (81.5)	260 (95.6)	282 (94.3)	
Skin closure	Subcuticular	4 (14.8)	39 (14.3)	43	1.04 (.25-3.28) .999
	Interrupted	23 (85.2)	233 (85.7)	256	
Complications at caesarean	bleeding, extension	4 (14.8)	29 (10.7)	33 (11.0)	1.84 (.42-6.05) .292
	Nil	23 (85.2)	243 (89.3)	266 (89.0)	
Operation duration	45+	5 (18.5)	30 (11.0)	35 (11.7)	1.83 (.58-1.51) .272
	<45	22 (81.5)	242 (90.0)	264 (88.3)	

Logistic Regression Model and adjusted Odds ratios

Logistic regression did not show any factor that was significantly associated with post – caesarean sepsis. The unadjusted odds ratio for sepsis in HIV positive vs. HIV negative women as shown previously in table 5 was 1.21 (95% CI .46-3.15), $p=.682$ (non-significant).

Incorporating variables into the model that could be possible confounders for the association between HIV and sepsis (based anecdotally), (and including: age; whether emergency or elective caesarean; single or multiple skin preparation used; separate blade used for deeper tissues or not; use of pre-operative antibiotics; blood loss greater than 1000ml; duration of operation >45 minutes or not) did not significantly alter the odds ratio for sepsis in HIV positive vs. HIV negative women – adjusted OR=1.39 (95%CI 0.5 - 3.59) $p=0.524$. The full model is shown below table 7.

Table 7: Odds ratio for sepsis in HIV positive vs. HIV negative women having caesarean section (n=299, only cases with no missing values used in analysis)

	Odds ratio for sepsis	95% CI	P value
No adjustment	1.21	46-3.15	.682
Adjusted*	1.39	0.5-3.87	.524

*Adjusted for emergency or elective caesarean; single or multiple skin preparation used; separate blade used for deeper tissues or not; use of pre-operative antibiotics; blood loss greater than 1000ml; duration of operation >45 minutes or not.

Logistic regression model

Deviance goodness of fit chi-square = 115.13 df = 174 P > 0.999
Deviance (likelihood ratio) chi-square = 10.96 df = 8 P = 0.204

<u>Parameter</u>	<u>Odds Ratio</u>	<u>95% CI</u>	<u>P</u>
HIV Positive	1.39	0.5 to 3.87	0.524
Age	0.95	0.89 to 1.02	0.172
Emergency CS	0.91	0.19 to 4.35	0.906
Single skin prep	2.2	0.93 to 5.24	0.074
No separate blade	3.23	0.41 to 25.21	0.263
No pre-op antibiotics	2	0.7 to 5.7	0.193
Blood loss>1000ml	1.63	0.49 to 5.41	0.428
Duration >45mins	1.73	0.52 to 5.76	0.369

6.0 DISCUSSION

The objective of this study was to compare the incidence of maternal complications in HIV infected and HIV uninfected women undergoing caesarean section at the University Teaching Hospital, to determine correlates of post-operative complications overall as well as comparing them in the two HIV status groups ,and to determine socio-demographic factors associated with post caesarean section complications.

The results indicate that the risk of post caesarean infection is not significantly higher in HIV positive women compared to HIV negative women at UTH thus disputing the results of previous studies (e.g. Bjorklund et al 2005 in Uganda). The study also revealed that there is limited access to antiretroviral in HIV positive women in Lusaka such that a good number of them reach term and deliver without CD₄ cell count test. As a result, most of them are not on ART but ARVs (in the form of short course zidovudine monotherapy) or no ARVs at all.

In general, there was low use of pre operative antibiotics at UTH in women undergoing caesarean section (whether HIV positive or negative). Of the 299 women, 216 (72.2%) did not receive any prophylactic antibiotics pre-operatively. However, this low use of pre operative antibiotics was not different in the two HIV status groups. This finding is consistent with the findings of previous studies in other developing countries (Bjorklund et al). In this study considering use or non-use of pre-operative antibiotics alone was not associated with sepsis (unadjusted OR 1.77, 95%CI .63-6.19, p=.368). Nevertheless, there is need for policy or protocol to ensure prophylactic antibiotics are given as a routine in all patients undergoing caesarean section.

Both of the maternal deaths recorded during the study period were HIV positive. The first one who had laparotomy for ruptured uterus did not receive any preoperative antibiotics. She subsequently developed peritonitis and had hysterectomy but later developed overwhelming sepsis and died. This case perhaps illustrates the importance of preoperative antibiotics especially in HIV positive women. The second maternal death was due to suspected Stevens Johnson syndrome in a patient with abruption placenta. Further research is needed on the relationship between HIV/ART and placenta abruption.

