THE UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

A STUDY OF ADEQUACY OF INFORMED CONSENT FOR CAESAREAN SECTION AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.

DR. DAVID C. LUBANSA MB.ChB. (UNZA)

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY.

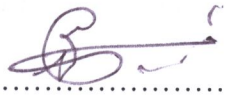
2010

DEDICATION

This work is dedicated to my children Jessie and Peter and to my wife Priscilla. It is also dedicated to my late father Peter Lubansa and my late sister Mary Lubansa. Last but not least I would like to dedicate this work to my mother Jessy Lubansa and my other sisters Emma, Kasonde and Mumba.

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. DAVID C LUBANSA

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:.....

DR. DAVID C. LUBANSA

APPROVED BY:.....

DR. BELLINGTON VWALIKA (SUPERVISOR)

APPROVAL

THIS DISSERTATION OF DR DAVID C LUBANSA IS APPROVED AS FULFILLING PART OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY BY THE UNIVERSITY OF ZAMBIA.

SIGNATURES

ABSTRACT

Background. Informed consent consists of availing information to the patient in an understandable manner without coercion to allow the patient to make an informed decision about their health care. In the case of informed consent for caesarean section, this information must include the name, nature, intended benefits of the procedure, risks of the procedure, alternative procedures, implications on future reproductive health and anaesthetic options Little attention, in Zambia, has been paid to whether patients receive adequate consent before operation and its implications for future reproductive capacity; this study aims to explore this aspect.

Methods. This was a cross sectional study in which post-caesarean section mothers were interviewed in the postnatal wards at the University Teaching Hospital (UTH), Lusaka, Zambia after under going emergency (n=115) and elective caesarean section (n=32). Information was obtained using a standardized questionnaire. Adequacy was determined by asking about elements of the consent process for caesarean section. Responses were scaled as: strongly agree, agree, don't know, disagree and strongly disagree – the first 2 categories were considered 'adequate' for each element. An overall 'adequacy' was determined based on responses to the name of procedure, nature of procedure and indications (as stated by the patient and verified from the case notes). Association of responses with type of informed consent was tested by calculating odds ratios. A p-value of 0.05 was taken as significant. The data was analysed using the SPSS software.

Results. Of the 150 patients interviewed, overall 77 (51.3 %) were adequately consented. Factors significantly associated with adequacy of informed consent included: age, type of caesarean i.e. elective or emergency, outcome, whether consented by a doctor or nurse, asked questions, and told of the right to decline. Factors found not to have a significant association with adequacy of informed consent included: parity, marital status, educational level, residence, previous caesarean, agreed that caesarean was necessary, debriefing after caesarean and learnt of caesarean during the antenatal visits. In only 11 patients (7.3%) was the risk of caesarean section discussed and in 27 (18%) the implications for future pregnancies. Only 7 patients discussed anaesthetic options and 2 patients said they were allowed to choose their preference. Under half (about 40.7%) were unsure of what to expect in their next delivery but most (62.0%) would prefer to deliver normally. There was poor documentation of the consenting process in patients' notes – in only 14% were the process well documented.

Conclusion. The wide variation in the extent of information provided for the different elements of the consent process for a caesarean section, the fact that overall only about half were considered adequately consented, poor documentation, uncertainty of how they will deliver in their next pregnancy, despite a preference to deliver normally rather than undergo another caesarean section, illustrates the need for a more detailed standardized consent form. This is to ensure consistency of information provided to patients. Further, this study draws attention for more training for health care workers involved in administering and documenting consent, and providing more awareness regarding caesarean section to patients in the antenatal period.

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ABBREVIATIONS

ACOG	AMERICAN COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS
PMTCT	PREVENTION OF MOTHER TO CHILD TRANSMISSION
SPSS	STATISTICAL PACKAGE FOR THE SOCIAL SCIENCES
UTH	UNIVERSITY TEACHING HOSPITAL
VBAC	VAGINAL BIRTH AFTER CAESAREAN
WHO	WORLD HEALTH ORGANISATION
ZDHS	ZAMBIA DEMOGRAPHIC AND HEALTH SURVEY

1.0 INTRODUCTION

A caesarean section is a common surgical operative procedure in obstetric practice that entails delivery of the fetus through an abdominal incision. When a decision is made to do a caesarean section, health care personnel do so on the basis of sound clinical judgement and the pregnant woman has the responsibility of accepting or rejecting the decision made after being appropriately counselled.

A decision to perform a caesarean section must be followed by a valid informed consent given by the woman or her guardian.[1-9] The woman must be provided evidence-based information on indications for the caesarean section, procedure, risks, benefits and implications for future childbirths in a manner that she will understand. There is a requirement on the part of the health worker to provide sufficient information to the woman so that she makes an informed decision in favour of the best option under the circumstances without delaying the intervention or refusing it altogether. This is both an ethical and legal requirement. Those that have given a valid informed consent for caesarean section are also expected to be more satisfied with the procedure to be carried out.[8]

Previously, all women who had undergone a caesarean section would have to undergo elective caesarean section in all subsequent pregnancies.[10, 11] Currently, vaginal birth after caesarean (VBAC) has become an acceptable option. This is also sometimes termed trial of labour or trial of scar.[7, 10, 11, 12, 13] These practices entail that women who have previous caesarean section should be given more attention at the consenting process.

Caesarean section is one of the commonest operations done in obstetrics worldwide.[14] The WHO target is a maximum caesarean section rate not exceeding 15%.[15] At the University Teaching Hospital (UTH) the institutional caesarean section rate was 18% in 2005.[16] However, as it is the only public sector hospital providing the procedure in the city of Lusaka with some 60,000 deliveries per year, the proportion of caesarean deliveries city-wide is closer to between 4-5%. The Zambia Demographic and Health Survey (ZDHS) of 2001-2 shows an overall caesarean section rate for Zambia of 2%,[17] a figure not dissimilar to that also found in a recent Emergency Obstetric Care Services Needs Assessment.[18] Also in the 2001-2 ZDHS, the percentage of deliveries by caesarean section in Lusaka Province is cited as 4.7%.