Most of the studies reviewed were carried out in Europe or USA. In those studies up to 80% of HIV positive women were on antiretroviral treatment and 98% of them had received prophylactic antibiotics (Panburama 2008). The incidence of puerperal sepsis was 0-16% in the HIV positive women and 0 – 11% in the HIV negative women. In contrast, 69% of the women in our study were only on short course ARVs while only 22.4% were on life-long ART for more than a year. This is so despite HIV testing being routine in our antenatal clinics through the “Opt Out” approach.

This study found that the incidence of puerperal sepsis in HIV positive women is 10.3% and 8.7% in HIV negative women. This means that the incidence of post caesarean infections at UTH is similar to that in other countries. HIV positive women also tended to have increased risk of wound sepsis although this did not reach statistical significance in this study.

Because of the general lack of CD₄ count and viral load tests, analysis for these important confounders was not possible as we could not reach a good number of valid cases for statistical analysis. Another study is suggested to address this information gap. However, socio-demographic factors showed no relationship to risk of post-operative complications. Specifically, parity, gravidity, gestation age, education level, occupation, religion and marital status had no significant association with risk of complications. Furthermore, there was no statistically significant difference in the relationship between HIV positive and HIV negative women.

Although there was no statistical significant difference between use of separate surgical blade for deeper tissues and risk of post-caesarean complications there was a trend towards benefit in those women where a separate surgical blade was used for deeper tissues compared to where it was not used. This finding is consistent with the general theatre practice in favour of a policy of using separate surgical blades for deeper tissues. However, separate surgical blades for deeper tissues were only used in 12.7% of cases, and this was mostly likely only when theatre students were undergoing practical assessments by their clinical instructors. It is recommended that this good practice be put in routine practice as it has scientific evidence of benefit. This recommendation applies to both HIV

positive and HIV negative women, as the benefit trend was similar in the two groups.

Of interest was the finding that blood loss was similar in both HIV status groups. 10.3% HIV positive and 10.8 HIV negative women had blood loss more than 1000mls. As a result, the number of women who needed transfusion was also similar. This means that, although there were significantly more adverse Intraoperative findings in the HIV positive group, this did not result in significantly more intraoperative bleeding.

Measures of outcome.

In this study, sepsis was used as the main outcome reflecting 'complications' post caesarean section. The other two complications considered were: need for transfusion because of excessive bleeding at caesarean and death. There were two deaths recorded in this study and a summary of the cases is outlined after table 4. There were 17 cases that required transfusion (4 [6.9% of cases] in HIV positive women and 13 [5.4% of cases] in HIV negative women. Overall, this was 5.7% of all cases (compared to 9% for sepsis) and therefore analysis was restricted to sepsis. Although not shown, HIV was not a factor associated with need for transfusion.

Logistic regression model

The logistic regression model enabled us to study the role of any potential confounders in the association between sepsis and HIV status. Potential factors were based on anecdotal evidence of those likely to cause sepsis. Regardless, the odds of sepsis in HIV positive women were not statistically affected by the candidate factors used in the regression model.

7.0 STUDY LIMITATIONS AND STRENGTHS

7.1 STUDY LIMITATIONS

-Because of the costs involved, it was not possible to perform some laboratory tests that could have been important confounders such as CD₄ count, viral loads.

-The study was not specifically powered to compare specific complication between HIV positive and negative women.

7.2 STRENGTHS OF THE STUDY

Data collection was very systematic and had few omissions/missing data. Follow-up of participants was also very good as nearly all participants returned for follow-up at 6 weeks. Patients were encouraged to return for follow-up at each visit and some had been prompted by phone.

8.0 CONCLUSION

This study demonstrates that the risk of post-caesarean sepsis is 9% but statistically not different in HIV infected women compared to HIV-uninfected women

9.0 RECOMMENDATIONS

1. All HIV infected women should be evaluated for ART as soon as they test HIV positive to enable them start ART early in pregnancy.
2. Prophylactic pre-operative antibiotics should be routine for all women undergoing caesarean section but is especially important in HIV infected women and should be available in labour ward, maternity wards and operating theaters.
3. Routine use of a separate surgical blade for deeper tissues is likely associated with less post-caesarean infections and be a routine practice in theatre.
4. It is necessary to improve maternity services in a comprehensive manner-increasing theatre space, human resources and logistics so that women can be operated on within a short time once decision for caesarean section has been made.
5. A larger study specifically powered to detect a difference in HIV positive vs. HIV negative women is needed to address the issue of post caesarean sepsis in the high HIV prevalence settings.