It is unclear to what extent the current consenting process offers women the opportunity to make informed decisions at UTH. This study explores the adequacy of the consenting process for caesarean sections. A study of this nature exploring the patients` role in and perception of the consent process and their understanding of the messages within the process has not been previously conducted at the UTH.

2.0 STATEMENT OF THE PROBLEM

Informed consent is required from all women about to undergo an elective or emergency caesarean section operation but information about the adequacy and practices of informed consent is either lacking or not well documented.

3.0 JUSTIFICATION OF THE STUDY

Caesarean section, either for emergency or elective indications, is one of the commonest operations done at UTH. The caesarean section rate was approximately 18% in 2005 and this figure has been almost constant for the past six years.[16] Most patients go through caesarean section without much information being availed to them because there is inadequate information on the UTH consent forms and case records, and sometimes this is given just on an improvised sheet of paper. A copy of a standard consent form that is used at UTH is appended in Appendix 1. In addition, the first page of the maternity case file has a short generic consent form as illustrated in Appendix 2.

This study evaluated comprehension of information obtained by patients undergoing caesarean section and their participation in the consenting process and hence was aimed at providing insight into the adequacy of the informed consent for caesarean section at UTH. This study was also designed to generate information to guide the best way to present and obtain informed consent from the mothers who are to benefit from caesarean section.

4.0 LITERATURE REVIEW

Informed consent is not a new concept. The earliest recorded mention of need for consent was in 1350 when Guy de Chauliac recorded his discussion with a patient about the need to cut a discoloured and hardened part of the body (as reported by Miller, 2006).[19] Thereafter several authors have written on various aspects of consent and various legislations have evolved over the years.[1-9]

The following description of elements and issues around informed consent is synthesised based on statements from the Royal College of Obstetricians and Gynaecologists on caesarean section (2009)[1] and on obtaining valid consent (2008)[20], from corresponding statements by the American College of Obstetricians and Gynaecologists (ACOG) Committee on Ethics[9], Miller (2006)[19], and from a widely distributed paper on healthcare risk management (2005)[21]. Informed consent consists of two parts: provision of information and thereafter authorization being granted for a particular course of action to be taken. An appropriate person with decision-making capacity is given adequate information in an understandable manner without coercion to make a decision to allow a course of action to be pursued. Informed consent serves to respect individuality, self-determination, and autonomy of the patient. It helps to foster good relationship between the patient and health care provider and gives the patient more power in the relationship. It also helps the health care provider learn the patient's preferences and expectations. Informed consent enhances the outcome of an intervention by ensuring that the patient has realistic expectations. It also enhances patient cooperation and participation in their care.

Informed consent may be limited by the complexity of the environment in an emergency situation. Decisions may be made before information is provided. Time consumption may be costly. Subjective experiences, preferences and emotions influence comprehension. Framing of the information to be provided may be problematic especially where translation is required. Other influences on informed consent may be information obtained from other patients as well as cultural and gender aspects. It may be difficult to assess attainment of informed consent. Some patients may be unwilling to accept the responsibility of decision-making. Family members may be involved if possible. However failure to allow a patient to make an informed consent risks litigation.

Information required for an informed consent to be made should include a description of the intervention as well as its nature, purpose and benefits. Risks, complications, side effects of the intervention should be explained. However not every conceivable risk need be mentioned, only possible harmful risks and common risks. Risks of not having the proposed intervention need to be explained as well as options or alternatives to the procedure, if any. Questions must be encouraged and the patient asked to restate what has been said. Good results must never be guaranteed. Documentation of informed consent must be made and where possible the patient to have a signed copy. A mention of whether interpretation was required or not must be made.

The American College of Obstetricians and Gynaecologists (ACOG) Committee on Ethics stated that informed consent is an ethical concept integral to medical ethics and practice and gave the following eight statements about it which are summarized below.[9]

1. Informed Consent is an ethical requirement partially reflected in legal doctrine.
2. Informed Consent is an expression of respect for the patient as a person.
3. Informed Consent protects the patient from unwanted medical treatment and allows the patient to participate in his or her own care.
4. Communication necessary in direct relation to individual patient as well as in the structured context of the medical care institution.
5. Informed Consent is a process and not a signature on a form.
6. Ethical requirement of informed consent not to conflict with overall ethical obligations to provide medical benefit.
7. When informed consent is not possible a surrogate decision maker may be identified. In an emergency the Practitioner may act according to their best perception of benefit. Public Health ethical considerations may override need for informed consent.
8. Ethical requirement does not equal legal requirement therefore Practitioners have to acquaint themselves with legal requirements of the state they are operating in.

Every patient has a right to make an informed consent or informed refusal to any intended medical intervention.[1-9] In order to make an informed choice the patient has a right to be availed appropriate evidence-based information. This must include the nature of the procedure and the indication; the intended benefits and risks must be explained; alternative approaches must be discussed including the option of not

performing the procedure and its implication. The type of anaesthesia, its use, benefits and complications must also be discussed with the patient. The right to seek an alternative opinion must be reserved by the patient.[1, 3, 9] The information must be given in a manner comprehensible to the patient ideally before labour begins, though this is more difficult for emergency caesarean sections.[7] The emotional changes associated with emergency caesarean section and the need for urgent intervention may hinder proper comprehension of the consenting process. Nevertheless, even a patient undergoing an emergency caesarean section is entitled to be availed a chance to make an informed choice.

Some centres have designed special consent forms for caesarean section that contain all the necessary information required to be given to the patient.[4] This ensures consistency in the information provided and allows for proper documentation of the consent process. At UTH, a consent form is signed for caesarean section, which only states that the effect and nature of the procedure have been explained. (Appendix 1 and 2).