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APPENDICES

Appendix I: The UTH caesarean section protocol

All the caesarean sections were performed by UTH Doctors according to the following protocol:-

1. Safe surgical practices were followed by observing all the infection prevention practices, appropriate skin preparation, tissue handling and proper use of instrument.
2. A transverse abdominal skin incision was made unless other type of incision was indicated.
3. Oxytocin was routinely used after delivery of the fetus.
4. Uterine incision was sutured in two layers using appropriate suture materials.
5. Standard wound care, removed wound dressing after 24 hrs, wound kept clean and dry.
6. Urinary bladder catheter was removed after 24 hrs.
7. Antibiotics were given pre-operatively in some cases and post-operatively in other instances.

Appendix II

PARTICIPANT INFORMATION AND CONSENT SHEET. 'UTH CAESAREAN SECTION STUDY'

Principal Investigator: Dr Allan Musonda

Sponsor: GRZ.

Dear Patient,

You are invited to take part in this research study. It is being conducted by Dr Allan Musonda as part of the Masters Degree in Medicine.

This study is being done on women that have had a caesarean section at UTH. At the end of the six weeks after the caesarean section, you will be asked to provide information as to whether you have had any problems. This research is being done because it will help us to look after women having a caesarean section even better.

Anyone having a caesarean delivery can be part of this study and that is why you are being asked. If you agree, you will answer some questions to help us know you better. The information copied from your medical file, about this and past pregnancies, and some other things about you will also be checked. The study staff will see you on the ward daily after the caesarean and at week 2, and 6 weeks after. This will be to check you are getting better and treat any problems if they are there. The study will not interfere in the way your doctors have planned to take care of you in this pregnancy. The study will not alter the plan of care your doctors have for you.

What you tell us will not be shared with anyone. The research assistants will see you every day while you will be in hospital. Also at two weeks and six weeks as you come back to see your doctor. If you agree to take part, please sign the consent form attached to allow us to see you if you choose to be part of this study. If you have any questions later, please contact Dr Musonda on cell 0977 786495 in the Maternity Wing, UTH. You may also contact the Secretary, UNZA Research Ethics Committee, Ridgeway Campus, phone 256067

Participation Consent Form – Study ID

‘UTH Caesarean Section Study’

I understand all that has been explained to me as above and it is clear to me what this study is all about. I voluntarily Consent to take part in the study. I also understand that I will need to come back according to the schedule that has been explained to me to be followed up. I agree to participate in the study on my own without coercion.

Name: Tel:

Signature: Date:

Witness name:

Sign:

Date:

Appendix III: QUESTIONNAIRE

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PART I (Socio-Demographic and Baseline Health Information)

UTH File number:	Initials:
Date of Caesarean:	Study Participant ID:

- 1. Age (years):
(Write number' or Adult if patient does not know; check in file if not known).

- 2. Parity:

- 3. Gestation age (weeks):

- 4. Gravidity:

- 5. Number of children alive:

- 6. Marital status
 - (0) Single ☐
 - (1) Married ☐
 - (2) Widowed ☐
 - (3) Divorced ☐
 - (4) Other (Specify)

7. Education level

(0) None ☐

(1) Primary ☐

(2) Secondary ☐

(3) Tertiary ☐

8. Occupation type

(0) Unemployed ☐

(1) Formal employment ☐

(2) Informal Sector ☐

(3) Other (Specify)

9. Religion

(0) Christian ☐

(1) Muslim ☐

(2) Other (Specify)

10. Residential address (Write name of compound).

(0) High density ☐

(1) Medium density ☐

(2) Low density ☐

(3) Rural ☐

11. RPR (from antenatal Record)

(0) Reactive (R) ☐

(1) Non-reactive (NR) ☐

(2) Indeterminate ☐

(3) Not available ☐

12. (i) Last Hb (Preoperative)

(ii) Date of Hb test

13. (i) HIV status (from antenatal record)

(0) Reactive (R) ☐

(1) Non Reactive (NR) ☐

(2) Indeterminate (I) ☐

(ii) Date of HIV Test (if available)

14.(i) CD₄ count (Option) if available

(ii) Date of CD₄ count (if available)

15. Viral Load (Option) if available copies/ml

16.Date of viral load (if available)