History of Caesarean section

Caesarean section is delivery of the fetus through a surgical incision on the abdominal wall (laparatomy) and uterine wall (hysterotomy). Synonyms are 'Caesarean delivery' and 'Caesarean birth'.[1, 7] The U.S. National Library of Medicine has summarised and published a paper on the history of caesarean section, from which this section is summarised.[22] The etymology of the term 'caesarean section' is controversial. One school of thought is that it arose in the middle ages from the Latin word ' caedere' (to cut) with children of such births being called Caesones. Others attribute the terminology to an eighteenth century b.c. Roman law 'lex cesarae' which required post-mortem operative delivery for separate burial of mother and baby.

In1581 Francois Rouset described 14 such procedures from letters but never witnessed the procedure himself. By the mid 17th Century there were more reports about the procedure by obstetricians, but this was rare. Lack of anaesthesia and infection control were major limiting factors. In 1846 diethyl ether was introduced at Massachusetts General Hospital. (Queen Victoria delivered Leopold in 1853 and Beatrice in 1857 with chloroform used for anaesthesia, but not by caesarean section).

Mortality and morbidity, however, still remained high from infection. Surgical technique was also a limiting factor as surgeons were reluctant to close the uterine wound leading to high mortality from blood loss. In 1882 Max Sanger, from Leipzig, described the value of suturing the uterus with silver wire and silk leading to reduction of haemorrhagic morbidity. He documented survival of 8 of 17 mothers delivered by American surgeons.

In 1907, Frank described the extra peritoneal approach, modified in 1909 by Latzko, which decreased the risk of peritonitis. In 1912 Kronig showed that the extra peritoneal approach allowed access to the thinner lower segment and used a vertical median uterine incision with delivery aided by forceps. The lower segment was then covered with peritoneum. Beck in 1919 and DeLee in 1922 later modified this technique. Kerr described the low transverse incision in the lower uterine segment in 1926 and is the most commonly used today. In1928 Alexander Fleming discovered penicillin thereby reducing infectious morbidity and mortality hence eliminating the need for an extraperitoneal approach.

Types of caesarean section and its implication to the consent process

The lower segment caesarean section involves a transverse uterine incision in the thinner lower segment. This is easier to repair and heals better. It is the most commonly used incision today. The risk of uterine rupture after one such operation if vaginal delivery is attempted subsequently is about 0.5-2%.[11]

Classical caesarean section involves a vertical incision on the uterus. The risk of uterine rupture after one such operation if vaginal delivery is attempted is about 5-10%. It is less commonly used today (accounts for less than 1% of all caesareans). It is used for certain indications where access might be limited by a lower transverse incision. Some of these indications are transverse lie, major placenta praevia, advanced cancer of the cervix with pregnancy and operations done before formation of well recognisable lower segment. It is associated with poorer healing and subsequent pregnancies have to be delivered by elective caesarean section.

Indications for caesarean section are many and varied and have evolved over the years. The indication for the caesarean section could be for the sake of the mother, the baby or both. A caesarean section may be planned (elective) or arise as an

emergency.[2, 7, 10, 13] For elective caesarean section, the indication is noted prior to the onset of labour leading to the scheduling of the operation. Some indications for elective caesarean section include obstructive lesions of lower genital tract, prior myomectomy or classical caesarean section, prior perineal or rectal surgery, abdominal cervical cerclage, malpresentation, for prevention of mother to child transmission of HIV and placenta praevia.[7, 23, 24] Caesarean section on maternal request may also be an indication for elective caesarean section.[25] In all these situations there is enough time to avail enough information to the expectant mothers to allow for a valid informed consent to be given.

Emergency caesarean sections are performed without prior scheduling. The indications given for elective caesarean section could all turn into emergency if the woman goes into labour before the scheduled date or if she develops complications. Other indications for emergency caesarean section include fetal distress, cord prolapse, obstructed labour and hypertensive disorders. An emergency caesarean section is often performed to save the life of the mother, the baby or both. An emergency caesarean section has to be performed shortly after the decision is made in order to achieve the intended benefits. The consenting process for emergency caesarean section is therefore limited by such factors as lack of time to give sufficient information and the emotional and physical well being of the mother. Despite these limitations a woman undergoing an emergency caesarean section is as entitled to give an informed consent for caesarean section as a woman undergoing an elective caesarean section.

Some important factors may have to be considered to decide on the appropriateness of caesarean section in a particular situation. Some factors may be availability of safe anaesthesia, blood transfusion services and presence of a competent surgeon.[24,26] Viability of the pregnancy and suitability of the patient for the intended anaesthesia is also another important factor to consider before embarking on a caesarean section. Regional anaesthesia is more beneficial for the mother and the baby in that mother remains awake and there is less sedation for the baby. General anaesthesia has increasingly become less justified for routine use. [7, 23, 24, 26]

Caesarean section may be beneficial in that it is more predictable than prolonged or difficult vaginal delivery and in the modern setting it can be done relatively quickly

and safely. [24] However, risks of caesarean section include injury to nearby structures like bladder, ureter or bowel. Injury to large blood vessels may lead to haemorrhage during the procedure. There is also increased risk of post partum haemorrhage, puerperal sepsis and thromboembolism. There is also increased risk of uterine rupture and increased probability of a repeat caesarean section in future pregnancies. For the foetus there is a risk of laceration during the procedure and an increased risk of respiratory distress syndrome after delivery.[26]

Some factors noted to contribute to increasing caesarean section rate include, an increase in rate of hospital deliveries subjecting mothers to hospital "management" protocols coupled with fear of litigation by health personnel. Increased safety and predictability of the procedure has also contributed to increasing the caesarean section rate.[25] Support and individualisation of a woman in labour with an increase in home deliveries may help decrease the caesarean section rate. However, as long as the need for caesarean sections remains, they should be done for appropriate maternal and fetal indications and with full informed consent.

5.0 RESEARCH QUESTION

Do patients undergoing caesarean section at UTH receive adequate information to give a valid informed consent?

6.0 HYPOTHESIS

The process of informed consent for patients undergoing caesarean sections at UTH is inadequate.

7.0 OBJECTIVES

General objective

To evaluate the adequacy of informed consent for women who undergo caesarean section at UTH.

Specific objectives

1. To determine the proportion of mothers who receive adequate informed consent before caesarean section at UTH.
2. To determine what elements of an informed consent for caesarean section are provided.
3. To study the expectations and preferences with regard to future childbirth in women that undergoes caesarean section.
4. To establish adequacy of documentation of the consenting in the patient case notes.

8.0 METHODS (STUDY DESIGN AND DATA HANDLING)

This was a cross sectional study. The target population was all women having their deliveries at UTH while the study population was the group of women who underwent emergency and elective caesarean section who fulfilled the eligibility criteria.

The size of the study population was calculated using Epi info software for a single proportion. Assuming from anecdotal evidence that 10% undergoing caesarean section were adequately consented, for a confidence interval of 95% and a power of 80% the required sample size was 136. To account for non-response and to increase the power of the study this was adjusted to 150. The subjects were recruited by simple random sampling after the caesarean section had been done and they had sufficiently recovered from anaesthesia to be able to undergo the interview over a six-month period from June 2008 to December 2008. The response rate was 98%.

An elective caesarean section was defined as one, which was planned for and performed before labour, or any complications arose while an emergency caesarean section was defined as one which was unplanned for and was performed during labour or after complications arose.

The inclusion criteria included women who had a caesarean section performed at UTH up to three weeks previously, those 18 years old and above, and those who had given informed consent to participate in the research study and answer the interview questionnaire. The exclusion criteria involved women who had a caesarean section not done at UTH, those who had a caesarean section done more than three weeks previously and those were aged below 18 years. Women who refused to consent to participate in the study or were unable to provide informed consent for the interview were also excluded. Also excluded were those cases in which consent for the caesarean section had been provided by another person.

A research assistant obtained written informed consent (Appendix 3) from women that had a caesarean section and were now in the postnatal ward and then administered a structured and standardized questionnaire (Appendix 4). Data once collected was entered into a database created by using Epi-info version 6 software.

Double entry by two research assistants was used and any inconsistencies were corrected. The data was subjected to consistency and range checks. The cleaned data was then transferred for analysis to the statistical softeware package SPSS version 10 software. All study variables, are summarised in Appendix 5. The researcher (this author) developed the study instrument, oversaw the data collection, entry, and analysis.

Distributions of data describing the study participants and their responses from the questionnaire were examined and tabulated. To simplify analyses the type of caesarean section was treated as a binary exposure (elective vs. emergency). For variables regarding the process of informed consent there were 5 choices: 1)Strongly Agree, 2) Agree, 3)Not sure, 4)Disagree, 5)Strongly Disagree. For any process, the outcome was also treated as binary; thus 'strongly agree' and 'agree' were scored as 'adequate'; any other as 'inadequate'.

Women who gave an affirmative response ('strongly agree' or 'agree') to having received information on all of the following and reported to have understood the information were deemed to have received adequate informed consent in this study: name of procedure, nature of procedure and indications (which corresponded to the indication in the case notes).

Since the numbers of subjects with missing values were low 3 (2% in total) and excluding them would not be likely to introduce bias it was decided to conduct the multivariate analyses only on those with complete data for any variables in the analysis. Univariate analyses were conducted using all data available. Association of supplied characteristics with type of informed consent was tested by calculating odds ratios for categories of the variables, and testing for statistical significance of deviation of the odds ratios from one. Significant predictors of adequacy of informed consent were also tested (using chi-square test) for statistical association with type of caesarean section. A p-value of 0.05 was taken as significant.

Approval was obtained from the Research and Ethics Committee of the University of Zambia before commencing the study. Permission was also obtained from the Managing Director of the University Teaching Hospital through the Head of Department of Obstetrics and Gynaecology.

9.0 RESULTS

Type of caesarean section:

A total of 150 women who had undergone caesarean section were interviewed. Of these 115 (76.7%) had an emergency caesarean section, 32 (21.3%) had an elective caesarean section while in 3 cases (2%) the type was undetermined. (Table 1)

Adequacy of informed consent:

Using the working definition of adequate informed consent described in the methods section (i.e. considering the 3 responses: name of procedure, nature of procedure and knowing the indications) 77 (51.3%) women was found to be adequately consented while 73 (48.7%) were inadequately consented. (Table 1).

Associations of adequate and inadequate informed consent:

Factors which were found to have a significant association with adequate informed consent included age, type of caesarean (i.e. elective or emergency), outcome, consented by, asked questions and told right to decline. (Table 2). Similarly, factors that were found not to have a significant association with adequate informed consent included parity, marital status, educational level, residence, had previous caesarean, agreed caesarean necessary, debriefing after caesarean and learnt at antenatal. (Table 2).

Information on risks of caesarean section:

Out of the 150 respondents only 11 (7.3%) reported having discussed risks of caesarean section while 139 (92.7%) reported not having received any information on risks. (Table 1). Out of the above 11 respondents who reported having discussed risks of caesarean section, 8 (72.7%) fulfilled our criteria for adequately informed consent while 3 respondents (27.3%) did not (P=0.126) (Table2).

Implications of caesarean for future deliveries:

Out of the 150 respondents 27 (18.0%) reported having discussed implications of caesarean section on future deliveries while 122 (81.3%) reported not having received any information in this regard and 1 response (0.7%) was missing (Table 1). Of the above 27 respondents 12 (44.4%) fulfilled our criteria for adequately informed consent while 15 respondents (55.6%) did not (P=0.451) (Table 2).

Information on anaesthetic options:

Out of the 150 respondents 7 (4.7%) reported having received information on anaesthetic options for caesarean section while 143 (95.3%) reported they had not having received any information in this regard. (Table 1). Concerning choice of anaesthesia 2 (1.3%) reported having been allowed to choose their anaesthetic preference while 148 (98.7%) reported not having been given an option to choose their anaesthetic preference. (Table 1).

Expectations and preferences for future pregnancies:

With regards to expectations for future pregnancies, of the 150 respondents 20 (13.3 %) expect to deliver normally, 18 (12.0%) expect to deliver by caesarean section, 61 (40.7 %) were unsure, and the rest 51 (34.0%) were planning to or had undergone bilateral tubal ligation (Table 3).

With regards to preferences for future pregnancies, of the 150 respondents 93 (62.0%) preferred to deliver normally, 9 (6.0%) preferred to deliver by caesarean section, 4 (2.7%) were unsure, and the rest 44 (29.3 %) were planning to or had undergone bilateral tubal ligation (Table 4).

Documentation of consent process:

With regard to documentation of the consent process in the patient's case notes, in 86 (57.3%) cases there was no documentation, in 33 (22%) there was merely an order to obtain consent, and in 10 (6.7%) there was a statement that the patient had been offered information (Table 1).

Only in 21 case notes (14%) was there a full documentation of the consenting process having taken place including the patient's response after being given the relevant information. Better documentation of the consent process was not associated with more adequate consent. (P =0.193) (Table 2).

Table 1. Frequency Table of Patient Responses.

Variable	N (%)
Age	
18-20	23 (15.3)
21-25	40 (26.7)
26-30	36 (24.0)
31-35	30 (20.0)
>35	21 (14.0}
Parity	
1-2	74 (49.3)
3-5	61 (40.7)
>5	15 (10.0)
Had previous caesarean	
Yes	36 (24.0)
No	114 (76.0)
Marital Status	
Single	6 (4.0)
Married	143 (95.3)
Divorced	1 (0.7)
Widowed	0 (0)
Educational Level	
None	12 (8.0)
Primary	69 (46.0)
Secondary	46 (30.7)
Tertiary	23 (15.3)
Residence	
High Density	74 (49.3)
Medium Density	55 (36.7)
Low Density	21 (14.0)
Language of interview	
English	42 (28.0)
Nyanja	75 (50.0)
Nyanja/Bemba	1 (0.7)
Bemba	32 (21.3)
Outcome of caesarean	
Term live birth	124 (82.7)
Preterm live birth	14 (9.3)
Stillbirth	9 (6.0)
Type of caesarean	
Elective	32 (21.3)
Emergency	115 (76.7)
Told Name of Operation	
Yes	134 (89.3)
No	16 (10.7)
Told Nature of Operation	
Yes	111 (74.0)
No	39(26.0)
Told Indication	
Yes	135 (90.0)
No	14 (9.3)
Indication(corresponding to case notes)	
Yes	112 (74.7)
No	27 (18.0)

Variable	N (%)
Adequately consented	
Yes	77 (51.3)
No	73 (48.7)
Understood indication	
Yes	140 (93.3)
No	10 (8.7)
Agreed caesarean necessary	
Yes	142 (94.7)
No	8 (5.3)
Told risks	
Yes	11 (7.3)
No	139 (92.7)
Asked questions	
Yes	37 (24.7)
No	112 (74.7)
Told right to decline	
Yes	75 (50.0)
No	75 (50.0)
Told anaesthetic options	
Yes	7 (4.7)
No	143 (95.3)
Chose anaesthetic options	
Yes	2 (1.3)
No	148 (98.7)
Advised on future deliveries	
Yes	27 (18)
No	122 (81.3)
Debriefing after caesarean	
Yes	11(7.3)
No	138(92.0)
Learnt at antenatal clinic	
Yes	50(33.3)
No	99(66.0)
Consented by	
Nurse	35 (23.3)
Doctor	114 (76.0)
Adequacy of documentation	
no documentation	86 (57.3)
order for consent	33 (22.0)
information offered	10 (6.7)
information offered and patient responded	21 (14.0)

Table 2. Bivariate Relationship between Adequate Consent and Independent Variables

	N%	n (%) **adequate**	n (%) **inadequate**	P value
Told Name of Operation	134 (89.3)	77 (57.5)	57 (42.5)	<0.001
Told Nature of Operation	111 (74.0)	77 (69.4)	34(30.6)	<0.001
Told Indication	135 (90.0)	77 (57.0)	58 (43.0)	<0.001
Indication (corresponding to case notes)	112 (74.7)	77 (68.8)	35 (31.2)	<0.001
Reported above understood	140 (93.3)	77 (55.0)	63 (45.0)	=0.001
Agreed caesarean necessary	142 (94.7)	75 (52.8)	67 (47.2)	0.126
Type of caesarean				
Elective	32 (21.3)	23 (71.9)	9 (28.1)	
Emergency	115 (76.7)	54 (46.9)	61 (53.1)	0.016
Outcome of caesarean				
Term live birth	124 (82.7)	59 (47.6)	65 (52.4)	0.025
Preterm live	14 (9.3)	12 (85.7)	2 (14.3)	
Stillbirth	9 (6.0)	5 (55.6)	4 (44.4)	
Told risks	11 (7.3)	8 (72.7)	3 (17.3)	0.140
Asked questions	37 (24.7)	24 (64.9)	13 (35.1)	0.052
Told right to decline	75 (50.0)	47 (62.7)	28 (37.3)	0.005
Debriefing after caesarean	11 (7.3)	6 (54,5)	5 (45.5)	0.807
Learnt at antenatal clinic	50 (33.3)	26 (52.0)	24 (48.0)	0.863
Age				
18-20	23 (15.3)	9 (39.1)	14 (60.9)	0.018
21-25	40 (26.7)	14 (35.0)	26 (65.0)	
26-30	36 (24.0)	24 (66.7)	12 (33.3)	
31-35	30 (20.0)	20 (66.7)	10 (33.3)	
>35	21 (14.0}	10 (47.6)	11(52.4)	
Parity				
1-2	74 (49.3)	34 (45.9)	40 (54.1)	0.412
3-5	61 (40.7)	35 (52.2)	26 (47.8)	
>5	15 (10.0)	8 (53.3)	7 (46.7)	
Marital Status				
Single	6 (4.0)	4 (66.7)	2 (33.3)	0.457
Married	143 (95.3)	72 (50.3)	71 (49.7)	
Divorced	1 (0.7)	1 (100.0)	0	
Widowed	0 (0)	0	0	
Educational Level				
None	12 (8.0)	8 (66.7)	4 (33.3)	0.366
Primary	69 (46.0)	36 (52.2)	33 (47.8)	
Secondary	46 (30.7)	20 (43.5)	26 (56.5)	
Tertiary	23 (15.3)	12 (52.2)	11 (47.8)	

.....Table 2 continued overleaf

Table 2 continued
Bivariate Relationship between Adequate Consent and Independent Variables

	N%	N (%) adequate	N (%) inadequate	P value
Residence				
High Density	74 (49.3)	35 (47.3)	39 (52.7)	0.254
Med Density	55 (36.7)	33 (60.0)	22 (40.0)	
Low Density	21 (14.0)	9 (42.8)	12 (57.2)	
Had previous caesarean				0.457
Yes	36 (24.0)	16 (44.4)	20 (55.6)	
No	114 (76.0)	61 (53.5)	53 (46.5)	
Advised future deliveries	27 (18)	12 (44.4)	15 (55.6)	0.451
Consented by				
Nurse	35 (23.3)	10 (28.6)	25 (71.4)	0.002
Doctor	114 (76.0)	67 (58.8)	47 (41.2)	
Adequacy of documentation				
no documentation	86 (57.3)	44 (51.2)	42 (48.8)	0.193
order for consent made	33 (22.0)	19 (57.6)	14 (42.4)	
information offered	10 (6.7)	2 (20)	8 (80)	
information offered and patient responded	21 (14.0	12 (57.1)	9 (42.9)	

Table 3. Expectations for future deliveries by patient that had a caesarean section

	n	Percent
Normal Delivery	20	13.3
Caesarean Section	18	12.0
Unsure	61	40.7
Had bilateral tubal ligation	51	34.0
Total	150	100

Table 4. Preferences for future deliveries by patients that had a caesarean section

	n	Percent
Normal Delivery	93	62.0
Caesarean Section	9	6.0
Unsure	4	2.7
Had bilateral tubal ligation	44	29.3
Total	150	100

10.0 DISCUSSION

The objective of this study was to evaluate the adequacy of informed consent for women who undergo caesarean section at UTH, determine what elements of an informed consent for caesarean section are provided, study the expectations and preferences with regard to future childbirth in women that undergoes caesarean section and to establish adequacy of documentation of the consenting in the patient case notes. Based on these objectives, the findings were that the consenting process for caesarean section was generally not well done, not all elements of the consent process were discussed with the patient expectations for the next pregnancy and there was poor documentation of the consenting process in patients' notes. Specifically, of the 150 patients in this study, 134(89.3%) patients reported having been told the name of the operation, 111(74.0%) were told the nature of the operation and 135(90.0%) were told the benefits or indication. Half the respondents (n=75, 50%) reported having been advised on their right to decline the intervention. In only 11 patients (7.3%) was the risk of caesarean section discussed and in 27 (18%) the implications for future pregnancies. Only 7 patients discussed anaesthetic options and 2 patients said they were allowed to choose their preference. Under half (about 40.7%) were unsure of what to expect in their next delivery but most (62.0%) would prefer to deliver normally. There was poor documentation of the consenting process in patients' notes – in only 14% were the process well documented.

In this study overall adequate consent was defined to mean receiving comprehensible information on the name of the procedure, the nature of the procedure and indication that corresponded to the official indication in the case notes. Despite using only these few elements of the consent process, only 51.3% of respondents were found to be adequately consented. There was inadequate information provided on risks and implications on future reproductive health. Discussion on anaesthetic options was almost non-existent. This may have been due to the fact that different anaesthetic options, e.g. spinal anaesthesia, are not always available. Half the respondents reported having been advised on their right to decline the intervention. Some factors have been shown to be associated with quality of the consent. These include age of respondent, gestation age at which the caesarean section was done, whether it was elective or emergency and the level of health care provider providing the information. The results show that doctors were the predominant health care

workers involved in obtaining informed consent. Clients consented by doctors were better consented (58.8%) as compared to those consented by nurses (28.8%) perhaps due to the fact that the doctors might have more information about the caesarean section than the nurses. In any case, a comprehensive consent form and training would enable a better informed consent.

Those clients with preterm deliveries were better informed (85.7%) perhaps due to the fact that they are more concerned about the survival of their babies and would most likely ask health care providers more questions. Clients undergoing elective caesarean section were also better consented (76.7%) most likely because they would have more time to gather more information by the time the caesarean section was done. Attendance at antenatal sessions can be a useful opportunity to sensitize and inform women of the possibility of a caesarean in certain conditions and this has the possibility to improve the consenting process if it were required. In this study, 50 women (33.3% of all respondents) reported having discussed the possibility of caesarean section at antenatal clinic. Of these, just over half (n=26, [52%]) fulfilled our criteria for adequate informed consent while the remaining (n=24, [48%]) did not. This illustrates that even the opportunity to counsel during the antenatal period did not result in marked improvement in adequacy of consent.

With regard to expectations for the next delivery, most respondents were unsure as to whether they would deliver normally or undergo another caesarean section (40.7%). With regard to preference for the next delivery, most respondents said they would prefer to deliver vaginally rather than undergo another caesarean section (62.0%).

Most of the case files showed poor documentation of the consent process with only 14% of well-documented cases. Again, this could be improved by use of a proforma/checklist that enables all the important elements of the consent process to be covered.[4]

Even in developed countries, e.g. Australia, a sizeable minority of women (one third) may not have received sufficient information.[8] Once again a proforma/checklist that enables all the important elements of the consent process to be covered could be utilised.

Adisa et al in Nigeria (2008) reported in a study involving surgical procedures (including obstetric procedures) that only 26.3% of patients knew any alternative to the procedure, 36.3% knew at least one complication of the procedure and 15% knew an option or complication of anaesthesia.[27] Fifty six percent of the consent forms were properly filled while other forms had one error or another. Adisa et al also recommend a well structured and standardized method of obtaining informed consent from surgical patients.[27]

Ezeome and Marshall, reporting on informed consent in Nigeria (2009) made recognition of individual autonomy but also that decisions were made within the family.[28] They also noted that consent practices, as in this study, were influenced by the level of education, extended family system, urbanization, and religious practices.

11.0 STUDY LIMITATIONS

The requirement of informed consent is applicable to many other medical interventions apart from caesarean section. Also including other common interventions (e.g. instrumental deliveries) and looking at them from the same perspective would have strengthened this study. This study was confined to one institution (UTH) and could have been strengthened by conducting the study in other institutions within Zambia including private ones.

12.0 STRENGTHS OF THE STUDY

Caesarean section is a very common procedure performed at UTH and it would be considered to be a suitable subject in the study of informed consent. The sample size and good response rate would make this study representative of the actual prevailing situation with regard the consenting process at UTH.

13.0 CONCLUSIONS

Overall there was inadequate consenting of clients for caesarean section at UTH. Some of the information was fairly adequately provided while some other information was very inadequately provided or not provided at all. Most women were unsure of how they would deliver in their next pregnancy, however, the vast majority would prefer to deliver normally rather than undergo another caesarean section. Documentation of the consenting process was also poorly done.

14.0 RECOMMENDATIONS

1. A more detailed and standardized consent form should be designed and administered to ensure consistency of information provided to patients.
2. All health care workers involved in administering consent should receive training on how to do so.
3. Consent should preferably be administered by the surgeon who will perform the caesarean section.
4. More information should be provided in the antenatal clinics to raise awareness about various aspects of caesarean section even to women who will not need a caesarean section.
5. Feedback should be provided to the Anaesthesia Department to regarding the provision of information on anaesthetic options and enabling options to be made available.
6. Further research is needed to determine barriers to obtaining informed consent, not only for caesarean section but for other procedures, in a variety of settings.

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APPENDIX 2 Page 1 of the Lusaka Maternity case file with consent form

Surname_____ Forename _____Other names _____ Age____

Religion_____ Church Attended _____
Residential Address_____
Location/Landmarks_____

_____

Name of Husband_____
Occupation of Husband_____Tel No. of Husband_____
Name of Guardian_____
Occupation of Guardian_____ Tel No. of Husband _____

PCR _____ / _____ / _____	TR _____ / _____ / _____	MGN _____ / _____ / _____
PCR _____ / _____ / _____	TA _____ / _____ / _____	MRN _____ / _____ / _____
PCR _____ / _____ / _____	R _____ / _____ / _____	IGA _____ / _____ / _____
PCA _____ / _____ / _____	NR _____ / _____ / _____	INGA _____ / _____ / _____
IFB _____	I _____ / _____ / _____	
IFR _____		

PREVIOUS OBSTETRIC HISTORY

No.	Date	Health During Pregnancy	Duration of Pregnancy	Duration of Labour	Spontaneous or Instrumental	Sex	Wt	Alive/Miscarriage / FSB/MSB/Died *If Died state age and cause*	Problems During Puerperium

Family History of Twins: No.____Yes ____ Comment_____

Previous illness:	✓	When?	Details:
TB	____	_____	_____
Heart Disease	____	_____	_____
High BP	____		_____
Kidney Disease	____	_____	_____
Diabetes	____	_____	_____
Anaemia	____	_____	_____
Asthma	____	_____	_____
Malaria	____	_____	_____
STI	____	_____	_____
Epilepsy	____	_____	_____
Sickle Cell Anaemia	____	_____	_____

Previous Operations: _____

_____

Allergies: _____

CONSENT FOR OPERATION

I _____ hereby consent to the operation of _____the effect and nature of which have been explained to me, and to such further or alternative measures as may be found to be necessary during the course of such operation and to the administration of local or other anaesthetic for any of the foregoing purposes. I understand that an assurance has NOT been given that the operation will be performed by a particular surgeon. I also consent to being delivered by any Doctor or Midwife in the Department.

Date this _____ day of _____

Signature _____ Witness _____

1

APPENDIX 3 INFORMATION SHEET AND CONSENT FORM FOR PARTICIPANTS

A STUDY OF ADEQUACY OF INFORMED CONSENT FOR CAESAREAN SECTION AT UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.

Dear Participant,
My name is .....I am asking you to take part in a research study for patients who have recently undergone caesarean section at University Teaching Hospital. This study is being carried out by Dr. David C. Lubansa .He is a postgraduate student in the Department of Obstetrics and Gynaecology.

The purpose of this study is to find out your understanding of the circumstances which led to your having to undergo a caesarean section and what role you played in the consenting process. This study will also aim to find out your satisfaction with the procedure having been done and your future reproductive goals.

If you choose to take part in the study, you will be required to answer some questions on a questionnaire while additional information will be obtained from your Medical records. There will be no payment made to you for participating in this study.
This study will be of benefit in helping to improve the quality of the informed consent process and thus contribute to the provision of high quality health care. There is no envisaged risk to you for participating in this study.

Participation in the study is voluntary and you can opt out anytime without affecting the quality of health care you receive at this centre.

The study will take place over a period of six months however you will be interviewed for a period not exceeding forty-five minutes.

You are urged to answer the questions frankly and truthfully. Your responses will not affect your care.

Everything will be done to keep your information confidential. Your study document can be reviewed by the study staff and the representatives of the University of Zambia Research Ethics Committee.

You are encouraged to ask any questions you have at any time.

The contact details of the investigator are: Dr. David C. Lubansa Department of Obstetrics and Gynaecology University Teaching Hospital P.B. RW 1X, Lusaka Cell: 0955 835095 e-mail dclubansa@yahoo.com.	Alternatively you can contact: The Secretariat, The University of Zambia Research Ethics Committee, Ridgeway Campus, P.O. Box 50110, Lusaka; Tel: 260-1-256067, Fax: 260-1-250753; e-mail: unzarec@zamtel.zm.

INFORMED CONSENT FOR PARTICIPANTS

I have understood the information that has been given to me, and my questions have been answered to my satisfaction. I do agree to participate in this study.

Name of Participant	**Signature/ Thumb Print**	**Date**
Name of Witness (If thumbprint used)	**Signature**	**Date**
Name of Interviewer	**Signature**	**Date**

APPENDIX 4

STUDY QUESTIONNAIRE

Date ..... **sequential ID #**

Is translation required for this interview? (circle appropriate number)

1) Yes (state language.....)
2) No

PART 1. (INFORMATION TO BE ABSTRACTED FROM PATIENTS RECORDS)

Q1) Participant Initials

Q2) Age (years)

Q3) Parity after caesarean

Q4) Marital status (circle appropriate number)

1) single
2) married
3) widowed
4) divorced

Q5) Residential Address as defined by City Council (circle appropriate number)

1) High density
2) Medium density
3) Low density

Q6) Past Reproductive History

Year	Duration of Pregnancy	Mode of Delivery	Birth Weight	A/SB/D

A=alive SB= still birth D= born live but died

Q7) Length of time since the caesarean section was done? (Days)

Q8) The outcome of this caesarean (circle appropriate number)

1) Term Live birth
2) Preterm Live birth
3) Stillbirth

Q9) The indication for this caesarean section was officially recorded as

1) Elective
2) Emergency
3) Not clear

Notes:.....

.....

Q10) Documentation of the consenting in patient's case notes.

1) A statement that the patient had been offered information and given her response
2) A statement that the patient had been offered information but without a statement on her response
3) An order to obtain consent but without a statement that the patient had been offered information
4) Entirely no documentation on consent

Comments:

.....

.....

PART 2. (INFORMATION FROM PATIENT AFTER INFORMED CONSENT)

Q11) You were told the name of the operation? (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q12) You were told that you were going to be cut on the abdomen and the baby delivered through the abdomen? (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q13) You were told why a caesarean was necessary. (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q14) If answer to Q (13) is 1) or 2) what were you told? (patient's own words)

.....

.....

.....

.....

Corresponds with indication in Part 1 (Q9) (as Judged by the Interviewer)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q15) You understood the reason why a caesarean was necessary ? (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagre

Q16) You agreed that a caesarean was necessary? (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q17) You were told that a caesarean section has risks of its own (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

If answer to Q (17) is 1) or 2) what were you told? (patient's own words)

.....

.....

.....

Q18) You were given a chance to ask questions about the intended caesarean section. (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q19) You were told you had the right to refuse or defer the caesarean section decision? (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q20) You were told about options of general or regional anaesthesia (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q21) You were allowed to choose your anaesthetic preference (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q22) You were advised on your delivery options for future pregnancies (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q23) After the caesarean section a health care provider discussed the operation with you. (debriefing)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q24) In antenatal clinic health talks you were told about possibility of delivery by caesarean section (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Comments.....
.....
.....
.....
.....

PART 3. (EXTRA INFORMATION FROM PATIENT)

Q25) In the next pregnancy you **expect** to deliver normally (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q26) In the next pregnancy you **expect** to undergo elective caesarean section (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q27) In the next pregnancy you prefer to deliver normally (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q28) In the next pregnancy you **prefer** to undergo elective caesarean section (circle appropriate number)

1) Strongly Agree
2) Agree
3) Not sure
4) Disagree
5) Strongly Disagree

Q29). Who administered the informed consent? (circle appropriate number)

1) Nurse

2) Doctor

3) Other (specify).....

Q30) What is your educational level? (circle appropriate number)

1) None

2) Primary

3) Secondary

4) Tertiary

Comments.....

.....

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APPENDIX 5: Descriptive Table of Study Variables.

Variable	Description
Told Name of Operation	Told that operation was called caesarean section: yes/no
Told Nature of Operation	Told baby to be delivered through cut on abdomen: yes/no
Told Indication	Told the reason why caesarean needs to be done: yes/no
Indication (corresponding to case notes)	Indication from patient matches the case notes: yes/no
Understood indication	Understood why caesarean section was done: yes/no
Adequately consented	Reported to have been told Name, Nature of Operation and Indication and understood: **adequate/inadequate**
Agreed caesarean necessary	Reported agreed caesarean was necessary: yes/no
Told risks	Reported told risks of undergoing caesarean: yes/no
Asked questions	Reported allowed to ask questions before caesarean: yes/no
Told right to decline	Reported told had a right to decline caesarean: yes/no
Told anaesthetic options	Reported told about types of anaesthesia: yes/no
Chose anaesthetic options	Reported allowed to choose type of anaesthesia: yes/no
Advised future deliveries	Discussed effect of caesarean on future pregnancies: yes/no
Debriefing after Caesarean	Discussed with Doctor after caesarean done: yes/no
Learnt at antenatal clinic	Had been told about caesarean in antenatal clinic health talks yes/no
Type of caesarean	Whether elective or emergency
Outcome of caesarean	Fetal outcome of the caesarean
Age	Age last birthday as reported by respondent
Parity	Number of deliveries after present caesarean
Had previous caesarean	Had caesarean before present one yes/no
Marital Status	As reported by respondent as reported by respondent
Educational Level	Highest level ever attained as reported by respondent
Residence	Low, medium or high density
Language of interview	Language used when administering questionnaire
Consented by	Who consented patient nurse/doctor
Adequacy of documentation	Adequacy of documentation of the consent process in the patients case notes: no documentation / order for consent / information offered / information offered and patient responded