17. HIV clinical stage (WHO) classification (in case of HIV positive)

- (0) Stage 1 ☐
- (1) Stage 2 ☐
- (2) Stage 3 ☐
- (3) Stage 4 ☐

18. Current HIV related illness

- (0) Yes ☐
- (1) No ☐

Condition

19. Prenatal HIV management

- (0) On HAART >1year ☐
- (1) On HAART < 1 year ☐
- (2) Short course ARVs ☐
- (3) N/A ☐ Since(Date)

20. Pre-existing medical conditions

- (0) Diabetes Mellitus ☐
- (1) Hypertension ☐
- (2) Cardiac disease ☐
- (3) Other (Specify)

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PART II (Intrapartum Information)

UTH File number:	Initials:
Date of Caesarean:	Study Participant ID:

21 Indication for the c/s (tick all relevant)

- (0) Placenta Praevia ☐
- (1) >1 previous C/S (or scared uterus) ☐
- (2) CPD ☐
- (3) Multiple Gestation ☐
- (4) Hypertension conditions ☐
- (5) PMTCT only ☐
- (6) Other (Specify)

22. Type of caesarean section

- (0) Emergency ☐
- (1) Elective ☐

23. Type of anaesthesia

- (0) General anaesthesia ☐
- (1) Spinal/Epidural anaesthesia ☐
- (2) Local ☐
- (3) Other (Specify)

24. Surgeon level

- (0) JRMO ☐
- (1) PG1 ☐
- (2) PG2 ☐
- (3) PG3 ☐
- (4) PG4 ☐
- (5) SR ☐
- (6) Consultant ☐

25. Skin preparation solutions or antiseptics

- (0) All: Savlon, Iodine, Spirit ☐
- (1) Iodine only ☐
- (2) Spirit only ☐
- (3) Savlon only ☐
- (4) Savlon with either spirit or iodine ☐
- (5) Other (Specify)

26. Skin incision

- (0) Transverse suprapubic ☐
- (1) Vertical ☐
- (2) Other (Specify)

27. Was a separate surgical blade used for deeper tissue?

- (0) Yes ☐
- (1) No ☐

28. (i) Prophylactic antibiotics used

(0) None ☐

(1) X-pen metronidazole ☐

(2) Ceftriaxone, metronidazole ☐

(3) Others (Specify)

(ii) Preoperative ☐

(iii) Per-operative ☐

29. Important intra operative findings

(0) Adhesions ☐

(1) Fibroid uterus ☐

(2) Poorly formed lower segment ☐

(3) Other (Specify)

30. Estimated blood loss:mls

31. Transfused in theatre

(0) Yes ☐

(1) No ☐

32 .Sutures used on sheath

(0) Nylon ☐

(1) Chromic ☐

(2) Vicryl ☐

(3) Other (specify)

33. Type of skin closure

(0) Continuous subcuticular ☐

(1) Interrupted mattress ☐

(2) Others (Specify)

34. Complications at caesarean (Specify)

35. Operation duration (minutes).....

Neonatal

36 Plurality (tick one)

(0) Singleton ☐

(1) Twins ☐

(2) Triplets or higher ☐

37 .Neonatal outcome

(0) Stillborn ☐ Live born ☐ AS 1 minBwt Time

(1) Stillborn ☐ Live born ☐ AS 1 minBwt Time

(2) Stillborn ☐ Live born ☐ As 1 min Bwt Time

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PART III (Postpartum Data)

UTH File number:	Initials:
Date of Caesarean:	Study Participant ID:

38.

Complications	Day 0	1	2	3	4	5		
1. Febrile illness								
2. Septic wound								
3. Endometritis								
4. Paralytic ileus								
5. Transfusion								
6. Other (specify)								

39. Hb Post-caesareanmg/dL on date; Hb..... mg/dL on date; Hbmg/dL on date.....

40. Discharge date

41. Baby alive on discharge?

(0) Yes ☐

(1) No ☐

If not, died when? (Date)

42. (i) At (approx.) 2 weeks postpartum (Date.....)

(0) Febrile illness ☐

(1) Septic wound ☐

(2) Endometritis ☐

(3) Paralytic ileus ☐

(4) Other (Specify)

(ii) Baby alive at visit?

(0) Yes ☐

(1) No ☐

If not, died when? (Date

43. (i) Morbidities at (approx) 6 weeks postpartum (Date

(0) Febrile illness ☐

(1) Septic wound ☐

(2) Endometritis ☐

(3) Paralytic ileus

(4) Other (Specify)

(ii) Baby alive at visit?

(0) Yes ☐

(1) No ☐

If not alive, died when? (Date: